11-2-79
Vol. 44 No. 214
Pages 63077-63508

federal register

Friday
November 2, 1979

Highlights

Briefings on How to Use the Federal Register—For details on briefings in Washington, D.C., and Dallas, Tex., see announcement in the Reader Aids Section at the end of this issue. An interpreter for hearing impaired persons will be present for the November 16 briefing.

63077 **Relief Funds for Kampuchea** Presidential determination

63115 **Persons with Disabilities** HEW/Sec'y proposes to amend procurement regulations to assure minimum accessibility standards; comments by 12-17-79

63098 **Part-Time Career Employment** ICA publishes rule governing program; effective 11-2-79

63485 **Equal Pay** EEOC is planning a January 1980 meeting on job segregation and wage discrimination (Part VII of this issue)

63084 **Home Loans** Treasury/Comptroller issues rule designed to provide a basis for a more effective fair housing monitoring program; effective 1-1-80

63478 **Head Start** HEW/HDSO publishes final program policy pertaining to enrollment and attendance; effective 11-2-79 (Part VI of this issue)

CONTINUED INSIDE

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

Area Code 202-523-5240

Highlights

63496 **Food Stamps** USDA/FNS proposes regulations for the provision of social security numbers, fraud disqualification and recoupment, and group living arrangements under the Act; comments by 12-17-79 (Part IX of this issue)

63270 **Oral Mucosal** HEW/FDA proposes to establish conditions under which over-the-counter (OTC) injury drug products are generally recognized; comments by 1-31-80; reply comments by 3-3-80 (Part II of this issue)

63292 **Medical Devices** HEW/FDA proposes general rules applicable to the classification of all anesthesiology devices; comments by 1-2-80 (150 documents) (Part III of this issue)

63132 **National Environmental Policy** Council on Environmental Quality publishes fourth progress report on agency's implementation of procedures of the Act

63083 **Radioactive Material** NRC amends rules on packaging and transportation; effective 12-3-79

63108 **Improving Government Regulations** DOE issues semiannual agenda

63082 **Harry S. Truman Animal Import Center** USDA/APHIS establishes a specific date of receipt of applications for special permits for the allotment of quarantine space for the second group of cattle; effective 10-30-79

63488 **Animal Welfare** USDA/APHIS amends its regulations concerned with humane handling, care, treatment and transportation of certain warmblooded animals; effective 11-2-79 (Part VIII of this issue)

63081 **Tobacco** USDA/ASCS terminates existing form marketing quota for cigar-binder (types 51 and 52); effective 11-2-79

63107 **Tobacco Loan Program** USDA/CCC issues proposal on 1979 crop grade loan rates of dark air cured (types 35 and 36); comments by 12-3-79

63183 **Sunshine Act Meetings**

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Presidential Documents

Title 3—

The President

Presidential Determination No. 80-1 of October 15, 1979

Determination Pursuant to Section 2(c)(1) of the Migration and Refugee Assistance Act of 1962, as Amended, ("the Act") Authorizing the Use of $2 Million of the Funds Made Available From the United States Emergency Refugee and Migration Assistance Fund

Memorandum for the Secretary of State

In order to make an initial rapid response to the Joint Appeal of the United Nations International Children's Emergency Fund and the International Committee of the Red Cross for the establishment of a Relief Program within Kampuchea, I hereby determine because of widespread famine and disease resulting from wholesale dislocation and other causes that the general population within Kampuchea constitutes a class of refugees eligible for assistance under the Act. Pursuant to section 2(c)(1) of the Act, I determine that it is important to the national interest that up to $2 million from the United States Emergency Refugee and Migration Assistance Fund be made available through the Department of State for transfer to the United Nations International Children's Emergency Fund and the International Committee of the Red Cross for these purposes.

The Secretary of State is requested to inform the appropriate Committees of Congress of the Determination and the obligation of funds under this authority.

This Determination shall be published in the Federal Register.

Jimmy Carter

THE WHITE HOUSE,
Washington, October 15, 1979.

[FR Doc. 79-34150
Filed 10-31-79; 4:19 pm]
Billing code 3195-01-M

Rules and Regulations

Federal Register
Vol. 44, No. 214
Friday, November 2, 1979

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.
The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each month.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 213

Excepted Service; Department of Justice

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: Criminal Investigator (Special Agent) positions in the Drug Enforcement Administration are excepted under Schedule B because competitive examination for these positions is impracticable. New appointments to these positions may be made only at grades GS-5 through 11. Service under this authority is limited to 4 years. Schedule A authority for 154 Special Agents is revoked because these positions are now covered under the Schedule B authority.

EFFECTIVE DATE: July 30, 1979.

FOR FURTHER INFORMATION CONTACT:

On position authority: William Bohling, Office of Personnel Management, 202-632-4533

On position content: Lee Probst, Department of Justice, 202-633-3351

Office of Personnel Management.

Beverly M. Jones,

Issuance System Manager.

Accordingly, 5 CFR 213.3110(c)(1) is revoked and 5 CFR 213.3210(a) is added as follows:

§ 213.3110 Department of Justice.

* * * * *

(c) *Drug Enforcement Administration.*

(1) [Revoked]

* * * * *

§ 213.3210 Department of Justice.

* * * * *

(a) Criminal Investigator (Special Agent) positions in the Drug Enforcement Administration. New appointments may be made under this authority only at grades GS-5 through 11. Service under the authority may not exceed 4 years.

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

[FR Doc. 79-34004 Filed 11-1-79; 8:45 am]

BILLING CODE 6325-01-M

5 CFR Part 213

Excepted Service; Department of the Treasury

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: Clerical positions at grades GS-5 and below established in Emergency Disbursing Offices to process emergency payments to victims of catastrophes or natural disasters requiring emergency disbursing services are excepted under Schedule A because it is impracticable to examine for them. Employment under this authority may not exceed 1 year.

EFFECTIVE DATE: September 5, 1979.

FOR FURTHER INFORMATION CONTACT:

On position authority: William Bohling, Office of Personnel Management, 202-632-4533

On position content: Carole O'Leska, Department of the Treasury, 202-566-8301

Office of Personnel Management,

Beverly M. Jones,

Issuance System Manager.

Accordingly, 5 CFR 213.3105(i) is added as set out below:

§ 213.3105 Department of the Treasury.

* * * * *

(1) *Bureau of Government Financial Operations.*

(i) Clerical positions at grades GS-5 and below established in Emergency Disbursing Offices to process emergency payments to victims of catastrophes or natural disasters requiring emergency disbursing services. Employment under this authority may not exceed 1 year.

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

[FR Doc. 79-34002 Filed 11-1-79; 8:45 am]

BILLING CODE 6325-01-M

5 CFR Part 213

Excepted Service; Office of Personnel Management

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: Not to exceed 500 positions in Federal Job Information Centers, to be filled under the Community Outreach Information Network program, are excepted under Schedule A because it is impracticable to examine for them. Appointments under this authority may not exceed 90 days, and no one may receive more than one appointment.

EFFECTIVE DATE: May 10, 1979.

FOR FURTHER INFORMATION CONTACT: William Bohling, 202-632-4533.

Accordingly, 5 CFR 213.3190(a) is added as follows:

§ 213.3190 Office of Personnel Management

(a) Not to exceed 500 positions in Federal Job Information Centers, to be filled under the Community Outreach Information Network program. Appointments under this authority may not exceed 90 days, and no one may receive more than one appointment under the authority.

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

Office of Personnel Management.

Beverly M. Jones,

Issuance System Manager.

[FR Doc. 79-34003 Filed 11-1-79; 8:45 am]

BILLING CODE 6325-01-M

5 CFR Part 213

Excepted Service; Veterans Administration

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: This authority excepts from the competitive service 200 positions at grades GS-3 through GS-11 of the Veterans Administration Vietnam Era Veterans Readjustment Counseling Program with the provision that no one may serve under this authority after August 31, 1984. This exception is granted because it is impracticable to examine for these positions.

EFFECTIVE DATE: August 7, 1979.

FOR FURTHER INFORMATION CONTACT:

On position authority: William Bohling, Office of Personnel Management, 202-632-4533

On position content: Dr. Don Crawford, Veterans Administration, 202-389-3317

Office of Personnel Management.

Beverly M. Jones,

Issuance System Manager.

Accordingly, 5 CFR 213.3127(d) is added as set out below:

§ 213.3127 Veterans Administration.

* * * * *

(d) Not to exceed 200 positions at grades GS-3 through GS-11, involved in the Veterans Administration Vietnam Era Veterans Readjustment Counseling Program. No one may serve under this authority after August 31, 1984.

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

[FR Doc. 79-34001 Filed 11-1-79; 8:45 am]

BILLING CODE 6325-01-M

5 CFR Part 315

Career and Career-Conditional Employment

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: This document renumbers the sections of OPM regulations on conversion from other types of employment to career or career-conditional employment. This revision is an editorial change only and will facilitate the use, expansion, and printing of these regulations.

EFFECTIVE DATE: November 2, 1979.

FOR FURTHER INFORMATION CONTACT: Beverly M. Jones 202-254-7086.

SUPPLEMENTARY INFORMATION: 5 CFR Part 315, Subpart G, contains regulations on conversion to career or career-conditional employment from other types of employment. In the past, each time a new category of "other" types of employment has been added to this subpart, a section with a letter designation was inserted (e.g., § 315.703b, § 315.703c), rather than a new number.

In order to make this subpart easier to read and reference, as well as to accommodate a new typesetting system used for the Federal Register/Code of Federal Regulations, the Office of Personnel Management is redesignating the section numbers in this subpart to eliminate letter designations.

Office of Personnel Management,

Beverly M. Jones,

Issuance System Manager.

Accordingly, the Office of Personnel Management is revising the Table of Sections and the section headings for Subpart G of 5 CFR Part 315 to read as follows:

Subpart G—Conversion To Career or Career-Conditional Employment From Other Types of Employment

	Old section	New section
Incumbents of positions brought into the competitive service	315.701	315.701
Employees serving without competitive examination in rare cases	315.702	315.702
Employees formerly reached on a register	315.703	315.703
Conversion to career employment from indefinite or temporary employment	315.703a	315.704
Employees serving under transitional or veterans readjustment appointments	315.703b	315.705
Certain nonpermanent employees of the Department of Energy	315.703c	315.706
Disabled veterans	315.703d	315.707
Conversion based on service as a Presidential management intern		315.708
Mentally retarded and severely physically handicapped employees serving under schedule A appointments. [Reserved]		315.709
Disqualifications	315.704	315.725

Authority: 5 U.S.C. 1302, 3301, 3302; E.O. 10577, 3 CFR, 1954-1958 Comp., p.218

[FR Doc. 79-34006 Filed 11-1-79; 8:45 am]

BILLING CODE 6325-01-M

5 CFR Part 315

Career and Career-Conditional Employment

AGENCY: Office of Personnel Management.

ACTION: Final rulemaking.

SUMMARY: The Office of Personnel Management is revising its regulations to provide for the noncompetitive conversion to career or career-conditional appointment of Presidential Management Interns appointed under Executive Order 12008, "Presidential Management Intern Program."

EFFECTIVE DATE: December 3, 1979.

FOR FURTHER INFORMATION CONTACT: Maribeth Zankowski, Office of Policy Analysis and Development, Staffing Services, (202) 632-6817.

SUPPLEMENTARY INFORMATION: On April 24, 1979, the Office of Personnel Management published proposed regulations which provide for the noncompetitive conversion to career or career-conditional appointment of Presidential Management Interns and invited comments from the public (44 FR 24080). Since comments were favorable and no recommendations for change were proposed, the Office has not modified its final regulation as set out below except to renumber the section for editorial purposes.

Office of Personnel Management,

Beverly M. Jones,

Issuance System Manager.

Accordingly, the Office of Personnel Management is revising 5 CFR Part 315 by adding a new § 315.708 to read as follows:

§ 315.708 Conversion based on service as a Presidential Management Intern.

An agency may convert noncompetitively to career or career-conditional employment, a Presidential Management Intern who:

(a) has satisfactorily completed a 2-year Presidential Management Internship at the time of conversion;

(b) is recommended for conversion within 90 calendar days before completion of the internship; and

(c) meets the citizenship requirement.

E.O. 12008, 42 FR 43373, 3 CFR 1977 COMP.

[FR Doc. 79-34005 Filed 11-1-79; 8:45 am]

BILLING CODE 6325-01-M

5 CFR Part 733

Political Participation by U.S. Government Employees in Local Elections in Stafford County

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: In response to a request from a Federally employed resident of Stafford County, Virginia, OPM is designating that county as one where Government employees may participate in local elections subject to the limitations established by OPM pursuant to the authority of the Hatch Act.

EFFECTIVE DATE: November 2, 1979.

FOR FURTHER INFORMATION CONTACT: Ann Wilson, Office of the General Counsel, Office of Personnel Management, 1900 E Street, N.W., Washington, D.C. 20415, (202) 632-5524.

SUPPLEMENTARY INFORMATION: On August 14, 1979, OPM published a proposed rule (44 FR 47543) to grant Federal Government employees a partial exemption from the political activity restrictions of the Hatch Act, 5 U.S.C. 7321 *et seq.* OPM has received only one comment on the proposed rule.

A resident of Stafford County has complained that the proposed exemption is unfair because it would allow Federal employees to participate only as or on behalf of independent candidates. This resident contends that it is arbitrary and unreasonable to grant an exemption solely for nonpartisan participation while denying both political parties access to a large, rapidly increasing Federal employee population and denying Federal employees complete freedom of choice.

OPM previously has heard and answered the foregoing objection. In *Committee for Montgomery County, Maryland, et al.*, v. *Adolsek, et al.*, 249 F. Supp. 1009 (D. Md. 1966), the Court held that the Hatch Act exemption regulations were not unreasonable, arbitrary, or capricious. OPM maintains its position that the exemption regulations are consistent with the policy of the Hatch Act prohibiting partisan political activities. OPM believes that changes to this policy can most appropriately be made through Congressional revision of the Hatch Act.

5 U.S.C. § 553(d)(1) provides: "The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except a substantive rule which grants or recognizes an exemption or relieves a restriction." The Director of OPM has determined that the Hatch Act exemption does not require a notice period before its effective date and that no public interest is served by delaying the effective date. Therefore, the Hatch Act exemption for Stafford County will become effective immediately.

OPM hereby revises 5 C.F.R 733.124(b) by adding Stafford County to the designated Virginia localities with Hatch Act exemptions, to be listed after Prince William County and before Vienna.

Office of Personnel Management.

Beverly M. Jones,

Issuance System Manager.

[FR Doc. 79-34009 Filed 11-1-79; 8:45 am]

BILLING CODE 6325-01-M

DEPARTMENT OF AGRICULTURE

Agricultural Stabilization and Conservation Service

7 CFR Part 724

Termination of Marketing Quotas for 1979—Crop Cigar-Binder Tobacco

AGENCY: Agricultural Stabilization and Conservation Service, USDA.

ACTION: Final rule.

SUMMARY: This rule terminates existing farm marketing quotas for cigar-binder (types 51 & 52) tobacco for the 1979–80 marketing year and is intended to increase the supplies of cigar-binder tobacco which are free of marketing restrictions.

EFFECTIVE DATE: November 2, 1979.

FOR FURTHER INFORMATION CONTACT: Robert L. Tarczy, Price Support and Loan Division, ASCS, USDA, 3754 South Building, P.O. Box 2415, Washington, D.C. 20013. (202) 447-6733.

SUPPLEMENTARY INFORMATION: Notice that an investigation would be made to determine whether the operation of quotas would cause a short supply of cigar-binder tobacco, and, if such fact were found, published in the Federal Register on June 19, 1979 (44 FR 35230). The public was given an opportunity to be heard and to submit data, views, and recommendations pertaining to the investigation and what actions, if any, should be taken.

Discussion of Comments

During the cigar binder termination comment period, one written response was received. It stated that the present supply-demand situation warrants termination of marketing quotas for the 1979–80 marketing year.

On the basis of the investigation which has been made, it has been found and determined that the operation of farm marketing quotas on cigar-binder (types 51 & 52) tobacco for the 1979–80 marketing year will cause the amount of such tobacco which is free of marketing restrictions to be less than the normal supply of such kind of tobacco and that farm marketing quotas on such kind of tobacco for the 1979–80 marketing year should be terminated.

The latest available statistics of the Federal Government have been used in making these determinations.

Final Rule

Accordingly, 7 CFR 724.36 and the centerhead which precedes it are revised to read as follows effective with respect to the 1979 crop of cigar-binder (types 51 & 52) tobacco. The material previously appearing in this section under centerhead, "Termination of Quotas—1978–79 Marketing Year" remains in full force and effect as to the crop to which it was applicable.

Termination of Quotas, 1979–80 Marketing Year

§ 724.36 Cigar-binder (types 51 & 52) tobacco.

It has been found and determined that operation of farm marketing quotas in effect on cigar-binder (types 51 & 52) tobacco for the 1979–80 marketing year will cause the amount of such kind of tobacco which is free of marketing restrictions to be less than the normal supply of such kind of tobacco for the 1979–80 marketing year. Therefore, marketing quotas for such kind of tobacco for the 1979–80 marketing year are hereby terminated.

(Secs. 371, 375, 52 Stat. 64, as amended, 66, as amended; 7 U.S.C. 1371, 1375).

Since producers of cigar-binder tobacco are preparing to harvest their 1979 crop and need to know the provisions of this rule immediately, it is essential that this rule be made effective as soon as possible.

This final rule has been reviewed under the USDA criteria established to implement Executive Order 12044, "Improving Government Regulations." A determination has been made that this action should not be classified "significant" under those criteria. A Final Impact Statement is available from Robert L. Tarczy, Price Support and Loan Division, ASCS, USDA, 3741 South Building, P.O. Box 2415, Washington, D.C. 20013. (202) 447-3391.

Signed at Washington, D.C. on October 26, 1979.

Ray Fitzgerald,

Administrator, Agricultural Stabilization and Conservation Service.

[FR Doc. 79-33616 Filed 11-1-79; 8:45 am]

BILLING CODE 3410-05-M

Agricultural Marketing Service

7 CFR Part 910

[Lemon Regulation 224]

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 November 4–10, 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: November 4, 1979.

FOR FURTHER INFORMATION CONTACT: Malvin E. McGaha, 202-447-5975.

SUPPLEMENTARY INFORMATION: *Findings.* This regulation is issued under 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. The agreement and order are effective under

the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). The action is based upon the recommendations and information submitted by the Lemon Administrative Committee, and upon other information. It is hereby found that this action will tend to effectuate the declared policy of the act.

The committee met on October 30, 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 is somewhat easier.

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 December 3, 1979 (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.

Further, in accordance with procedures in Executive Order 12044, the emergency nature of this regulation warrants publication without opportunity for further public comment. The regulation has not been classified significant under USDA criteria for implementing the Executive Order. An Impact Analysis is available from Malvin E. McGaha, 202–447–5975.

§ 910.524 Lemon Regulation 224.

Order. (a) The quantity of lemons grown in California and Arizona which may be handled during the period November 4, 1979, through November 10, 1979, is established at 200,000 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)

Dated: October 31, 1979.

Charles R. Brader,
Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 79-34140 Filed 11-1-79; 8:45 am]

BILLING CODE 3410-02-M

7 CFR Part 959

Onions Grown in South Texas; Expenses and Rate of Assessment

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This regulation authorizes expenses for the functioning of the South Texas Onion Committee. It will enable the committee to collect assessments from first handlers on all assessable onions and to use the resulting funds for its expenses.

EFFECTIVE DATES: During fiscal period ending July 31, 1980.

FOR FURTHER INFORMATION CONTACT: Donald S. Kuryloski (202) 447–6393.

SUPPLEMENTARY INFORMATION: *Findings.* Pursuant to Marketing Order No. 959, as amended (7 CFR Part 959), regulating the handling of onions grown in South Texas, 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 committee, established under the marketing order, and upon other information, it is found that the expenses and rate of assessment, as hereinafter provided, will tend to effectuate the declared policy of the act.

It is further found that it is impracticable and contrary to the public interest to provide 60 days for interested persons to file comments, engage in public rulemaking procedure, and that good cause exists for not postponing the effective date until 30 days after publication (5 U.S.C. 553), as the order requires that the rate of assessment for a particular fiscal period shall apply to all assessable onions handled from the beginning of such period. Handlers and other interested persons were given an opportunity to submit information and views on the expenses and assessment rate at an open meeting of the committee. To effectuate the declared purposes of the act it is necessary to make these provisions effective as specified.

The budget and rate of assessment has not been determined significant under USDA criteria for implementing Executive Order 12044.

7 CFR Part 959 is hereby amended to add a new § 959.220 as follows:

§ 959.220 Expenses and rate of assessment.

(a) The reasonable expenses that are likely to be incurred during the fiscal period ending July 31, 1980, by the South Texas Onion Committee for its maintenance and functioning and for such other purposes as the Secretary may determine to be appropriate will amount to $137,866.

(b) The rate of assessment to be paid by each handler in accordance with this part shall be two cents ($0.02) per 50-pound container or equivalent quantity of onions handled by him as the first handler thereof during the fiscal period.

(c) Unexpended income in excess of expenses for the fiscal period may be carried over as a reserve.

(d) Terms used in this section have the same meaning as when used in the marketing agreement and this part.

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

Dated: October 29, 1979.

Charles R. Brader,
Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 79-33958 Filed 11-1-79; 8:45 am]

BILLING CODE 3410-02-M

Animal and Plant Health Inspection Service

9 CFR 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 establishes a specific date for receipt of applications for special permits to be drawn on a lottery basis for the allotment of quarantine space for the second group of cattle to be imported through the Harry S Truman Animal Import Center. This action is being taken because of the necessity to coordinate and allocate personnel and resources for the operation of the Harry S Truman Animal Import Center during a given quarantine period and to maximize the utilization of the Center. The intended effect of this action is to obtain applications for special permits to import cattle through the Harry S Truman Animal Import Center as soon as possible.

EFFECTIVE DATE: October 30, 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 August 19, 1977, (42 FR 41848–41849) procedures were established for awarding special import permits to

prospective importers of cattle from countries affected with foot-and-mouth disease (FMD). Included in these procedures were provisions to notify the public at least 90 days before a public drawing is held and to ensure receipt of completed applications for special permits by Veterinary Services at least 15 days prior to the announced date of the drawing.

Delays in construction have caused the Department to delay the first shipment which will initiate the operation of the facility. The Department now anticipates the first shipment will enter quarantine at the Import Center about January 1, 1980. The first shipment of animals would be in quarantine for five months at the Import Center. A period of 30 days for cleaning and disinfecting the center is necessary before another group of animals can enter the Import Center. Consequently, the second group of animals could not enter the Import Center before June 1, 1980. Section 92.41(a)(2) of the regulations requires that the drawing for special permits for animals to be imported into the Import Center be held at least six months before their proposed date of entry into the center. Consequently, the drawing for the second group of animals must be held by January 1, 1980, in order that the Import Center be fully utilized. In other words, in order to insure that the second group of animals can enter the Import Center as soon as possible after the first group of animals have left the Import Center, the drawing must be held as close to January 1, 1980, as possible. However, as noted above, the regulations also provide that 90 days notice be afforded to potential applicants for special permits prior to the date of the drawing for permits (9 CFR 92.41(a)(1)). Consequently, if the drawing were to be held on or about January 1, 1980, notice had to be given by October 1, 1979, obviously this is not possible. Consequently, the Department has determined to reduce the notice period to approximately 70 days for the second quarantine period from the 90 day period. This should still provide adequate notice to persons who wish to apply for a special permit. Therefore, the drawing is scheduled for January 28, 1980, and then applications would be due by January 11, 1980.

The costs associated with the operation of the Fleming Key facility to be borne by the importers using this facility will vary in accordance with the actual number of animals utilizing the facility. At the present time, the Department estimates that the cost to each importer will be approximately $4,571 per animal if the facility is fully utilized, that such costs will necessarily increase if the facility is not fully utilized, and that such increase will be in proportion to the number of animals actually utilizing the facility. In this connection, the Department will engage in rulemaking regarding the costs in the near future.

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

In § 92.41, paragraph (a)(1), the second sentence is amended to read:

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

(a) * * *

(1) * * * Each applicant shall complete an application for importing animals into this amimal import center at least 15 days prior to the date of the drawing.[5a] *Provided,* That for the second drawing on January 28, 1980, applications must be received by Veterinary Services on or before January 11, 1980, to be considered. * * *

(Sec. 2, 32 Stat. 792, as amended; sec. 1, 84 Stat. 202 (21 U.S.C. 111, and 135); 37 FR 28464, 28477; 38 FR 19141.)

The amendment revises the notice provisions relating to the issuance of special permits for quarantine of cattle at the Harry S Truman Animal Import Center and is essential in order to allow the Department to better coordinate and allocate personnel and materials to the facility and to provide maximum utilization of the facility. The amendment is of an emergency nature and must be placed in effect immediately in order to serve the purpose intended.

Therefore, pursuant to 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 this final rule are impracticable and contrary to the public interest and good cause is found for making this final rule effective less than 30 days after publication of this document in the Federal Register.

Further, this final rule has not been designated as "significant," and is being published in accordance with the emergency procedures in Executive Order 12044 and Secretary's Memorandum 1955. It has been determined by Dr. M. J. Tillery, Director, National Program Planning Staffs, Veterinary Services, Animal and Plant Health Inspection Service, that the emergency nature of this final rule warrants publication without opportunity for public comment and preparation of an impact analysis statement at this time.

This final rule will be scheduled for review under provisions of Executive Order 12044 and Secretary's Memorandum 1955.

Done at Washington, D.C., this 30th day of October 1979.

Pierre A. Chaloux,

Deputy Administrator, Veterinary Services.

[FR Doc. 79-34013 Filed 11-1-79; 8:45 am]

BILLING CODE 3410-34-M

[5a] Application forms may be obtained upon request from the Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Hyattsville, MD 20782.

9 CFR Part 113

Standard Requirements; Miscellaneous Amendments; Correction

In FR Doc. 79-31434 appearing at page 58897 in the issue of Friday October 12, 1979, the following change should be made:

On page 58899, second column, in "(2)", sixteenth line, "conforming" should read "confirming".

BILLING CODE 1505-01-M

NUCLEAR REGULATORY COMMISSION

10 CFR Part 71

Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions; Shipment in Accordance With Department of Transportation Regulations

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Effective rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its regulations for packaging and transportation of radioactive material. The amendments would require all shipments of radioactive materials made by NRC licensees, other than shipments subject to the regulations of the U.S. Postal Service, to be made in accordance with the regulations of the U.S. Department of Transportation. The regulations are being amended to allow the NRC to inspect the activities of its licensees involved with shipment of radioactive materials.

EFFECTIVE DATE: December 3, 1979.

FOR FURTHER INFORMATION CONTACT: Ralph J. Jones, Office of Standards Development, U.S. Nuclear Regulatory

Commission, Washington, D.C. 20555 [(301)-443-5949].

SUPPLEMENTARY INFORMATION: An increased number of shipments are being made each year of low specific activity materials and of type A quantities of radioactive materials. This trend is expected to continue in the future. Recently, there has also been a growing number of incidents involving the shipment of these materials. The basic cause of many transportation incidents can be attributed to the use of defective shipping containers or to improper loading and preparation of packages for shipment. After consulting with the U.S. Department of Transportation, the U.S. Nuclear Regulatory Commission has determined that there is a need to further assure that these shipments are being conducted in accordance with Federal regulations. Therefore, the NRC is amending 10 CFR Part 71 to require that all shipments of licensed material, except those shipments subject to the regulations of the U.S. Postal Service, be made in accordance with the regulations of the U.S. Department of Transportation. This change to the regulations which will not alter any substantive requirements will permit the NRC to inspect the activities of its licensees in this area and to take enforcement actions if warranted.

The Nuclear Regulatory Commission has overlapping authority with the Department of Transportation to regulate the transportation of radioactive materials. Because of the numerous transportation incidents that have occurred involving low specific activity and type A quantities of radioactive materials, a need exists for additional inspection and enforcement efforts to more fully assure that these shipments are made in accordance with Federal regulations. Augmenting the inspection and enforcement efforts of the Department of Transportation with those of the Nuclear Regulatory Commission will further assure that applicable Federal regulations are observed with respect to packaging and shipment of low specific activity and type A quantities of radioactive materials. In view of the foregoing and of the importance from the standpoint of the public health and safety of assuring that NRC licensees are in compliance with Federal regulations applicable to the packaging and shipment of radioactive material, the Commission has found that there is immediate need to increase the level of its inspection and enforcement activities in this area, that this change relates primarily to matters of Commission practice and procedures, and therefore, good cause exists for omitting notice of proposed rulemaking and public procedure thereon as contrary to the public interest. The amendments will become effective December 3, 1979.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Sections 552 and 553 of Title 5 of the United States Code, the following amendment to Title 10, Chapter I, Code of Federal Regulations, Part 71, is published as a document subject to codification.

1. In § 71.1, paragraph (a) is revised to read as follows:

§ 71.1 Purpose.

(a) This part establishes requirements for transportation and for preparation for shipment of licensed material and prescribes procedures and standards for approval by the Nuclear Regulatory Commission of packaging and shipping procedures for licensed materials and prescribes certain requirements governing such packaging and shipping.

* * * * *

2. In § 71.5, paragraphs (a) and (c) are revised to read as follows:

§ 71.5 Transportation of licensed material.

(a) No licensee shall transport any licensed material outside of the confines of his plant or other place of use, or deliver any licensed material to a carrier for transport, unless the licensee complies with the applicable requirements to the regulations appropriate to the mode of transport, of the Department of Transportation in 49 CFR Parts 170-189, and the U.S. Postal Service in 39 CFR Parts 14 and 15 insofar as such regulations relate to the packaging of byproduct, source, or special nuclear material, marking and labeling of the packages, loading and storage of packages, placarding of the transportation vehicle, monitoring requirements and accident reporting.

* * * * *

(c) Paragraph (a) of this section shall not apply to the transportation of licensed material, or to the delivery of licensed material to a carrier for transport, where such transportation is subject to the regulations of the U.S. Postal Service.

3. In § 71.7, paragraph (a) and the prefatory language of paragraph (b) are revised to read as follows:

§ 71.7 Exemption for certain quantities.

(a) A licensee is exempt from all the requirements of this part to the extent that he delivers to a carrier for transport packages each of which contains no licensed material having a specific activity in excess of 0.002 microcurie/gram.

(b) Except for the requirements specified in § 71.5, a licensee is exempt from all the requirements of this part to the extent he delivers to a carrier for transport packages subject to the regulations of the Department of Transportation in 49 CFR Parts 170-189 or the U.S. Postal Service in 39 CFR Parts 14 and 15, each of which contains no more than a Type A Quantity of radioactive material, as defined in § 71.4(q), which may include one of the following:

* * * * *

(Secs. 53, 63, 81, 161, b, i, o, Pub. L. 83-703, 68 Stat. 930, 933, 935, 948, as amended (42 U.S.C. 2073, 2093, 2111, 2201); Sec. 201, Pub. L. 93-438, 88 Stat. 1242, as amended (42 U.S.C. 5841))

Dated at Washington, D.C. this 29th day of October, 1979.

For the U.S. Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 79-33883 Filed 11-1-79; 8:45 am]

BILLING CODE 7590-01-M

DEPARTMENT OF THE TREASURY

Comptroller of the Currency

12 CFR Part 27

Fair Housing Home Loan Data System

AGENCY: Comptroller of the Currency.

ACTION: Final rule.

SUMMARY: The Office of the Comptroller of the Currency is issuing a regulation designed to provide a basis for a more effective fair housing monitoring program for home loans. The regulation establishes new recordkeeping requirements and a data collection system for monitoring national bank compliance with the Fair Housing Act (Title VIII of the Civil Rights Act of 1968), 42 U.S.C. 3601 *et seq.*, and the Equal Credit Opportunity Act, 15 U.S.C. 1691 *et seq.* In addition, the issuance of this fair housing regulation will assist in the implementation of certain parts of the settlement reached in "National Urban League et al. v. Office of the Comptroller of the Currency et al." The burdens imposed on national banks under this final regulation are significantly less than the burdens which would have been created under the proposed regulation, thus reducing the expense to national banks.

EFFECTIVE DATE: January 1, 1980.

FOR FURTHER INFORMATION CONTACT: Patrick Marr, Senior Compliance Fair

Lending Examination Specialist, or Coreen Arnold, Senior Compliance Examiner—Fair Lending, Office of the Comptroller of the Currency, Washington, D.C. 20219, (202) 447-1600.

SUPPLEMENTARY INFORMATION: On April 13, 1979, the Comptroller of the Currency published for comment (44 FR 22396) a proposed regulation and guideline in furtherance of its responsibility to monitor and enforce national bank compliance with the provisions of the Federal fair housing and lending laws. In response to the proposed regulation, 144 written comments were received from national banks and bank holding companies, trade associations, fair housing and other public interest groups, and several individuals. All comments were reviewed and analyzed in detail insofar as they related to matters within the scope of the proposed regulation. In addition, written comments were obtained in the course of several meetings held with groups of bankers representing a variety of types of banks and regions of the country. Many of the comments aided in directing the attention of this Office to requirements of the proposed regulation which were particularly burdensome or insufficiently related to the goal of providing a fairly administered, cost-effective fair housing monitoring system.

The proposed regulation would have required all national banks to:

(1) Maintain and retain a Fair Housing Inquiry/Application Log ("Log") on in-person inquires and applications for home loans;

(2) Retain certain data collected in connection with an application for a home loan; and

(3) Submit to the Comptroller, on a form to be supplied, information retained under (2) for statistical analysis prior to a scheduled examination.

In response to many of the suggestions, three major changes have been adopted:

(1) Elimination of the Log maintenance and retention as a general requirement. The Log, however, has been retained in the regulation for use on a case by case basis to monitor the inquiry and application pattern of a bank where the Comptroller has cause to believe that the bank is not in compliance with the fair housing laws. In light of this change, the scope of the Log has been enlarged to provide the Comptroller with a better method to detect the presence or absence of discrimination.

(2) Exclusion of certain categories of loans from the recordkeeping and data submission provisions; *i.e.*, home improvements, mobile homes that are not permanently affixed to land, and vacant land.

(3) Establishment of a simple, substitute requirement for banks which receive fifty or more home loan applications a year. In place of the Log, such banks shall record and maintain monthly information on the volume of home loan activity and make this data available to the Comptroller on request.

The "guideline", originally published as an explanatory adjunct to the proposed regulation, has been eliminated from the final version. It has been replaced by more specific provisions in the final regulation. Additional guidance will be incorporated into the instructions and explanatory material which will be sent to each bank along with copies of the forms which are in the Appendix to the final regulation.

Many of the issues raised by the comments, and their resolution in the final regulation, are discussed below.

Discussion of Comments

Scope

At least half of the comments addressed the scope of the regulation, particularly in relation to the inclusion of mobile home loans and home improvement loans.

With few exceptions, the banks and trade organizations objected to the inclusion of those loans within the data collection system, and noted the substantial burden that would result from the inconsistency between the type of records required under the recordkeeping requirements proposed in § 27.3 (b) and (c) and the type of information generally collected for mobile home and home improvement loans. In addition, many comments pointed out that home improvement and mobile home loans are generally treated by banks as consumer loans, which do not require the extensive financial disclosures or monitoring information required for real estate loans in § 202.13 of Regulation B of the Federal Reserve Board, 12 CFR 202.13.

On the other hand, nearly all of the civil rights and fair housing groups, together with a few of the banks, urged the inclusion of all home improvement loans, rather than only home improvement loans secured by a first lien, as proposed. They argued that the Fair Housing Act of 1968 includes all housing-related activity and that discrimination occurs in the extension of credit for home improvement loans regardless of the type of security or status of the junior lien.

The principal purpose of the regulation is to provide for the collection and retention of information necessary to establish a valid statistical analysis of a bank's home lending decisions without placing an undue burden upon the banks. Thus, the scope of the analysis should be limited to the types of loans which can be effectively analyzed.

The Comptroller has concluded that inclusion of home improvement and mobile home loans is unfeasible because there is no consistency among banks in methods or techniques for granting credit in the general consumer area. On the other hand, statistical analysis is possible in residential real estate because of the highly standardized underwriting practices used in making those loans. Therefore, the final regulation eliminates all home improvement and mobile home loans (except a loan which is made in reliance upon the security of a mobile home and the parcel of land to which it is permanently affixed) from its coverage.

Nearly all of the civil rights groups' comments and a few of the bank comments questioned the exclusion of Federal Housing Administration (FHA) and Veterans Administration (VA) insured loans from the recordkeeping and data submission requirements. There were two reasons for this omission. First, the FHA and VA, rather than the bank, generally make the lending decisions and conduct the appraisal on loans which they insure or guarantee. Secondly, the relevant data on FHA insured loans is already collected by FHA, and is available for analysis should the Comptroller decide to review lending decisions on FHA mortgages extended by national banks.

The use of electronic data processing to analyze loan decisions (including rates and terms) is a new and developing process. The Comptroller, therefore, has limited the scope of the regulation to those types of loans which our research and public comment indicate can be effectively analyzed. However, the Comptroller will regularly review the efficiency and effectiveness of these requirements, as well as the value of statistical analysis through the use of electronic data processing, to determine whether the regulatory scope should be reexamined in the future.

Definition of "Application"

A number of comments questioned the proposed definition of "application" in § 27.2(b). This definition comes directly from § 202.2(f) of Regulation B, 12 CFR 202.2(f). The comments, however, underscored the confusion that exists among some banks about the meaning of this term, particularly in relation to oral applications. Therefore, the definition of

application will be amplified in the explanatory material which will be sent to each bank along with the regulation, forms, and instructions.

Conventional Credit

Section 27.2(e) of the proposed regulation contained a definition of conventional credit. In response to the many comments, this definition has been eliminated and replaced by a definition of "real estate loan", which, consistent with the Comptroller's definition of real estate loan in 12 CFR Part 7, excludes any loan in which a lender places substantial reliance on the insurance or guarantees of a government agency.

Dwelling

Section 27.2(f) of the proposed regulation defined "dwelling". A substantial number of comments were received regarding the inappropriate inclusion of vacant land within the scope of this regulation and within the definition of "dwelling". Since the definition of "residential real property" in § 202.13(a)(2) of Regulation B has been interpreted not to include vacant land, and because the underwriting standards for vacant land are not generally consistent with those for improved land, vacant land has been eliminated from coverage under this regulation. The definition of "dwelling" has, therefore, been eliminated and replaced by a definition of "residential real property" which is consistent with Regulation B, and which contains an explicit exclusion of vacant land.

More than half of the comments questioned the suitability of including mobile homes within the scope of this definition. These comments have been addressed previously under "Scope".

Home Loan

Section 27.2(g) of the proposed regulation defined home loan to include loans for purchase, construction-permanent, or refinancing of a dwelling, as well as home improvement loans secured by a first lien. For the reasons described above under the discussion of "Scope", the definition of "home loan" no longer includes home improvement loans.

Many bankers' comments urged that the definition of home loans be limited only to the purchase of a dwelling, and recommended the omission of construction, construction-permanent and refinancing loans. Other bank comments, however, noted that construction-permanent is a common type of mortgage in inner city lending, and also noted that refinancing (not to be confused with a home equity loan which is generally a consumer loan) is also increasing in popularity. Therefore, the Comptroller has decided to continue to include construction-permanent and refinancing in the definition of home loan because these loan types will provide a more accurate picture of a bank's home loan activity.

Construction loans without permanent financing were not intended to be included in the proposed regulation and are excluded from the scope of the final regulation.

Inquiry

Section 27.2(i) of the proposed regulation defined "inquiry" to include in-person inquiries when they related to a specific property. Most comments expressed concern about the tying of the inquiry concept to specific properties. The banks felt that it would be confusing to accurately maintain a distinction between inquiries which related to a property and those which did not. The civil rights groups, in contrast, felt that addressing only inquiries on specific properties was too limited. Since the final regulation requires the Log only where the Comptroller has cause to believe that a bank is not complying with the fair housing laws, the definition of "inquiry" has been expanded to include all written and in-person requests for information about home loans, including requests for general information on rates and terms.

Prohibited Basis

A number of comments argued that the definition of "prohibited basis" in Section 27.2(j) of the proposed regulation was too narrow a construction of the law, and suggested that definitions used by various States be covered as well. In order to avoid possible substantive conflicts between Regulation B, the Fair Housing Act, and State laws, the term "prohibited basis" will not be defined in the regulation. All laws and regulations which are applicable to national banks will apply.

Inquiry/Application Log

Section 27.3(a) of the proposed regulation would have required every bank to maintain an Inquiry/Application Log for home loans. Nearly every bank and banking association that commented on the regulation objected to this provision. Most commentators felt that the burden would be excessive considering the information to be gained. It was also pointed out that those banks which were prescreening illegally might not list the inquiries on the Log, while banks which were not discriminating would be unjustly burdened by the requirement.

The Comptroller was also concerned that under the proposed regulation banks which have a significant volume of home lending would have many pages of Log forms, which would be in excess of what an on-site examiner would require in order to conduct a routine fair housing examination. Significantly, the Log was intended to be used to provide information to determine which banks must submit data for computer analysis. However, that need can be met with basic management information which many banks presently maintain; *i.e.*, the volume of home loan applications, which is now required in the final regulation in § 27.3(a), and which is far less burdensome than the Log. Based on all of these considerations, the final regulation eliminates the Log as a general requirement.

While the Inquiry/Application Log will not be required of all banks, the Comptroller may, as an enforcement mechanism, require a bank to maintain the Log when there is cause to believe that the bank may not be in compliance with the fair housing laws, and particularly, where there are indications that a bank is prescreening or otherwise discouraging applications on a prohibited basis. In order to reflect this new function of the Log, the Log requirement has been removed from § 27.3, Recordkeeping Requirements, and placed in a new § 27.4, Inquiry/Application Log.

The new § 27.4 contains the factors to be considered by the Comptroller in determining whether a bank shall be required to keep a Log. Because the Log will be limited to enforcement purposes, certain requirements have been added or expanded in order to increase its effectiveness in this regard: (1) the definition of inquiries has been expanded (see discussion of "inquiries", above); (2) Government-insured home loans (*i.e.*, FHA, VA and FmHA) will be included in order to obtain a more complete picture of requests for home loans; and (3) the census tract of the subject property which will secure the loan will also be required when the property is located in a Standard Metropolitan Statistical Area (SMSA) in which the bank has a home office or branch office.

Unlike the provisions of § 27.3(a) and § 27.7, which set general exemptions for banks which receive fewer than 50 or 75 home loan applications per year, respectively, the enforcement provisions of this regulation will not be subject to any exemption. The Comptroller specifically reserves the right to use other corrective measures, in addition to

the Log, in enforcing the provisions of applicable fair housing laws. A bank which has been directed to maintain the Log must record and maintain the information on the form prescribed in Appendix III. However, the Comptroller reserves the option of directing a bank to maintain the Log data in any manner that the Comptroller may deem appropriate. Additional information may be recorded and maintained at the bank's discretion.

Home Loan Activity: Monthly Data

In place of the Inquiry/Application Log, each bank which receives fifty or more home loan applications per year will be required to maintain certain data specified in a revised subsection 27.3(a), Monthly Home Loan Activity. This data will include the monthly volume of home loan applications received by each decision center, and the number of home loans closed, withdrawn and denied. In order to maximize flexibility, banks may obtain and record this information in a manner compatible with their own internal management systems. Banks will, however, be requested prior to examinations to submit this information to the Comptroller in the format specified in the regulation (set forth in Appendix I). The purpose of this requirement is to establish whether the volume of home loan applications is significant enough to permit statistical analysis, and if so, to provide the Comptroller with sufficient information so as to enable the Comptroller to direct the selection of an appropriate sample.

Information Required on Application for Home Loan

Section 27.3(b) of the proposed regulations contained a listing of items that must be maintained for each application. This particular listing of items was arranged to enable those banks utilizing the application forms of the Federal Home Loan Mortgage Corporation and the Federal National Mortgage Association (FHLMC/FNMA) to obtain the required information in the least burdensome manner.

Many comments were particularly helpful in clarifying these requirements. Those items which received the most comment include:

(1) Section 27.3(b)(1) (ii) and (iii) of the proposed regulation required banks to record "interest rate requested" and "number of months requested" by the applicant. Many banks commented that this information was not generally "requested" but more often "suggested" by the bank. However, since these items, regardless of how they are obtained, are important variables in determining an applicant's eligibility for a loan, these items have been retained in the final regulation.

(2) Section 27.3(b)(1)(iv) of the proposed regulation required banks to record on the application the year the house was built. A number of comments noted that many home purchasers do not know this information. However, information about the age of the house is crucial in the analysis of discriminatory practices. Thus, the final regulation still requires that this information be provided, but the requirement has been modified to permit a bank to approximate the date to the nearest decade where the exact date is unknown.

(3) Section 27.3(b)(1) (xiii) and (xiv) of the proposed regulation defined the components of monthly housing payment to include principal, interest, insurance, real estate taxes, and assessments for homeowner dues or condominium fees. Since all banks compute monthly housing payment by including principal and interest, at a minimum, the final regulation retains these items. However, several comments noted that banks did or did not include such items as condominium fees, real estate taxes, insurance or utilities. Because of the lack of uniformity about the inclusion of certain items, this section has been revised to give each bank discretion as to whether it will include any of the other fees or items in its assessment of the monthly housing payment. However, as stated in the regulation, whatever practice a bank follows in including or excluding certain items must be followed consistently. When a bank changes its regular practice, such change and its effective date should be identifiable with respect to the bank's new policy.

(4) Section 27.3(b)(1)(xvii) of the proposed regulation contained a definition of net worth. A number of comments noted that the proposed definition was inconsistent with the FHLMC/FNMA Form on which it was based. The final regulation has been revised to be consistent with the FHLMC/FNMA Form.

Additional Information Required in the Loan File

Section 27.3(c) of the proposed regulation contained a further listing of items, apart from that obtained on a standard FHLMC/FNMA application, which were to be retained in the loan file.

Two additional elements have been incorporated into the loan file requirements under the final regulation. They are the "commitment date" and the "type of mortgage." Both of these items are important variables for a statistical analysis of loan rates and terms. Commitment date establishes the date a particular rate/term applied and mortgage type permits differentiation between rates and terms based on mortgage type; *e.g.*, fixed rate, variable rate, graduated payment, etc. The Comptroller does not believe that the furnishing of these items will impose a significant burden on a bank.

Section 27.3(c)(2) of the proposed regulation would have required banks to record and maintain the census tract data in the loan file for those applications in which an appraisal was completed. In general, banks and banking organizations objected to the requirement, while civil rights and fair housing groups objected to limiting the requirement only to those properties where an appraisal had been undertaken. After careful consideration, the Comptroller has determined not to delete the requirement because census tract is the only geographic unit for which income and racial data are consistently and readily available to facilitate analysis of the possible use by lenders of racial or national origin characteristics of a neighborhood in the evaluation of loans. While a bank will still be required to record census tract information of the subject property (where available), the Comptroller has decided to limit the recordation and maintenance of this data to those banks which have a home office or branch office in the SMSA in which the property is located.

Although the Comptroller is not expanding the requirement to identify census tracts for all applications because it is not cost-effective, a bank that is directed to maintain the Inquiry/Application Log, as discussed above, will be required to supply census tract data on each application and inquiry, if applicable.

Section 27.3(c)(1) of the proposed regulation, which provided for coordinating the loan file with the Log, has been eliminated as the Log is no longer a general requirement.

Monitoring Information on Sex and Race/National Origin

Many banks were troubled by the requirement in § 27.3(b)(2) of the proposed regulation to provide monitoring information on sex and race/national origin when the applicant does not voluntarily do so. Their primary concern was the problem of accuracy, *i.e.*, the inability of the loan officer to accurately identify the sex and/or race/national origin of the applicant. It should be emphasized, however, that the information is not being collected for the purpose of establishing a statistical

count as to the racial and/or ethnic characteristics of applicants for home loans. The regulations are designed, rather, to reveal possible discriminatory practices. Such discrimination which may exist would occur not on the basis of how the applicant characterizes himself or herself, but on how the lender perceives the applicant. For example, some blacks of Hispanic origin may consider themselves as Hispanic, while to the lender, the most overwhelming characteristic of the applicant would generally be his or her color.

Other comments were concerned that characterizing applicants by race would defeat all efforts to prevent discrimination by calling attention to race. Ending discrimination does not require people to become color blind. The fact that a person is of a certain color or of a particular sex is overwhelmingly evident when a person comes to file or inquire about an application; however, whether a practice of discrimination exists cannot be ascertained unless the examiner has the information on the applicant's race and sex. Also, without this information in each file, corrective action for the class of persons who may have been discriminated against cannot be undertaken. This is the same conclusion that the Federal Home Loan Bank Board and the Federal Deposit Insurance Corporation have apparently reached in instituting similar home loan data requirements for lending institutions under their respective jurisdictions.

Several comments expressed concern that the monitoring provisions would violate the inquirer's or the applicant's right to privacy, especially when an individual has clearly demonstrated that he or she does not wish to have the information supplied to the Federal Government. Specific mention was made of the applicability of the Right to Financial Privacy Act of 1978, 12 U.S.C. § 3401 *et seq.* However, the Act does not purport to bar the Federal Government from obtaining a customer's financial records from his or her depository institution, but merely requires that certain procedural steps be followed. In any event, the collection by the Comptroller of the sex and race/national origin monitoring information is exempted under the supervisory agency provision of 12 U.S.C. § 3413(b), which permits the examination by or disclosure to any such agency of financial records or information in the exercise of its supervisory, regulatory, or monetary functions.

One comment also expressed the opinion that the involuntary collection of the required monitoring information may violate an individual's constitutional right to privacy. However, an examination of the case law in this area does not support a conclusion that an individual may prevent the collection of information which is ascertainable by anyone and which is collected for the purposes of enforcing the provisions of an anti-discrimination statute.

The Comptroller does, however, recognize the concerns raised by these comments, and has taken all possible action to insure that in transferring information by the mails between the banks and the Comptroller, the anonymity of the individuals be preserved.

The content of the required disclosure has been amended to render it identical to that contained on the FHLMC/FNMA Application insert ("Information for Government Monitoring Purposes"), which requests this information. The final regulation also provides that banks which elect to use this insert will be deemed to be in compliance with the disclosures required under § 27.3(b)(2)(i). A bank which uses the insert in conjunction with other home loan application forms will also be in compliance with § 27.3(b)(2)(i).

Submission of Data

Section 27.6 of the proposed regulation would have required banks to submit home loan data, to be specified, at the Comptroller's request. In consideration of the many comments that expressed concern over the submission, particularly the nature and form of the requested data, the final regulation has been revised to specify the exact data and format to be requested. In addition, the banks will receive guidance in the Instructions to the Home Loan Data Submission Form (Appendix IV) on the ways that this data might be obtained.

A number of banks also commented on the difficulty of gathering this data in a 30-day period. It should be noted, however, that many banks will be completing these forms prior to storing each file. In addition, the regulation provides for an extension of this 30-day period. Since each call for data will be done on an individual bank basis, there will be opportunity to extend this period, if necessary.

Finally, a few comments suggested that an undue burden would be created by the proposed requirement that a bank retain the application data after a loan is purchased. It should be noted that this requirement is not new, but is presently contained under the recordkeeping provisions of § 202.12 of Regulation B, 12 CFR 202.12. Thus, the adoption of this requirement in a substitute monitoring program as authorized under 12 CFR 202.13 does not increase the burden on national banks.

Several comments expressed concern that the Comptroller would determine compliance with fair housing laws and regulations without all the data in the file, with inexperienced personnel, and/or would apply a national underwriting standard to all home loan lending decisions. This is not the case. Underwriting standards in one bank will not be compared to standards in other banks, or to a national standard derived by the Comptroller.

The statistical analysis will generally be performed with the assistance of electronic data processing. It will compare each accept/reject decision of a bank to that bank's own underwriting practices, as determined from the total sample, to identify deviations that *may be* occurring on a prohibited basis. This analysis will serve as the basis for more in-depth review, if appropriate, by national bank examiners.

If deviations on a prohibited basis are identified, the appropriate loan files will be reviewed in the bank by a national bank examiner to determine whether there is evidence in the file which explains the deviation; *e.g.*, poor credit report or job instability. Where, however, the file shows no appreciable difference in creditworthiness standards between rejected applicants and approved applicants with similar characteristics, the examiner will discuss those findings with bank management prior to determining whether or not there is noncompliance with Regulation B, the Fair Housing Act, or applicable State law.

The same is true for rates and terms. Rates and terms for each loan will be compared against the bank's own rate/term standards at the time of loan commitment, and against the pattern of rates/terms granted for all sample loans during that period, to determine if deviations may be occurring on a prohibited basis. Deviations, if any, will be investigated in the bank by a national bank examiner.

General Comments

A number of comments expressed reservations about the need and appropriateness of requiring all national banks, regardless of their apparent level of compliance with these laws, to solicit and maintain all of the data specified in the proposed regulation. They believe that the procedures outlined in the regulation should be applied only in those instances where examination of the bank has revealed some indication of possible noncompliance with fair housing laws or where the Comptroller

has some other basis to believe that the bank's level of compliance is subject to question or in need of more detailed review. As noted above, the Comptroller has agreed to this principle for purposes of the Inquiry/Application Log, determining that it would be more appropriate to require the Log in those instances where an examination of the bank has revealed some indication of noncompliance with the laws or where the Comptroller has some other basis to believe that a bank's level of fair housing compliance is subject to question or in need of more detailed review.

However, the revised recordkeeping and data submission requirements are integral to an examination for compliance with applicable laws and are not in any way construed as punitive. Rather, they are designed to assist the examiner in his or her attempts to do a full and complete fair housing examination. It is anticipated that the effect of the recordkeeping and statistical analysis procedures will include, not only more effective monitoring of the fair housing laws, but also a reduction in the time required of both bankers and bank examiners during bank examinations.

Drafting Information

The principal drafter of this document was Zina Greene, Special Assistant for Civil Rights, Office of Customer and Community Programs. Legal assistance was provided by Sharon Miyasato, Attorney, Legal Advisory Services Division.

In consideration of the foregoing, the Comptroller of the Currency hereby establishes a new Part 27 as set forth below.

PART 27—FAIR HOUSING HOME LOAN DATA SYSTEM

Sec.
27.1 Scope.
27.2 Definitions.
27.3 Recordkeeping requirements.
27.4 Inquiry/application log.
27.5 Record retention period.
27.6 Substitute monitoring program.
27.7 Availability and submission of data.
Appendix I—Monthly Home Loan Activity Format.
Appendix II—Information for Government Monitoring Purposes—Insert.
Appendix III—Inquiry/Application Log Sheet.
Appendix IV—Home Loan Data Submission.

Authority: 15 U.S.C. 1691 *et seq.;* 12 U.S.C. 1818; 12 U.S.C. 1 *et seq.;* 12 U.S.C. 161; 12 U.S.C. 481; 42 U.S.C. 3601, *et seq.;* 5 U.S.C. 301; 12 CFR 202.

§ 27.1 Scope.

This Part applies to the activities of national banks and banks located in the District of Columbia, and their subsidiaries, which make home loans for the purpose of purchasing, construction-permanent financing, or refinancing of residential real property.

§ 27.2 Definitions.

For the purpose of this Part, including all forms and instructions issued for use under this Part:

(a) "Applicant" means a natural person, including a co-applicant, who makes an application.

(b) "Application" means an oral in-person or written request for an extension of credit for a home loan that is made in accordance with procedures established by a bank for the type of credit requested.

(c) "Bank" means a national bank or bank located in the District of Columbia, and any subsidiaries of such a bank.

(d) "Completed application" means an application in connection with which a bank has received all the information that it regularly obtains and considers in evaluating the amount and type of credit requested.

(e) "Decision center" means the place where home loan applications are accepted or rejected.

(f) "Home loan" means a real estate loan for the purchase, permanent financing for construction, or the refinancing of residential real property which the applicant intends to occupy as a principal residence.

(g) "Inquirer" means a natural person who makes an inquiry.

(h) "Inquiry" means a written or an oral in-person request for information about the terms of a home loan by a natural person on his/her own behalf which is received on a bank's premises by any person at the bank who customarily receives or is authorized to receive such requests. Telephonic communications do not constitute an inquiry for purposes of this Part.

(i) "Real estate loan" means any loan secured by real estate where the bank relies upon such real estate as the primary security for the loan. Where the bank in its judgment relies substantially upon other factors, such as the general credit standing of the borrower, guaranties, or security other than real estate, the loan does not constitute a real estate loan, although as a matter of prudent banking practice it may also be secured by real estate.

(1) A loan made in reliance upon the security of a mobile home will not be considered a real estate loan, although as a prudent banking practice the security interest is recorded or otherwise perfected as if the mobile home were real estate. For purposes of this Part, a loan made in reliance upon the security of a mobile home and the parcel of land to which it is permanently affixed will be considered a real estate loan.

(2) Where the bank relies substantially on the insurance guaranty of a governmental agency in making a loan, it does not constitute a real estate loan except for the purposes of § 27.4 of this Part (Inquiry/Application Log).

(j) "Residential real property" means improved real property (not vacant land) used or intended to be used for residential purposes, including single family homes, dwellings for from two to four families, and individual units of condominiums and cooperatives.

§ 27.3 Recordkeeping requirements.

(a) Monthly Home Loan Activity.

(1) Each bank which receives fifty or more home loan applications a year, as measured by the previous calendar year, shall record and maintain for each "decision center" the following information on home loan activity:

(i) Number of applications received for each of the following: purchase; construction-permanent; refinance.

(ii) Number of loans closed for each of the following: purchase; construction-permanent; refinance.

(iii) Number of loans denied for each of the following: purchase; construction-permanent; refinance.

(iv) Number of loans withdrawn by applicant, for each of the following: purchase; construction-permanent; refinance.

(2) This information shall be updated monthly within 10 working days after the close of the month in a format consistent with the bank's recordkeeping procedures.

(3) A bank exempted under paragraph (a)(1) of this section shall be covered by this requirement beginning the month following any quarter in which their average monthly volume of home loan applications exceeds four applications per month. Banks which are subject to this paragraph may discontinue keeping this information beginning the month following two consecutive quarters in which their average monthly volume of home loan applications drops to four or fewer applications per month. A bank which is otherwise exempted under this paragraph may be required upon notification received from the Comptroller, to record and maintain such information where there is cause to believe that the bank is not in compliance with the fair housing laws based on prior examinations and/or has

substantive consumer complaints, among other factors.

(b) Information Required on Applications for Home Loans.

(1) Each bank shall attempt to obtain all of the information listed below, as part of completed applications for home loans:

(i) Loan Amount requested by the applicant(s).

(ii) Interest rate requested by the applicant(s).

(iii) Number of months requested to maturity by the applicant(s).

(iv) Location. Complete street address, city, county, state and zip code of the dwelling which will secure the loan.

(v) Number of residential units (1–4) of the dwelling which will secure the loan.

(vi) Year built. The year in which the dwelling which will secure the loan was built. If the exact year is unknown, approximate to the nearest decade.

(vii) Purpose of the loan. Purchase; refinance; or construction-permanent.

(viii) Name and present address of applicant(s).

(ix) Age of applicant(s).

(x) Marital status of applicant(s) using the categories married, unmarried and separated.

(xi) Number of years employed in present line of work or profession for the applicant(s).

(xii) Years on present job. Number of continuous years employed by the current employer of the applicant(s). For self-employed persons, the number of continuous years self-employed.

(xiii) Gross total monthly income of each applicant, comprising the sum of normal base salary, wages, overtime pay, bonuses, commissions, dividends, interest, rental income, retirement or disability income and income from part-time employment. For self-employed persons, include the average or normal monthly income. Include alimony, separate maintenance and child support income information only if the applicant has been advised that such information need not be provided and nevertheless elects to have it considered.

(xiv) Proposed monthly housing payment, comprising the sum of principal and interest. The bank may also include insurance, real estate taxes and any monthly assessments for home owner dues or condominium fees, and/or utilities if the bank considers these factors in computing housing costs. However, if the bank includes any of these factors for computing the monthly housing payment, it must do so consistently. When a bank changes its regular practice, such change and its effective date should be identifiable with respect to the bank's new policy.

(xv) Purchase price. Sales price or approximate current market value of the property which will secure the loan.

(xvi) Applicant's or applicants' total monthly payments on all outstanding liabilities. Include installment debts, real estate loans and any alimony, child support or separate maintenance payments. Exclude any payments on liabilities which will be satisfied upon sale of real estate owned or upon refinancing of property associated with this application.

(xvii) Net worth. Applicant's or applicants' total assets, including cash checking and savings accounts, stocks and bonds, cash value of life insurance, value of real estate owned, net worth of business owned, automobile, furniture and personal property and other assets, minus total liabilities, including installment debts, automobile loans, real estate loans, and any other debts, including stock pledges.

(xviii) Date of application. The date on which a signed application is received by the bank.

(xix) Sex of applicant(s).

(xx) Race/national origin of applicant(s) using the categories: American Indian, Alaskan Native; Asian or Pacific Islander; Black; Hispanic; White; Other.

(2) Information on race/national origin and sex.

(i) Disclosure to applicant.

(A) In collecting the information required under § 27.3(b)(1) (xix) and (xx), the bank shall advise an applicant, either orally or in writing, that:

(1) The information on race/national origin and sex is requested by the Federal Government if this loan is related to a home loan, in order to monitor the lender's compliance with equal credit opportunity and fair housing laws;

(2) The applicant is not required to furnish the information but is encouraged to do so. The law provides that a lender may neither discriminate on the basis of this information, nor on whether the applicant chooses to furnish it;

(3) However, if the applicant chooses not to furnish it, Federal regulations require the lender to note race and sex on the basis of visual observation or surname.

(B) Banks which use the Federal Home Loan Mortgage Corporation/Federal National Mortgage Association (FHLMC/FNMA) insert form ("Information for Government Monitoring Purposes") requesting this information will be in compliance with paragraph (b)(2)(i) of this section. A copy of the insert form is set forth in Appendix II.

(ii) If the applicant does not voluntarily provide the information on sex and race/national origin which the bank is required to record and maintain under § 27.3(b)(1) (xix) and (xx), the bank shall request the applicant to note that fact (by initials or otherwise) on the application, and the bank shall provide the information based on visual observation or surname. If the applicant does not voluntarily provide the information and does not initial or otherwise note that fact, the bank shall initial, or otherwise note that fact on the application, as well as provide the information based on visual observation or surname.

(c) Additional Information Required in the Loan File. In addition to the information required by § 27.3(b), each bank shall maintain the following information in each of its home loan files:

(1) If an appraisal is completed:

(i) The appraised value; and

(ii) The census tract number, where available, for those properties which are in a Standard Metropolitan Statistical Area (SMSA) in which the bank has a home office or branch office.

(2) Disposition of loan application. The disposition of the completed applications using the following categories:

(i) Withdrawn before terms were offered;

(ii) Withdrawn after terms were offered;

(iii) Denied;

(iv) Terms offered and accepted by applicant(s).

(3) If final terms are offered, whether or not accepted:

(i) The loan amount.

(ii) Whether private mortgage insurance is required, and if so, the terms of the insurance.

(iii) Whether a deposit balance is required, and if so, the amount.

(iv) The note (simple) interest rate.

(v) The number of months to maturity of the loan offered.

(vi) Points. The loan origination or discount fee(s) charged to the buyer, computed as a percentage of the loan amount.

(4) Commitment date. The date final terms were offered.

(5) The type of mortgage using the following categories: Standard Fixed Payment; Variable Rate; Graduated Payment; Rollover; Other.

(6) The name or identification of the bank office where the application was submitted.

(7) Whenever credit is denied, copy(s) of the Equal Credit Opportunity Act credit notice and statement of credit denial.

(8) Any additional information used by the bank in determining whether or not to extend credit, or in establishing the terms, including, but not limited to, credit reports, employment verification forms, Federal Income Tax Forms, availability of insurance, and the complete appraisal.

§ 27.4 Inquiry/Application Log.

(a) The Comptroller, among other things, may require a bank to maintain a Fair Housing Inquiry/Application Log ("Log"), based upon, but not limited to, one or more of the following causes:

(1) There is reason(s) to believe that the bank may be prescreening or otherwise engaging in discriminatory practices on a prohibited basis.

(2) Complaints filed with the Comptroller or letters in the Community Reinvestment Act file are found to be substantive in nature, indicating that the bank's home lending practices are, or may be, discriminatory.

(3) Analysis of the data compiled by the bank under the provisions of the Home Mortgage Disclosure Act (12 U.S.C. § 2801 et seq. and Regulation C of the Federal Reserve Board, 12 CFR § 203) indicates a pattern of significant variation in the number of home loans between census tracts with similar incomes and home ownership levels, differentiated only by race or national origin (i.e., possible racial redlining).

(b) The Comptroller, when requiring the maintenance of a Log, will specify in writing:

(1) The location(s) where the information shall be obtained;

(2) The length of time it shall be maintained;

(3) The frequency with which it shall be submitted to the Comptroller; and

(4) The reason(s) for imposing this requirement.

(c) A bank which has been directed by the Comptroller to maintain a Log shall obtain and note all of the following information regarding each inquiry or application for the extension of a home loan and each inquiry or application for a government insured home loan (not otherwise included in this Part):

(1) Date of application or inquiry.

(2) Type of loan using the categories: purchase, construction-permanent; refinance; and government insured by type of insurance, *i.e.*, FHA, VA, and FmHA (if applicable).

(3) Indication of whether the entry refers to an application or an inquiry.

(4) Case identification (either a unique number which permits the application file to be located, or the name(s) and address(es) of the applicant(s)).

(5) Race/national origin of the inquirer(s) or applicant(s) using the categories: American Indian or Alaskan Native; Asian or Pacific Islander; Hispanic; Black; White, Other. In the case of inquiries, this item shall be noted on the basis of visual observation or surname(s) only. In the case of applications, the information shall be obtained pursuant to § 27.3(b)(2) of this Part.

(6) Location. Complete street address, city, county, state and zip code of the property which will secure the extension of credit. The census tract shall also be recorded when the property is located in an SMSA in which the bank has a home office or branch office.

(d) The information required under § 27.4(c), above, shall be recorded and maintained on the form set forth in Appendix III. Additional information may be recorded and maintained at the bank's discretion.

§ 27.5 Record retention period.

(a) Each bank shall retain the records required under § 27.3 for 25 months after the bank notifies an applicant of action taken on an application, or after withdrawal of an application. This requirement also applies to records of home loans which are originated by the bank and subsequently sold.

(b) The Comptroller of the Currency may, by written notice to a bank, extend the retention period.

§ 27.6 Substitute monitoring program.

The recordkeeping provisions of § 27.3 constitute a substitute monitoring program as authorized under § 202.13(d) of Regulation B of the Federal Reserve Board (12 CFR § 202.13(d)). A bank collecting the data in compliance with § 27.3 of this Part will be in compliance with the requirements of § 202.13 of Regulation B.

§ 27.7 Availability, submission and use of data.

(a) Each bank shall make all information collected under § 27.3 and § 27.4 available for review at the bank to national bank examiners upon request.

(b) Prior to a scheduled bank examination, the Comptroller will request the bank's monthly home loan activity information maintained under § 27.3(a) of this Part on the form prescribed as Appendix I. A bank which is exempt in whole or in part from maintaining the information required under § 27.3(a) and which has not otherwise been directed to maintain the information shall notify the Comptroller of this fact in writing within 30 calendar days of its receipt of the Comptroller's request.

(c) If, upon review of the bank's monthly home loan activity, the Comptroller determines that statistical analysis prior to examination is warranted, the bank will be notified.

(1) Within 30 calendar days after receipt of notification from the Comptroller, the bank shall submit, for application records specified by the Comptroller, completed Home Loan Data Submission Forms (set forth as Appendix IV). The Comptroller may, upon the request of a bank and for good reason, extend the 30-day period.

(2) The number of Home Loan Data Submission Forms requested by the Comptroller will not exceed 250 per "decision center," or 2,000 per bank with multiple "decision centers," unless there is cause to believe that a bank is not in compliance with fair housing laws based on examination findings or substantiated complaints, among other factors.

(3) A bank with fewer than 75 home loan applications in the preceding year will not be required to submit such forms unless:

(i) The home loan activity is concentrated in the few months preceding the request for data, indicating the likelihood of increased activity over the subsequent year, or

(ii) There is cause to believe that a bank is not in compliance with the fair housing laws based on prior examinations and/or complaints, among other factors.

(d) If there is cause to believe that a bank is in noncompliance with fair housing laws, the Comptroller may require submission of additional Home Loan Data Submission Forms. The Comptroller may also require submission of Monthly Home Loan Activity and Home Loan Data Submission Forms at more frequent intervals than specified in paragraphs (b) and (c) above.

Dated: October 29, 1979.

John G. Heimann,

Comptroller of the Currency.

BILLING CODE 4810-33-M

Appendix I

BANK NAME			
OCC CHARTER #	TOTAL NUMBER OF DECISION CENTERS		
PERSON RESPONSIBLE FOR COMPLETING THIS FORM AND PHONE NO			

COMPTROLLER OF THE CURRENCY MONTHLY HOME LOAN ACTIVITY FORMAT

DECISION CENTER NAME	NUMBER
ADDRESS	PHONE NO
PRINCIPAL SERVICE AREA (e g State, SMSA, County, City or Part Thereof)	

YEAR / MONTH	HOME LOAN APPLICATIONS											
	PURCHASE				CONSTRUCTION—PERMANENT				REFINANCE			
	No. Received	No. Closed	No. Rejected	No. Withdrawn	No. Received	No. Closed	No. Rejected	No. Withdrawn	No. Received	No. Closed	No. Rejected	No. Withdrawn
JANUARY												
FEBRUARY												
MARCH												
APRIL												
MAY												
JUNE												
JULY												
AUGUST												
SEPTEMBER												
OCTOBER												
NOVEMBER												
DECEMBER												
TOTAL												

Appendix II

INFORMATION FOR GOVERNMENT MONITORING PURPOSES

The following language is approved by the Comptroller of the Currency and will satisfy the requirements of 12 CFR 27. It may be inserted to complete the "Information for Government Monitoring Purposes" section of the Residential Loan Application Form (FHLMC Form 65/FNMA 1003) or may be used separately. This information may also be provided orally to the applicant.

The following information is requested by the Federal Government if this loan is related to a dwelling, in order to monitor the lender's compliance with equal credit opportunity and fair housing laws. You are not required to furnish this information, but are encouraged to do so. The law provides that a lender may neither discriminate on the basis of this information, nor on whether you choose to furnish it. However, if you choose not to furnish it, under Federal regulations this lender is required to note race and sex on the basis of visual observation or surname. If you do not wish to furnish the above information, please initial below

BORROWER: I do not wish to furnish this information (initials)_____	CO-BORROWER: I do not wish to furnish this information (initials)_____
RACE/ NATIONAL ORIGIN: ☐ American Indian, Alaskan Native ☐ Asian, Pacific Islander ☐ Black ☐ Hispanic ☐ White ☐ Other (specify) _____	RACE/ NATIONAL ORIGIN: ☐ American Indian, Alaskan Native ☐ Asian, Pacific Islander ☐ Black ☐ Hispanic ☐ White ☐ Other (specify) _____
SEX: ☐ Female ☐ Male	SEX: ☐ Female ☐ Male

Appendix III

COMPTROLLER OF THE CURRENCY FAIR HOUSING LENDING INQUIRY/APPLICATION LOG SHEET

BANK NAME	OCC CHARTER NO
BRANCH OFFICE OR SUBSIDIARY NAME	
NAME OF PERSON RESPONSIBLE FOR FORM	PHONE NUMBER

CITY	
COUNTY	STATE
SMSA	

INSTRUCTIONS: Use the codes listed below Indicate by an asterisk (*) if the information recorded is the banker s observation rather than the borrower's statement

Race Codes: W — White; B — Black; I — American Indian or Alaskan Native; H — Hispanic; A — Asian or Pacific Islander; O — Other

Type of Loan: P — Purchase; R — Refinance; C — Construction—Permanent; F — FHA (Federal Housing Admin.); V — VA (Veteran's Administration); M — FmHA (Farmers Home Administration)

	Date of Application or Inquiry	Type of Loan Code	Inquiry or Application (I) or (A)	Case Identification (Case Number or Name/Address)	Inquirer or Applicant		Co Inquirer or Co Applicant		LOCATION OF PROPERTY WHICH WILL SECURE LOAN			
					Sex (M or F)	Race Code	Sex (M or F)	Race Code	Street & Number, City, State	County	Zip Code	Census Tract
1												
2												
3												
4												
5												
6												
7												
8												
9												

Appendix IV

COMPTROLLER OF THE CURRENCY HOME LOAN DATA SUBMISSION

NAME OF BANK _____

CHARTER NUMBER (1-5)
DECISION CENTER NO (6-9)

(Enter dollar amounts as whole dollars)

APPLICATION FORM

1 Application File Number _ _ _ _ _ _ (10-21)
2. Amount of Loan Requested $ _ _ _ _ _ (24-29)
3 Number of Months Requested to Maturity (30-32)
4. County _ _ _ _ _ _ _ (33-39)
5 State _ _ (40-41)
6 Number of Units 1 2 3 4 (42)
7 Year House Was Built _ _ _ _ (43-46)
8. Purpose of Loan 1 Purchase 2 Construction-Permanent 3 Refinance (47)

Applicant	11. Co-Applicant? 1 Yes 2 No (51) (If #11 is No, proceed to #14)
9. Age _ _ (48-49)	12 Age _ _ (52-53)
10 Marital Status (50)	13. Marital Status (54)
1 Married 2 Separated	1 Married 2 Separated
3 Unmarried (includes single, divorced, widowed)	3 Unmarried (includes single, divorced, widowed)

14. Applicant Gross Monthly Income $ _ _ _ _ _ (55-60)
15 Co-Applicant Gross Monthly Income $ _ _ _ _ (61-66)
16. Proposed Monthly Housing Payments $ _ _ _ _ (67-71)
17. Purchase/Sales Price $ _ _ _ _ _ _ (72-77)
18. Other Total Monthly Payments $ _ _ _ _ _ _ (24-29)

Applicant	Co-Applicant (If none, proceed to #23)
19. Race: 1 American Indian, Alaskan Native (30)	21. Race 1 American Indian, Alaskan Native (32)
2 Asian or Pacific Islander	2 Asian or Pacific Islander
3 Black 4 Hispanic	3 Black 4 Hispanic
5 White 6 Other	5 White 6 Other
20. Sex: 1 Female 2 Male (31)	22. Sex 1 Female 2 Male (33)

23. Bank Relationship at Subject Bank (34)
1 Current Banking Relationship 2 Past Banking Relationship
3 No Banking Relationship 4 Unable to Determine

Appraisal

24. Census Tract _ _ _ _ _ _ (35-40)
25. Appraised Value $ _ _ _ _ _ _ (41-46)

Action Taken

26. Description of Action (47)
1 Withdrawn Before Terms Were Offered
2 Denied
} (If checked, skip remaining questions)
3 Withdrawn After Terms Were Offered
4 Approved and Loan Closed
} (If checked complete remaining questions)

Terms of Mortgage or of Mortgage Offer

27 Commitment Date _ _ / _ _ / _ _ (48-53)
M M D D Y Y

28. Type of Mortgage (54)
1 Standard Fixed Payment 2 Variable Rate
3 Graduated Payment 4 Roll-Over 5 Other

29 Private Mortgage Insurance Required? (55)
1 No 2 Yes

30 Loan Amount $ _ _ _ _ (56-61)
31. Note (Simple) Interest Rate _ _ % (62-65)
32. Points to Buyer (66-68)
33 Months to Maturity (69-71)
34 Downpayment Amount $ _ _ _ (72-77)

[FR Doc. 79-33697 Filed 11-1-79; 8:45 am]
BILLING CODE 4810-33-C

RAILROAD RETIREMENT BOARD

20 CFR Part 260

Procedural Handling of Erroneous Payment Decisions

AGENCY: Railroad Retirement Board.

ACTION: Final rule.

SUMMARY: The Railroad Retirement Board is amending § 260.1(b) and (d) and § 260.2(a), (b), and (c) of Part 260 of its regulations which govern the procedural handling of erroneous payment decisions. The regulations, as amended, provide that, prior to the initiation of recovery of an erroneous payment by reduction or suspension of a monthly benefit, the Board will notify the beneficiary of the possibility of waiver of recovery of the erroneous payment, of the conditions which must be met before waiver could be granted, and of the right to an oral hearing prior to commencement of recovery action. The regulations further provide that in such cases the beneficiary shall have the right to an oral hearing prior to commencement of recovery on the issues of waiver of recovery and correctness of the overpayment decision.

EFFECTIVE DATE: October 15, 1979.

FOR FURTHER INFORMATION CONTACT: R. F. Butler, 312-751-4920.

PART 260—APPEALS WITHIN THE BOARD FROM DECISIONS ISSUED BY THE BUREAU OF RETIREMENT CLAIMS AND THE BUREAU OF DATA PROCESSING AND ACCOUNTS

1. Section 260.1 (b) and (d) is amended to read as follows:

§ 260.1 Initial decisions by the Bureau of Retirement Claims.

* * * * *

(b) A decision to recover the amount of an erroneous payment under paragraph (a)(8) of this section by suspension or reduction of a monthly benefit payable by the Board shall not be made prior to a date 30 calendar days after the date on which notice of the erroneous payment decision was sent to the beneficiary.

* * * * *

(d) Where an initial decision that an erroneous payment has been made to a beneficiary has been made under paragraph (a)(7) of this section, the notice of decision shall include a statement notifying the beneficiary of the possibility of waiver of recovery of the erroneous payment, of the conditions which must be met before waiver of recovery could be granted, and of the possibility of an oral hearing with respect to the issues of waiver of recovery and reconsideration of the erroneous payment decision. The notice shall state that the beneficiary may, within 30 calendar days from the date of the issuance of the notice, file with the Board a request for waiver of recovery of the erroneous payment and/or for reconsideration of the erroneous payment decision.

2. Section 260.2 (a), (b), and (c) is amended to read as follows:

§ 260.2 Request for waiver of recovery of an erroneous payment and/or for reconsideration of the erroneous payment decision.

(a) A beneficiary who has been determined to have received an erroneous payment under paragraph (a)(7) of § 260.1 shall have the right, upon the filing of a timely request in accordance with the requirements of this section and § 260.1, to request waiver of recovery of the erroneous payment and/or reconsideration of the erroneous payment decision. The beneficiary shall have the right to an informal oral hearing on the issues of waiver of recovery and/or reconsideration of the erroneous payment decision, before an employee of the Board designated to conduct such a hearing, prior to commencement of recovery by suspension or reduction of a monthly benefit.

(b) A request for waiver of recovery and/or reconsideration of an erroneous payment decision and for an oral hearing under this section shall be in writing, and addressed to the district office of the Board set forth in the initial decision letter or to the Director of Retirement Claims. The request must be received by either the appropriate district office or the Director of Retirement Claims within 30 calendar days from the date on which notice of the erroneous payment decision was sent to the beneficiary. The beneficiary shall state in the request whether he or she elects to have an oral hearing. If the beneficiary does not elect to have an oral hearing with respect to his or her request for waiver or recovery or for reconsideration of the erroneous payment decision, he or she may, along with the request, submit any evidence and argument which he or she would like to present in support of his or her case.

(c) Where a timely request for waiver or reconsideration is filed as provided in this section, the Director of Retirement Claims shall not commence recovery of the erroneous payment by suspension or reduction of a monthly benefit payable by the Board until a decision with respect to such request for waiver or reconsideration has been made and notice thereof mailed to the claimant.

* * * * *

Dated: October 25, 1979.

By authority of the Board.

R. F. Butler,

Secretary of the Board.

[FR Doc. 79-33999 Filed 11-1-79; 8:45 am]

BILLING CODE 7905-01-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs Not Subject to Certification; Trichlorfon

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The agency is amending the regulations to delete that portion reflecting approval of a new animal drug application (NADA) sponsored by The Farnam Companies, Inc. The NADA provides for the use of trichlorfon as an oral anthelmintic in horses. This action has been requested by the sponsor.

EFFECTIVE DATE: November 12, 1979.

FOR FURTHER INFORMATION CONTACT: Louis L. Nangeroni, Bureau of Veterinary Medicine (HFV-216), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4093.

SUPPLEMENTARY INFORMATION: In a notice published elsewhere in this issue of the Federal Register, approval of NADA 43-166 is withdrawn. This document amends the regulations to delete that portion which reflects approval of this NADA.

§ 520.2520a [Amended]

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(e), 82 Stat. 345-347 (21 U.S.C. 360b(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.84), § 520.2520a *Trichlorfon oral* is amended in paragraph (b) by deleting the phrase ", 017135,".

Effective date: November 12, 1979.

(Sec. 512(e), 82 Stat. 345-347 (21 U.S.C. 360b(e)).)

Dated: October 26, 1979.

Lester M. Crawford,

Director, Bureau of Veterinary Medicine.

[FR Doc. 79-33916 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs Not Subject to Certification; Oxytocin Injection

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) filed by Medico Industries, Inc., providing for safe and effective use of oxytocin injection for treatment of horses, cows, sows, ewes, dogs, and cats. In addition, the regulations are amended to indicate those conditions of use for which approval of identical products need not include certain types of efficacy data. In lieu of such data, approval may require submission of bioequivalence or similar data.

EFFECTIVE DATE: November 2, 1979.

FOR FURTHER INFORMATION CONTACT: Richard A. Carnevale, Bureau of Veterinary Medicine (HFV-125), Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1788.

SUPPLEMENTARY INFORMATION: Medico Industries, Inc., P.O. Box 338, Elwood, KS 66024, filed a NADA (109-305) providing for use of oxytocin injection in horses, cows, sows, ewes, dogs, and cats as a uterine contractor and in cows and sows as a milk-releasing agent.

The NADA concerns a product that is similar to two others that were reviewed by the National Academy of Sciences/National Research Council, Drug Efficacy Study Group (NAS/NRC). The announcement of the NAS/NRC review was published in the Federal Register of February 13, 1969 (34 FR 2146). The NAS/NRC concluded that the products are effective for the above-mentioned conditions of use. The Food and Drug Administration (FDA) concurred with the NAS/NRC's conclusions provided certain labeling revisions were made.

On October 15, 1969, Wittney & Co., Denver, CO, filed an NADA (42-889) providing for use of oxytocin injection in conformance with the NAS/NRC and FDA recommendations published in the above-mentioned Federal Register document. Approval of the product is reflected in the regulations in 21 CFR 522.1680. Medico Industries' oxytocin injection is identical to that of Wittney. Medico has authorization from Wittney to refer to its entire approved NADA in support of the Medico application. Bioequivalence of the two products has been demonstrated. Therefore, Medico's application is approved on the basis of generic equivalence to the approved Wittney application.

This document amends 21 CFR 522.1680 to reflect approval of Medico's NADA, to editorially revise the existing text to conform to current format, and to indicate by footnote those conditions of use for which approvals for identical products need not include certain types of effectiveness data as specified by § 514.1(b)(8)(ii) or 514.111(a)(5) of the animal drug regulations (21 CFR 514.1(b)(8)(ii) or 514.111(a)(5)). In lieu of such data, approval may require bioequivalency or similar data as suggested in the guidelines for submitting NADA's for NAS/NRC-reviewed generic drugs. These guidelines are availabale from the office of the Hearing Clerk (HFA-305), Rm. 4-65, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

In accordance with the provisions of Part 20 (21 CFR Part 20) promulgated under the Freedom of Information Act (5 U.S.C. 552) and the freedom of information regulations in § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted supporting approval of this application is available for public examination at the office of the Hearing Clerk, 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 522 is revised in § 522.1680 to read as follows:

§ 522.1680 Oxytocin injection

(a) *Specifications.* Each milliliter of oxytocin injection contains 20 U.S.P. units of oxytocin.

(b) *Sponsors.* See Nos. 000010, 000381, 000845, 000856, 012481, 015562, and 032420 in § 510.600(c) of this chapter.

(c) *Conditions of use* [1]—(1) *Amount*—(i) *Obstetrical.* Administer drug intravenously, intramuscularly, or subcutaneously under aseptic conditions as indicated. The following dosages are recommended and may be repeated as conditions require:

	ml	U.S.P. units
Cats	0.25 to 0.5	5 to 10.
Dogs	0.25 to 1.5	5 to 30.
Ewes, Sows	1.5 to 2.5	30 to 50.
Cows, Horses	5.0	100.

(ii) *Milk letdown.* Intravenous administration is desirable. The following dosage is recommended and may be repeated as conditions require:

	ml	U.S.P. units
Cows	0.5 to 1.0	10 to 20.
Sows	0.25 to 1.0	5 to 20.

(2) *Indications for use.* Oxytocin may be used as a uterine contractor to precipitate and accelerate normal parturition and postpartum evacuation of uterine debris. In surgery it may be used postoperatively following cesarean section to facilitate involution and resistance to the large inflow of blood. It will contract smooth muscle cells of the mammary gland for milk letdown if the udder is in proper physiological state.

(3) *Limitations.* Do not use in dystocia due to abnormal presentation of fetus until correction is accomplished. For preparation usage, full relaxation of the cervix should be accomplished either naturally or by administration of estrogen prior to oxytocin therapy. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Effective date. This regulation is effective November 2, 1979.

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

Dated: October 26, 1979.

Lester M. Crawford,

Director, Bureau of Veterinary Medicine.

[FR Doc. 79-33915 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

21 CFR Part 522

Implantation or Injectable Dosage Form, New Animal Drugs Not Subject to Certification; Dinoprost Tromethamine Sterile Solution

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) filed by The Upjohn Co., providing for use of dinoprost tromethamine injectable in beef cattle and nonlactating dairy heifers for synchronization of estrus.

EFFECTIVE DATE: November 2, 1979.

FOR FURTHER INFORMATION CONTACT: William D. Price, Bureau of Veterinary Medicine (HFV-123), Food and Drug

Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3442.

SUPPLEMENTARY INFORMATION: The Upjohn Co., Kalamazoo, MI 49001, filed NADA 108-901 providing for intramuscular use in beef cattle and nonlactating dairy heifers of dinoprost tromethamine as a luteolytic agent for synchronization of estrus. The regulations are amended to reflect approval of this NADA. In accordance with the provisions of Part 20 (21 CFR Part 20), promulgated under the Freedom of Information Act (5 U.S.C. 552) and the freedom of information regulations in § 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 supporting approval of this application is available for public examination at the office of the Hearing Clerk (HFA-305), Rm. 4-65, Food and Drug Administration, 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 522 is amended in § 522.690 revising paragraph (d), to read as follows:

§ 522.690 Dinoprost tromethamine sterile solution.

* * * * *

(d) *Conditions of use.* (1) It is used as an intramuscular injection, as follows:

(i) *In mares:* (*a*) For its luteolytic effect to control the timing of estrus in estrous cycling mares and in clinically anestrous mares that have a corpus luteum.

(*b*) It is administered once as a single intramuscular injection of dinoprost tromethamine at a dosage level equivalent to 1 milligram of dinoprost per 100 pounds of body weight.

(*c*) Not for use in horses intended for food.

(ii) *In beef cattle and nonlactating dairy heifers:*

(*a*) For its luteolytic effect to control the timing of estrus and ovulation in estrous cycling cattle that have a corpus luteum.

(*b*) It is used for breeding cattle as follows:

(*1*) Estrus observation: Inject 5 milliliters of solution intramuscularly (25 milligrams dinoprost); repeat the injection 10 to 12 days after the first injection; then, observe for estrus after the second injection; and inseminate at the usual time relative to detection of each estrus following the second injection. If the cattle are estrous cycling, estrus is expected to occur 2 to 5 days after second injection. Cattle that do not become pregnant to that breeding will be expected to return to estrus between days 21 and 27 after the second injection.

(*2*) Timed artificial insemination: Inject 5 milliliters of solution intramuscularly (25 milligrams dinoprost); repeat the injection 10 to 12 days after the first injection; then, inseminate about 80 hours after the second injection without estrus detection or observation. Cattle that do not become pregnant to that breeding will be expected to return to estrus between 21 and 27 days after the second injection.

(*c*) Do not administer to pregnant cows, as abortion may result. Do not administer intravenously, as this route might potentiate adverse reactions.

(2) Women of child-bearing age, asthmatics, and persons with bronchial and other respiratory problems should exercise extreme caution when handling this product. In the early stages, women may be unaware of their pregnancies. Dinoprost tromethamine is readily absorbed through the skin and can cause abortion and/or bronchiospasms. Direct contact with the skin should, therefore, be avoided. Accidental spillage on the skin should be washed off with soap and water.

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

Effective date. This regulation shall become effective November 2, 1979.

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

Dated: October 26, 1979.

Lester M. Crawford,

Director, Bureau of Veterinary Medicine.

[FR Doc. 79-33832 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

INTERNATIONAL COMMUNICATION AGENCY

22 CFR Part 506

Part-Time Career Employment Program

AGENCY: International Communication Agency.

ACTION: Final rule.

SUMMARY: The regulations govern the operation of a part-time career employment program within the International Communication Agency which the Agency has established in compliance with the provision of the Federal Employees Part-Time Career Employment Act of 1978.

DATE: These regulations are effective November 2, 1979.

FOR FURTHER INFORMATION CONTACT: Michael J. Collins (202) 724-9863.

SUPPLEMENTARY INFORMATION: The International Communication Agency is publishing regulations to establish and maintain a part-time career program required by the provisions of the Federal Employees Part-Time Career Employment Act of 1978. Proposed regulations were published in the Federal Register on September 12, 1979 (44 FR 53089-53090). Sec. 506.6, has been amended to add college and university placement offices.

ANALYSIS OF COMMENTS: The proposed regulations provided for public comment to be submitted on or before September 20, 1979. The International Communication Agency received one comment from an individual. The commenter requested information concerning the types of positions and the potential for promotion and suggested that the program include the conversion of full-time Agency employees to part-time. The program does include the conversion of full-time Agency employees to part-time. The types of positions and their promotion potential will be publicized after the positions to be filled, under the program, are identified. The commenter also suggested that another possible source for publicizing vacancies were college and university Student Financial Aid and Employment Offices. This suggestion was adopted in substance and Sec. 506.6 of the regulations amended to include college and university placement offices.

The International Communication Agency is amending Title 22 of the Code of Federal Regulations by adding a new Part 506 as set forth below.

PART 506—PART-TIME CAREER EMPLOYMENT PROGRAM

Sec.
506.1 Purpose of program.
506.2 Review of position.
506.3 Establishing and coverting part-time positions.
506.4 Annual goals and timetables.
506.5 Review and evaluation.
506.6 Publicizing vacancies.
506.7 Exceptions.

Authority: 5 U.S.C. 3401 (note and 3402).

§ 506.1 Purpose of program.

Many individuals in society possess great productive potential which goes unrealized because they cannot meet the requirements of a standard workweek. Permanent part-time employment also provides benefits to other individuals in a variety of ways, such as providing older individuals with a gradual

transition into retirement, providing employment opportunities to handicapped individuals or others who require a reduced workweek, providing parents opportunities to balance family responsibilities with the need for additional income, providing employment opportunities for women returning to the workforce and assisting students who must finance their own education or vocational training. In view of this, the International Communication Agency will operate a part-time career employment program, consistent with the needs of its beneficiaries and its responsibilities.

(5 U.S.C. 3401 note)

§ 506.2 Review of positions.

Positions becoming vacant unless excepted as provided by § 506.7, will be reviewed to determine the feasibility of converting them to part-time. Among the criteria which may be used when conducting this review are:

(a) Mission requirements and occupational mix.

(b) Workload fluctuations.

(c) Employment ceilings and budgetary considerations.

(d) Size of workforce, turnover rate and employment trends.

(e) Affirmative action.

(5 U.S.C. 3402)

§ 506.3 Establishing and converting part-time positions.

Position management and other internal reviews may indicate that positions may be either converted from full-time or initially established as part-time positions. Criteria listed above may be used during these reviews. If a decision is made to convert to or to establish a part-time position, regular position management and classification procedures will be followed.

(5 U.S.C. 3402)

§ 506.4 Annual goals and timetables.

An agencywide plan for promoting part-time employment opportunities will be developed annually by the Office of Personnel Services after consultation with the operating elements. This plan will establish annual goals and set deadlines for achieving these goals.

§ 506.5 Review and evaluation.

The part-time career employment program will be reviewed through semiannual reports submitted by the Director, Office of Personnel Services to the Associate Director for Management. Regular employment reports will be used to determine levels of part-time employment.

(5 U.S.C. 3402)

§ 506.6 Publicizing vacancies.

When applicants from outside the Federal service are desired, part-time vacancies may be publicized through various recruiting means, such as:

(a) Federal Job Information Centers.

(b) State Employment Offices.

(c) USICA Vacancy Announcements.

(d) College and University Placement Offices.

(5 U.S.C. 3402)

§ 507.7 Exceptions.

The Director of the Agency and the Associate Director for Management may except positions from inclusion in this program as necessary to carry out the mission of the Agency.

International Communication Agency.

James D. Isbister,

Associate Director for Management.

[FR Doc. 79-33956 Filed 11-1-79; 8:45 am]

BILLING CODE 8230-01-M

DEPARTMENT OF DEFENSE

Corps of Engineers; Department of the Army

32 CFR Part 625

[ER 56-1-1]

Surface Transportation—Administrative Vehicles Management

AGENCY: U.S. Army Corps of Engineers.

ACTION: Final rule.

SUMMARY: This regulation provides policy guidance and the authority to allow employee dependents to travel in a Government-owned or leased motor vehicle during authorized Temporary Duty (TDY) travel.

EFFECTIVE DATE: November 1, 1979.

FOR FURTHER INFORMATION CONTACT: Mr. Robert E. Haske, (202) 693-6199 or write HQDA (DAEN-ASV), Washington, D.C. 20314.

SUPPLEMENTARY INFORMATION: To clarify the need and intent of this regulation we submit the last paragraph of Comptroller General Decision, B-190440, 20 January 1978 "Accordingly, where the transportation of a dependent in a Government vehicle is such that the dependent merely accompanies an employee on an otherwise authorized trip scheduled for the transaction of official business, and the agency involved makes a determination that it is in the Government's interest for the dependent to accompany the employee (for instance, for morale purposes), we do not believe that the provisions of section 638a(c)(2) would be violated. Thus, we are of the view that the provisions of 31 U.S.C. § 638a(c)(2) do not, by themselves, serve to make the AFGE proposal non-negotiable."

The Chief of Engineers 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 to warrant a regulatory analysis.

Dated: October 15, 1979.

For the Chief of Engineers.

Forrest T. Gay III,

Colonel, Corps of Engineers, Executive Director, Engineer Staff.

Accordingly, 32 CFR is amended by adding a new Part 625 to read as follows:

PART 625 SURFACE TRANSPORTATION—ADMINISTRATIVE VEHICLE MANAGEMENT

Sec.
625.1 Purpose.
625.2 Applicability.
625.3 References.
625.4 OCE Policy.
625.5 General.

Appendix A—Dependent Travel Waiver of Liability.

Authority: Comptroller General Decision, B-190440, 20 January 1978.

Source: ER 56-1-1.

§ 625.1 Purpose.

This regulation provides guidance, and authorizes dependents to accompany a Corps employee on Temporary Duty (TDY) in a Government-owned or leased motor vehicle.

§ 625.2 Applicability.

This regulation is applicable to all field operating agencies authorized to operate or lease Administrative Use Motor Vehicles.

§ 625.3 References.

(a) Title 31, U.S. Code, Section 638.

(b) Comptroller General Decision, 25 Comp. Gen. 844(1946) B-57732.

(c) Comptroller General Decision, 54 Comp. Gen. 855(1975) B-178342.

(d) Comptroller General Decision, B-190440, 20 January 1978.

(e) DOD Regulation 4500.36-R June 1977.

§ 625.4 OCE policy.

Pursuant to the authorities, penalties and interpretations cited in the preceding references, Commanders/Directors of field operating agencies may authorize dependents to accompany a Corps of Engineers employee during official travel when using a Government-owned or leased

motor vehicle, providing the following procedures and restrictions are adhered to:

(a) The Commanders/Directors of field operating agencies must make a Determination that transportation of the dependent is in "the interest of the Government".

(b) A determination of "the interest of the Government" is a matter of administrative discretion, taking into consideration the following limitations:

(1) The use of motor vehicles shall be restricted to the "official use" of the vehicles, and any questions concerning "official use" shall be resolved in favor of strict compliance with statutory provisions and policies of this and other pertinent regulations.

(2) When the travel of the dependent is in "the interest of the Government" and incidentally provides a convenience to the employee, then there can be no objection to the employee's enjoyment of that convenience. However, the convenience of itself, provides no justification to authorize dependent travel.

(3) Dependent travel will not be provided or authorized when justification is based on reasons of rank or prestige.

(4) Transportation to, from and between locations for the purpose of conducting personal business or engaging in other activities of a personal nature by military personnel, civilian officials and employees, members of their families or others is prohibited.

(c) Increased travel time (rest stops) and operational inefficiency (added weight) occasioned by the number of dependents to be transported will also be considered.

(d) Dependents must understand and agree never to operate the motor vehicle consigned to the employee for official travel.

(e) Neither the seating capacity nor the size of the motor vehicle will be changed or increased to accommodate dependent travel.

(f) Motor vehicles as used in this regulation applies to all types of motor vehicles, owned, consigned to or leased by the Corps of Engineers.

§ 625.5 General.

(a) In view of the potential liability the Government could incur by allowing dependents to accompany an employee in a government-owned, consigned or leased motor vehicle, a Dependent Travel Waiver of Liability will be obtained prior to each and every trip. Suggested language for such waiver is set forth in Appendix A.

(b) When dependents are to be transported in a GSA rented vehicle, an extra signed copy of the Dependent Travel Waiver will be furnished the GSA Interagency Motor Pool from which the vehicle is acquired.

BILLING CODE 3710-92-M

APPENDIX A

DEPENDENT TRAVEL WAIVER OF LIABILITY

"I _____ will be accompanying
(NAME OF DEPENDENT)

_____, who is my _____,
(NAME OF EMPLOYEE) (RELATIONSHIP)

and who is an employee of _____, on official Government
(AGENCY, DIVISION)

business in or while using a Government vehicle. Dates of travel are from _____

_____ to _____19____. I do hereby knowingly, freely and voluntarily waive any right or cause of action of any kind whatsoever, against the United States, arising as a result of such activity from which any liability may or could accrue while accompanying the above named employee in or while using said Government vehicle."

SIGNATURE OF DEPENDENT	NOTARY PUBLIC
DATE	DATE

ENG FORM 1 AUG 79 4700-R

[FR Doc. 79-33914 Filed 11-1-79; 8:45 am]
BILLING CODE 3710-92-C

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL 1350-5]

Approval and Promulgation of State Implementation Plans; Approval of PSD Plan for North Dakota

AGENCY: Environmental Protection Agency.

ACTION: Final rulemaking.

SUMMARY: The purpose of this notice is to approve the State Implementation Plan (SIP) revision for North Dakota which was received by EPA on July 17, 1978. This plan revision was prepared by the State to meet the requirements of Part C (Prevention of Significant Deterioration (PSD) of Air Quality) and various sections of the Clean Air Act, as amended in 1977. On July 16, 1979 (44 FR 41253), EPA published a notice of proposed rulemaking and requested public comment. No comments were received.

EFFECTIVE DATE: November 2, 1979.

ADDRESSES: Copies of the SIP revision and EPA's evaluation of the revision will be available for inspection at the offices of the EPA listed below:

Environmental Protection Agency, Region VIII, Air Program Branch, 1860 Lincoln Street, Denver, Colorado 80295.

Environmental Protection Agency, Public Information Reference Unit, 401 M Street SW, Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Mr. Robert R. DeSpain, Chief, Air Programs Branch, Region VIII, Environmental Protection Agency, 1860 Lincoln Street, Denver, Colorado 80295, (303) 837-3471.

SUPPLEMENTARY INFORMATION: On July 17, 1978, EPA received proposed revisions to the North Dakota SIP. The revisions include: (a) Revised new source performance standards (NSPS), (b) revised hazardous emission standards, (c) revised provisions for the prevention of significant deterioration (PSD), and (d) other administrative revisions.

The NSPS and hazardous emissions standards changes will be addressed in a separate Federal Register notice as they are not deemed a part of the SIP.

On July 16, 1979 (44 FR 41253), EPA proposed to approve the administrative provisions and the revised program for prevention of significant deterioration and requested public comment. No comments were received. The following is a discussion of those provisions and the issues involved in EPA's final approval.

Prevention of Significant Deterioration

Section 110(a)(2)(D) and Part C Title I, of the Clean Air Act establish specific requirements for the prevention of significant deterioration of air quality in areas where ambient levels are lower than the national standards. The Act defines the amount of deterioration that can be tolerated in an area in terms of maximum allowable increases in ambient air quality concentrations (increments). These increments vary and are a function of the classification of an area. There are three applicable classifications under this program (a) Class I where the increments are very stringent and practically no deterioration is allowed, (b) Class II where moderate, well controlled growth is allowed, and (c) Class III where a considerable amount of growth is allowed. While the Act established several mandatory Class I areas, most of the nation is now Class II, and the Act gives redesignation authority to state Governors and Indian governing bodies.

The principal means of protecting the increments are the review and regulation of major new stationary sources and modifications, the tracking of minor source growth, and the periodic review of increment consumption. At present, EPA is implementing the program by a federal permit system designed to meet the requirements of Part C. In that program, operators of major new sources and major modifications must obtain a permit before commencing construction and the permit will be granted only if, among other things: (a) The increments for the area are being protected, and (b) best available control technology will be employed.

As indicated above, this program is presently implemented by EPA through regulations in 40 CFR 52.21 promulgated on June 19, 1978, (43 FR 26388). On that same date, EPA promulgated requirements for state PSD programs at 40 CFR 51.24.[1]

The regulations submitted by the State of North Dakota are designed to meet the requirements of 40 CFR 51.24 through the review of major stationary source growth throughout the State.[2] Chapter 33-15-15 of the North Dakota regulations will prohibit new source construction in clean areas unless best available control technology is employed and a demonstration is made that the increments and air quality related values are being protected.

The provisions of Chapter 33-15-15, are in all major respects, identical to the Agency regulations. The principal differences between the two regulations are that the State's definitions for "Major Modification," "Reconstruction," and "Baseline Concentration" are more stringent than those promulgated by EPA in 40 CFR 52.21(b).

The only issue which surfaced since EPA proposed to approve the State's program is regarding the State's jurisdiction on new sources proposing to locate on Indian Reservations. The North Dakota SIP does not specifically address whether its PSD regulations apply to Indian Reservations within the State. EPA interprets this to mean that the State will not exercise any permitting authority over sources proposing to locate on Indian Reservations. Therefore, the EPA is retaining the Federal PSD permitting program (40 CFR 52.21) on Indian Reservations in North Dakota.

Administrative Revisions

Other revisions to the North Dakota SIP include: changes to the general requirements and definitions as located in the chapter on General Provisions; revision to the visible emission limitations for existing sources and particulate emission limitations for indirect heating equipment and incinerators; changes in the sampling procedures for measuring emissions of particulate matter and sulfur compounds; a revision to the requirements for emissions of organic compounds, the establishment of air pollution episode criteria for oxidants and revisions to the air pollution episode emission reduction plans; revisions to permit procedures concerning time limits for commencing

[1] On June 18, 1979, the United States Court of Appeals for the District of Columbia Circuit issued a decision that upheld some portions of 40 CFR 52.21 and 51.24 and overturned others. See *Alabama Power Company* v. *Costle*, 13 ERC 1225. The court's opinion gave only a summary of its conclusions, invited petitions for reconsideration, and promised supplemental opinions explaining the conclusions and disposing of any petitions. An order issued with the summary opinion stayed the effect of the decision until the issuance of the supplemental opinions. EPA has moved for a further stay to obtain adequate time to replace the overturned provisions. A notice specifying proposed replacement provisions, appeared in the Federal Register on September 5, 1979, at 44 FR 51924. Until EPA promulgates replacement provisions or the court's decision comes into effect, EPA proposes to find SIPs now approvable if they meet the minimum requirements of either the existing EPA regulations or the regulations as proposed in the September 5th Federal Register.

[2] North Dakota has confirmed that (1) it is aware of *Alabama Power Company* v. *Costle*, (2) it nevertheless wants EPA to continue to consider its PSD SIP revision as previously submitted, and (3) it recognizes that *Alabama Power* may require revisions in the future.

construction and public comments for modification and the adoption of restrictions for odorous air contaminants[3] and fugitive emissions of particulate matter and gaseous materials. These changes in the SIP are consistent with the EPA requirements as defined in 40 CFR 51.12, 51.13, and 51.14. The revisions to the air pollution episode and permitting procedures satisfy the requirements of 40 CFR 51.16 and 51.18 respectively.

By this notice, EPA approves the appropriate portions of the North Dakota SIP revision received on July 17, 1978.

This rulemaking action is issued under the authority of the Clean Air Act as amended.

Dated: October 29, 1979.

Douglas M. Costle,
Administrator.

Title 40, Part 52 of the Code of Federal Regulations is amended as follows:

1. In § 52.2620, paragraph (c)(10) is amended to read as follows:

§ 52.2620 Identification of plan.

* * * * *

(c) * * *

(10) Provisions to meet the requirements of Part C, Title I, and Section 110 of the Clean Air Act, as amended in 1977, were submitted on July 17, 1978.

2. Section 52.2630 is revised to read as follows:

§ 52.2630 Prevention of significant deterioration of air quality.

(a) The North Dakota plan, as submitted, is approved as meeting the requirements of Part C, Title I, of the Clean Air Act, except that it does not apply to sources proposing to construct on Indian Reservations.

(b) *Regulation for preventing of significant deterioration of air quality.* The provisions of § 52.21 (b) through (v) are hereby incorporated by reference and made a part of the North Dakota State Implementation Plan and are applicable to proposed major stationary sources or major modifications to be located on Indian Reservations.

[FR Doc. 79-33987 Filed 11-1-79; 8:45 am]
BILLING CODE 6560-01-M

[3] Odor provisions are not approved and enforced as part of the Federally enforceable SIP since they are not related to the criteria air pollutants.

40 CFR Part 65

[Docket No. A-79-19; FRL 1345-4]

Approval of a Delayed Compliance Order Issued by the State of Utah Through the Air Conservation Committee to Kaibab Industries

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Administrator of EPA hereby approves a Delayed Compliance Order issued by the State of Utah through the Air Conservation Committee to Kaibab Industries. The Order requires the company to submit for approval landfill plans; initiate on-site preparation for landfill, excavation, fencing and drainage; complete on-site preparation for landfill, and discontinue use of TP burners at Panguitch, Utah, into compliance with certain regulations contained in the federally-approved Utah State Implementation Plan (SIP). Because of the Administrator's approval, Kaibab Industries' compliance with the Order will preclude suits under the Federal enforcement and citizen suit provisions of the Clean Air Act for violation of the SIP regulations covered by the Order during the period the Order is in effect.

DATE: This rule takes effect on December 3, 1979.

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: Enforcement Division, EPA, Region VIII, 1860 Lincoln Street, Denver, Colorado 80295.

FOR FURTHER INFORMATION CONTACT: Cay White, Enforcement Division, EPA, Region VIII, 1860 Lincoln Street, Denver, Colorado 80295, telephone (303) 837-2361.

SUPPLEMENTARY INFORMATION: On June 29, 1979, the Regional Administrator of EPA's Region VIII Office published in the Federal Register 44 FR 37961, a notice proposing approval of a delayed compliance order, issued by the State of Utah through the Air Conservation Committee to Kaibab Industries. The notice asked for public comments by July 30, 1979, on EPA's proposed approval of the Order. No comments were received during this period.

Therefore, the delayed compliance order issued to Kaibab Industries 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 Kaibab Industries on a schedule to submit for approval landfill plans; initiate on-site preparation for landfill; excavation, fencing and drainage; complete on-site preparation for landfill; and discontinue use of TP burners at Panguitch, Utah, into compliance as expeditiously as practicable with Section 2.2.1 of the Utah Air Conservation Regulations, a part of the federally-approved Utah State Implementation Plan. If the conditions of the Order are met, it will permit Kaibab Industries, 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.

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. By adding the following entry to the table in § 65.491 to read as follows:

§ 65.491 EPA approval of State delayed compliance orders issued to major stationary sources.

* * * * * * *

Source	Location	Order No.	SIP regulation involved	Date of FR proposal	Final compliance date
* * *					
Kaibab Industries	Panguitch, Utah	A-79-19	Section 2.2.1	June 29, 1979	July 1, 1979.

EPA has determined that its approval of the Order shall be effective November 2, 1979, because of the need to immediately place Kaibab Industries, on a schedule which is effective under the Clean Air Act for compliance with the applicable requirements of the Utah State Implementation Plan.

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

Dated: October 29, 1979.

Douglas M. Costle,

Administrator.

[FR Doc. 79-33931 Filed 11-1-79; 8:45 am]

BILLING CODE 6560-01-M

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40 CFR Part 81

[FRL 1341-7]

Designation of Areas for Air Quality Planning Purposes; Attainment Status Designations: Florida, Kentucky, and Tennessee

AGENCY: U.S. Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Clean Air Act Amendments of 1977 required that the Environmental Protection Agency (EPA) designate the attainment status of all areas within the States on a State-by-State, pollutant-by-pollutant basis. This was done on March 3, 1978 (43 FR 8962). Either the State or EPA can initiate changes in these designations, and such changes if finalized by the Administrator will replace extant designations.

The attainment status designation of Broward County, Florida for carbon monoxide is changed from nonattainment to unclassifiable. This change is made because the original designation was based on a biased monitor. Siting problems have since been corrected and additional monitoring sites for carbon monoxide are being established throughout the County to provide an extensive network for data collection in the future. Additionally, the designation of Escambia County, Florida, for ozone is changed from nonattainment to unclassifiable because of the recent change in the national ambient air quality standard for ozone and limited valid data available for Escambia County.

In Kentucky, the Boyd County sulfur dioxide nonattainment area is redefined to exclude the northernmost portion of the County. This is done on the basis of a recently completed monitoring study. Also, Davies, and McCracken Counties are redesignated as attainment for ozone because of the recent change in the national ambient standard for this pollutant.

The designation of the Rockwood, Tennessee, particulate nonattainment area is changed to unclassifiable on the basis that the original ambient data supporting the initial nonattainment designation appears to have been unduly influenced by reentrained road dust.

DATE: These actions are effective [date of publication.]

FOR FURTHER INFORMATION CONTACT: Brian Mitchell (Florida), Barry Gilbert (Kentucky), or Archie Lee (Tennessee) of the EPA Region IV Air Programs Branch, 345 Courtland Street, N.E., Atlanta, Georgia, 30308. Mr. Mitchell may be reached by telephone at 404/881-3286 (FTS 257-3286); Messrs. Gilbert and Lee, at 404/881-2864 (FTS 257-2864).

SUPPLEMENTARY INFORMATION: On March 3, 1978 (43 FR 8962 at 8981), the Administrator designated Broward County, Florida nonattainment for carbon monoxide on the basis of air quality data from a continuous monitor operating at 2102 N.E. 6th Street in Fort Lauderdale. This data showed violations of the 8-hour standard in 1976, 1977, and 1978. After the nonattainment designation was made, EPA determined that the data from this site was not representative of the ambient air quality in the area. The major problem was undue influence from a nearby I-95 overpass: the 14-foot high intake for the sampler was located only 300 feet from the 18-foot high overpass. The site has been moved to a location in the vicinity of U.S. 441 and State Road 842. The designation of Broward County is changed from nonattainment for CO to unclassifiable. If data gathered at the new location subsequently show a violation, the nonattainment designation will be restored.

Escambia County, Florida was designated nonattainment for ozone (photochemical oxidant) by the Administrator on March 3, 1978 (43 FR 8962 at 8981), on the basis of monitoring data from a site in Pensacola. In September of 1978, a validation of Florida's oxidant data was performed by representatives of EPA-Region IV and staff of the Florida Department of Environmental regulation. It was recommended that 1976 and 1977 data not be used because of insufficient calibration of the ozone monitor, and that the more recent 1978 data be used for planning strategies. However, due to the national ozone standard change, the subsequent change in methodologies for determining attainment status and design values, and the limited valid data available for Escambia County, the designation of Escambia County is changed from nonattainment to unclassifiable. As additional monitoring data becomes available, the area will be redesignated, if necessary, to reflect its true attainment/nonattainment status.

Also on March 3, 1978 (43 FR 8962 at 8997), the Administrator designated Boyd County, Kentucky, nonattainment for sulfur dioxide on the basis of information supplied by the Kentucky Department for Natural Resources and Environmental Protection (KDNREP). Since that time, a monitoring study has been completed by Environmental Systems, Inc. for Ashland Oil Company. The results of this study show that the national ambient air quality standards for SO_2 have been attained in the northern part of the County for the last eight quarters. On March 9, 1979, the Secretary of the KDNREP formally requested that the nonattainment designation be made to apply only to that portion of Boyd County lying south of Universal Transverse Mercator Northing Line 4251 km. (zone 17).

The nonattainment area is redefined as the State requested. In his March 9, 1979, letter, the Secretary also asked that EPA change the ozone designation of Davies and McCracken Counties from nonattainment to attainment on the basis for three years of data showing no violation of the newly adopted NAAQS for ozone, 0.12 ppm. The designation of these two counties is changed as requested by the State.

A section of downtown Rockwood, Tennessee (Roane County) was designated nonattainment for TSP by the Administrator on March 3, 1978 (43 FR 8962 at 9036), on the basis of data from a monitor which showed violations of both primary and secondary standards for this pollutant. Subsequently, a microscopic analysis of filters from the original site was performed and the findings give some support to the State's position that the violations recorded there were caused by an undue influence of reentrained road dust. Accordingly, the State has asked that the area be redesignated unclassifiable until additional monitoring can provide a clearer idea of actual air quality. EPA is today making the change requested by the State.

These changes were announced as proposed rulemaking in the Federal Register of June 27, 1979 (44 FR 37515). No comments were received, however. These changes are effective immediately.

Under Executive Order 12044 EPA is required to judge whether a regulation is "significant" and therefore subject to the procedural requirements of the Order or whether it may follow other specialized development procedures. EPA labels these other regulations "specialized." I have reviewed this regulation and determined that it is a specialized regulation not subject to the procedural requirements of Executive Order 12044.

(Sections 107, 171, and 301 of the Clean Air Act (42 U.S.C. 7407, 7501, and 7601))

Dated: October 29, 1979.

Douglas M. Costle,

Administrator.

Part 81 of Chapter I, Title 40, Code of Federal Regulations, is amended as follows:

Subpart C—Section 107 Attainment Status Designations

* * * * *

1. In § 81.310, the attainment status designation table for ozone (O_x) is revised by deleting the entry for Escambia County, and the attainment status designation table for carbon monoxide is revised by deleting the entry for Broward County. As revised, these tables read as follows:

§ 81.310 Florida

* * * * *

Florida—O_3

Designated area	Does not meet primary standards	Cannot be classified or better than national standards
Broward County	X**	
Dade County	X**	
Duval County	X**	
Hillsborough County	X**	
Orange County	X**	
Palm Beach County	X**	
Pinellas County	X**	
Rest of State		X**

** EPA designation only.

Florida—CO

Designated area	Does not meet primary standards	Cannot be classified or better than national standards
Statewide		X**

** EPA designation only.

* * * * *

2. In § 81.318, the attainment status designation table for SO_2 is revised by replacing the words "Boyd County" with the words "That portion of Boyd County south of UTM northing line 4251 km."

3. In § 81.318, the attainment status designation table for ozone in § 81.318 is revised by deleting Davies and McCracken Counties. As revised, this table reads as follows:

§ 81.318 Kentucky

* * * * *

Kentucky—O_3

Designated area	Does not meet primary standards	Cannot be classified or better than national standards
Boyd County	X	
Cincinnati Area—Boone, Kenton, and Campbell Counties	X	
Fayette County	X	
Henderson County	X	
Jefferson County	X	
Rest of State		X

* * * * *

4. In § 81.343, the attainment status designation table for TSP is revised by changing the designation of Roane County to read as follows:

§ 81.343 Tennessee.

Tennessee—TSP

Designated area	Does not meet primary standards	Does not meet secondary standards	Cannot be classified	Better than national standards
* * * * *				
That portion of Roane County within a downtown section of Rockwood				X
* * * * *				

[FR Doc. 79-33979 Filed 11-1-79; 8:45 am]

BILLING CODE 6560-01-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 21 and 22

[FCC 79-595]

Domestic Public Fixed Radio Services and Public Mobile Radio Services

Correction

In FR Doc. 79-32026, published at page 60532, on Friday, October 19, 1979, the following corrections should be made:

1. On page 60534, in the second column, above "PART 21" heading, "Appendix—A" should be added;

2. On page 60573, in the third column, "§ 21.1 [Reserved]" and "§ 21.2 Definitions." should be corrected to read "§ 22.1 [Reserved]" and "§ 22.2 Definitions.".

BILLING CODE 1505-01-M

INTERSTATE COMMERCE COMMISSION

49 CFR 1033

[S.O. 1182-A]

Substitution of Stock Cars for Boxcars

AGENCY: Interstate Commerce Commission.

ACTION: Service Order No. 1182-A.

SUMMARY: Revised Service Order No. 1182 authorized the Burlington Northern Inc. to substitute specially prepared stock cars for boxcars for shipments of grain originating on the BN in order to augment the available supply of cars suitable for grain movement.

DATE: Since no further emergency exists, Revised Service Order 1182 is vacated effective 11:59 p.m., October 31, 1979.

FOR FURTHER INFORMATION CONTACT: J. Kenneth Carter (202) 275-7840.

Decided October 25, 1979.

Upon further consideration of Revised Service Order No. 1182 (42 FR 3844, 37000; 43 FR 2395, 31015, 59074; 44 FR 36184), and good cause appearing therefore:

It is ordered:

§ 1033.1182 Substitution of stock cars for boxcars.

Revised Service Order No. 1182 is vacated effective 11:59 p.m., October 31, 1979.

(49 U.S.C. (10304-10305 and 11121-11126))

A copy of this order shall be served upon the Association of American Railroads, Car Service Division, as agent of the railroads subscribing to the car service and car hire agreement under the terms of that agreement and upon the American Short Line Railroad Association. Notice of this order shall be given to the general public by depositing a copy in the Office of the Secretary of the Commission, at Washington, D.C., and by filing a copy with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board, members Joel E. Burns, Robert S. Turkington, and John R. Michael.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 79-33990 Filed 11-1-79; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 32

Migratory Bird Hunting; National Wildlife Refuges in Louisiana

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Amendment of Special Regulations.

SUMMARY: Previously published special regulations closed migratory waterfowl hunting for the 1979–1980 season on four national wildlife refuges in Louisiana to prevent the continued deposition of toxic lead shot on these important migratory waterfowl wintering areas. Approval to enforce regulations requiring the use of steel shot for hunting has been obtained from the appropriate State regulatory authority. The intended effect of this amendment is to prohibit the taking of waterfowl with 12 gauge toxic shot and to reopen these four refuges to waterfowl hunting for the 1979–80 Louisiana migratory waterfowl season.

DATES: November 3, 1979, through January 28, 1980.

FOR FURTHER INFORMATION CONTACT: The Director, Regional Director, Area Manager, or appropriate refuge manager at the address or telephone number listed below:

Lynn A. Greenwalt, Director, U.S. Fish and Wildlife Service, 18th and C Sts., NW, Washington, DC 20240. Telephone 202–343–4717.

Kenneth E. Black, Regional Director, U.S. Fish and Wildlife Service, Richard B. Russell Federal Building, 75 Spring St., SW, Atlanta, GA 30303. Telephone 404–221–3583.

Russell D. Earnest, Area Manager, U.S. Fish and Wildlife Service, 200 East Pascagoula Street, Suite 300, Jackson, MS 39201. Telephone 601–969–4900.

Daniel Doshier, Refuge Manager, D'Arbonne National Wildlife Refuge and Upper Ouachita National Wildlife Refuge, P.O. Box 3065, Monroe, LA 71201. Telephone 318–325–1735.

Bobby W. Brown, Refuge Manager, Lacassine National Wildlife Refuge, Route 1, Box 186, Lake Arthur, LA 70549. Telephone 318–325–2750

John R. Walther, Refuge Manager, Sabine National Wildlife Refuge, MRH Box 107, Hackberry, LA 70645. Telephone 318–762–5135.

SUPPLEMENTARY INFORMATION: The primary author of this rule is Ronald L. Fowler, Division of Refuge Management, U.S. Fish and Wildlife Service, 18th and C Sts., NW, Washington, D.C. 20240. Telephone 202–343–4305.

On October 29, 1979 (44 FR 61969), the Fish and Wildlife Service published special regulations closing four refuges in Louisiana to migratory waterfowl for the 1979–80 Louisiana migratory waterfowl season. This action was necessary because the authority to enforce regulations requiring the use of steel shot was not granted by the State of Louisiana. Subsequent to the publication of the special regulations on October 29, the Fish and Wildlife Service received assurances from the appropriate State regulatory authority authorizing the Service to enforce regulations requiring the use of steel shot in 12 gauge shotguns for the 1979–80 waterfowl season on the above four national wildlife refuges.

Special regulations published on September 6, 1979 (44 FR 51985) for Lacassine and Sabine National Wildlife Refuges, and on September 20, 1979 (44 FR 54487) for D'Arbonne National Wildlife Refuge and on October 29, 1979 (44 FR 61965) for Upper Ouachita National Wildlife Refuge permit migratory waterfowl hunting and made the use of steel shot ammunition mandatory during refuge waterfowl hunts. This rule amends the above regulations by limiting the steel shot requirement to 12 gauge only.

Note.—The Department of the 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.

The previously issued special regulations are amended as follows:

§ 32.12 Special regulations; migratory game birds; for individual wildlife refuge areas.

Louisiana

D'Arbonne National Wildlife Refuge

Lacassine National Wildlife Refuge

Sabine National Wildlife Refuge

Upper Ouachita National Wildlife Refuge

The above National Wildlife Refuges will be open to migratory waterfowl hunting during the 1979–80 Louisiana State waterfowl seasons under the following conditions: No person shall take waterfowl while possessing 12 gauge shells loaded with any shot other than steel shot. Shells loaded with toxic shot, such as lead, can be in the possession of hunters and used in taking waterfowl in these refuges provided these shells are gauges other than 12 gauge.

These special regulations supplement the regulations which generally govern hunting on National Wildlife Refuges which are set forth in Title 50, Code of Federal Regulations, Part 32. The public is invited to offer suggestions and comments at any time.

Dated: October 30, 1979.

Robert S. Cook,

Deputy Director, U.S. Fish and Wildlife Service.

[FR Doc. 79-34052 Filed 11-1-79; 8:45 am]

BILLING CODE 4310-55-M

Proposed Rules

Federal Register
Vol. 44, No. 214
Friday, November 2, 1979

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

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Parts 210 and 235

School Nutrition Programs

AGENCY: Food and Nutrition Service, USDA.

ACTION: Announcement of public meetings.

SUMMARY: The U.S. Department of Agriculture announces public meetings in which USDA officials will brief the public on the Assessment, Improvement and Monitoring System (AIMS) that was proposed in the October 30, 1979 edition of the Federal Register.

DATES: Public briefings will be presented on the following dates:

November 14, 1979—Boston, Massachusetts
November 14, 1979—Stroudsburg, Pennsylvania
November 20, 1979—Omaha, Nebraska
November 27, 1979—Seattle, Washington
November 28 and 29, 1979—Chicago, Illinois
December 4, 1979—Atlanta, Georgia

ADDRESSES: Public briefings will be presented at the following locations:

November 14, 1979, Minihan Hall of Hurley, State Office Building, Cambridge and Staniford Street, Boston, Massachusetts
November 14, 1979, Pocono Hilton Inn, 700 Main Street, Stroudsburg, Pennsylvania
November 20, 1979, Holiday Inn Holidome, 3321 South 72nd Street, Omaha, Nebraska
November 27, 1979, New Federal building, Room 390, 915 Second Avenue, Seattle, Washington
November 28 and 29, 1979, Best Western Lakeshore Hotel, 600 North Lakeshore Drive, Chicago, Illinois
December 4, 1979, Ladha Continental Hotel, 100 10th Street, Atlanta, Georgia

FOR FURTHER INFORMATION CONTACT: Stanley C. Garnett or Barbara Hallman, School Programs Division, USDA, FNS, Washington, D.C. 20250, (202) 447-9069.

SUPPLEMENTARY INFORMATION: On October 30, 1979, USDA proposed two regulations and reprinted one interim regulation in the Federal Register (44 FR 62442). The changes suggested by these proposed and interim regulations are known as the Assessment, Improvement and Monitoring System (AIMS). The objectives of the AIM System are to analyze current school lunch and school breakfast program management by States; to monitor effectively the use of Federal funds; and to protect the nutritional integrity of meals served under the programs.

The AIM System would set performance standards to be met by School Food Authorities. A review system would be proposed which would require States to undertake a specific number of reviews at definite time intervals. A method for choosing schools to be reviewed is also proposed. For each type of performance standard violation, a proposed method of assessing a claim is described. The type of records that must be kept and information to be included in annual State Plans of Child Nutrition Operations is given. In addition, the type of sanctions that will be applied for failure to implement AIMS is proposed.

Because AIMS is complex and contains many comprehensive provisions, the Department believes it would be beneficial to the public's understanding of AIMS to hold open briefings. Department officials will conduct the briefings, describing the system and answering questions raised by attendees.

Public comment is not being solicited at the briefings. The briefings are only intended to assist in the public's understanding of the proposed AIMS regulations. The Department hopes that this will increase the number of relevant and useful public comments that will be received during the comment period which ends January 2, 1980.

Persons interested in getting a copy of the AIMS proposal or in attending a briefing should contact the appropriate FNS Regional Office listed below.

Mr. Charles Kirby, Director, Special Nutrition Programs, Southeast Regional Office, Food and Nutrition Service, USDA, 1100 Spring Street NW., Atlanta, Georgia 30309, A.C. 404 881-4911—Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee

Mr. Robert Freiler, Director, Special Nutrition Programs, Mid-Atlantic Regional Office, Food and Nutrition Service, USDA, One Vahlsing Center, Robbinsville, New Jersey 08691, A.C. 609 259-3041 X303—Delaware, District of Columbia, Maryland, New Jersey, New York, Pennsylvania, Virginia, West Virginia, Virgin Islands, Puerto Rico

Mr. Robert Nelson, Director, Special Nutrition Programs, Midwest Regional Office, Food and Nutrition Service, USDA, 536 South Clark Street, Chicago, Illinois 60605, A.C. 312 353-6673—Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin

Mr. Jose Acosta, Acting Director, Special Nutrition Programs, Mountain Plains Regional Office, Food and Nutrition Service, USDA, 2420 West 26th Avenue, Denver, Colorado 80211, A.C. 303 837-5071—Colorado, Iowa, Kansas, Missouri, Montana, Nebraska, North Dakota, South Dakota, Utah, Wyoming

Hap Pullium, Director, Special Nutrition Programs, Southwest Regional Office, Food and Nutrition Service, USDA, 1100 Commerce Street, Dallas, Texas 75242, A.C. 214 767-0214—Arkansas, Louisiana, New Mexico, Oklahoma, Texas

Jack Bradley, Director, Special Nutrition Programs, Western Regional Office, Food and Nutrition Service, USDA, 550 Kearny Street, San Francisco, California 94108, A.C. 415 556-4956—Alaska, Arizona, California, Guam, Hawaii, Idaho, Nevada, Oregon, Washington, American Samoa, Trust Territory, Northern Marianas

John Ghiorzhi, Director, New England Regional Office, Food and Nutrition Service, USDA, 33 North Avenue, Burlington, Massachusetts 01803, A.C. 617 272-0861—Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont

Dated: October 29, 1979.

Carol Tucker Foreman,

Assistant Secretary for Food and Consumer Services.

[FR Doc. 79-33551 Filed 11-1-79; 8:45 am]
BILLING CODE 3410-30-M

Commodity Credit Corporation

7 CFR Part 1464

Tobacco Loan Program; Proposed 1979 Crop Grade Loan Rates—Dark Air-Cured (Types 35 & 36) Tobacco

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Proposed rule.

SUMMARY: This proposal would establish the loan rates to be applied to the various grades of 1979-crop dark air-cured (types 35 & 36) tobacco so as to provide the level of price support required by the Agricultural Act of 1949, as amended. Eligible dark air-cured (types 35 & 36) tobacco could be received for price support at the specified rates.

DATES: Written comments must be received on or before November 26, 1979 in order to be sure of consideration.

ADDRESS: Send comments to Director, Price Support and Loan Division, ASCS, P.O. Box 2415, Washington, D.C. 20013.

FOR FURTHER INFORMATION CONTACT: Robert L. Tarczy, ASCS, (202) 447-6733.

SUPPLEMENTARY INFORMATION: In accordance with the provisions of Section 106 of the Agricultural Act of 1949, as amended ("the Act"), the 1979 crop of dark air-cured (types 35 & 36) tobacco is required to be supported at the level of 80.4 cents per pound. It is expected that price support will be provided through loans to a producers' cooperative marketing association which would receive eligible tobacco from producers and make price support advances to the producers through auction warehouses. The tobacco received would serve as collateral for the loan. Price support advances would be based on the loan rates for each grade. The proposed loan rates would average the required level of support when weighted by the anticipated grade percentages as authorized by Section 403 of the Act. Price support advances to producers would be the amounts determined by multiplying the pounds of each grade received by the applicable loan rate for that grade.

Proposed Rule

Accordingly, it is proposed that 7 CFR Part 1464 be amended by revising § 1464.19 to read as follows effective for the 1979 crop of dark air-cured tobacco, types 35 and 36.

§ 1464.19 1979 Crop Dark Air-Cured Tobacco, Types 35 & 36 Grade Loan Schedule [1]

Loan rate

[Dollars per hundred pounds, farm sales weight]

Grade	Length 47	Length 46	Length 45	Length 44
A1F	122	122	122	
A2F	118	118	118	
A3F	112	112	112	
A1R	122	122	122	
A2R	118	118	118	
A3R	112	112	112	
B1F	112	112	112	109
B2F	107	107	107	106
B3F	102	102	102	100
B4F	92	92	92	91

[1] Only the original producer is eligible to receive advances. Tobacco graded "no-G" (no grade), "U" (unsound), or scrap will not be accepted. Tobacco graded "W" (doubtful keeping order) will be accepted at advance rates 20 percent below the advance rates otherwise applicable. Grades marked with the special factor "BH" shall have an advance rate 20 percent below the advance rate otherwise applicable without such special factor. Type 35 grades marked with the special factor "BL" shall have an advance rate 20 percent below the advance rate otherwise applicable without such factor.

Loan rate—Continued

[Dollars per hundred pounds, farm sales weight]

Grade	Length 47	Length 46	Length 45	Length 44
B5F	85	85	85	84
B1R	111	111	111	109
B2R	106	106	106	105
B3R	100	100	100	99
B4R	91	91	91	90
B5R	85	85	85	84
B1D	111	111	111	109
B2D	106	106	106	105
B3D	99	99	99	98
B4D	91	91	91	90
B5D		82	82	81
B3M	94	94	94	93
B4M	87	87	87	86
B5M	80	80	80	79
B3G	93	93	93	92
B4G	87	87	87	86
B5G	78	78	78	77
C1L	112	112	112	111
C2L	110	110	110	109
C3L	104	104	104	103
C4L	95	95	95	94
C5L	85	85	85	83
C1F	112	112	112	111
C2F	108	108	108	107
C3F	103	103	103	101
C4F	95	95	95	94
C5F	86	86	86	84
C1R	110	110	110	109
C2R	107	107	107	106
C3R	100	100	100	98
C4R	89	89	89	88
C5R	81	81	81	80
C3M	94	94	94	93
C4M	84	84	84	83
C5M	79	79	79	78
C3G	95	95	95	93
C4G	85	85	85	84
C5G	78	78	78	77

Grade	Length
T3F	78
T4F	75
T5F	67
T3R	79
T4R	74
T5R	66
T3D	79
T4D	74
T5D	66
T3M	77
T4M	69
T5M	64
T3G	78
T4G	72
T5G	62
X1L	102
X2L	98
X3L	95
X4L	91
X5L	83
X1F	101
X2F	97
X3F	93
X4F	90
X5F	81
X1R	100
X2R	96
X3R	89
X4R	83
X5R	77
X3D	88
X4D	82
X5D	75
X3M	85
X4M	80
X5M	71
X3G	79
X4G	73
X5G	61
N1L	61
N2L	52
N1R	53
N2R	48
N1G	50
N2G	46

All written submissions will be made available for public inspection from 8:15 a.m. to 4:45 p.m. Monday through Friday in Room 3741—South Building, USDA, 14th and Independence Avenue, S.W., Washington, D.C. 20013.

This amendment is being published under emergency procedures as authorized by Executive Order 12044 and Secretary's Memorandum No. 1955 without a full 60-day comment period. It has been determined by Jerome F. Sitter, Director, Price Support and Loan Division, ASCS that an emergency exists which warrants less than a full 60-day comment period on the proposal because the grade loan rates for the 1979-80 marketing year for dark air-cured (types 35 and 36) tobacco must be announced prior to the opening of markets in late November. Accordingly, comments must be received by November 26, 1979.

Note.—This proposal has been reviewed under the USDA criteria established to implement Executive Order 12044, "Improving Government Regulations". A determination has been made that this action should not be classified "significant" under those criteria. This proposal contains necessary operating provisions needed to implement the national average loan rate for dark air-cured (types 35 and 36) tobacco which was determined to be not significant, announced on September 14, for which a final impact statement was prepared and is available from Robert L. Tarczy, Price Support and Loan Division, Room 3741—South building, P.O. Box 2415, Washington, D.C. 20013.

Signed at Washington, D.C. on: October 26, 1979.

Ray Fitzgerald,

Executive Vice President, Commodity Credit Corporation.

[FR Doc. 79-33615 Filed 10-26-79; 10:26 am]

BILLING CODE 3410-05-M

DEPARTMENT OF ENERGY

10 CFR Chapters II, III and X

Improving Government Regulations; Semiannual Agenda of Regulations

AGENCY: Department of Energy.

ACTION: Notice of Regulations Under Development or Review.

SUMMARY: The Department of Energy (DOE) is publishing an agenda of regulations under development or review as of October 1, 1979. Because of delays that have arisen in preparation of the agenda, the original publication date of October 26, 1979 has been changed to November 9, 1979.

FOR FURTHER INFORMATION CONTACT: Sue D. Sheridan, Department of Energy, Forrestal Building, 1000 Independence Avenue SW., Washington, D.C. 20585, (202) 252-6754.

Issued in Washington, D.C. this 30th day of October, 1979.

Lynn R. Coleman,

General Counsel.

[FR Doc. 79-34124 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

Economic Regulatory Administration

10 CFR Part 221

[Docket No. ERA-R-79-50]

Priority Supply of Crude Oil and Petroleum Products Under the Defense Production Act

AGENCY: Economic Regulatory Administration, Department of Energy.

ACTION: Notice of Proposed Rulemaking and Public Hearing.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) hereby gives notice of a proposed rulemaking and public hearing regarding the adoption of regulations pursuant to sections 101(a) and 709 of the Defense Production Act of 1950 for priority supply of crude oil and petroleum products.

The proposed rules would permit the Department of Defense (DOD), whenever necessary or appropriate to promote the national defense, to request ERA to authorize DOD to use priority-rated orders to supply the Department of Defense on a priority basis with crude oil or petroleum products. Following a determination that the issuance of a priority rating is necessary to meet the national defense requirement identified by DOD and that a proposed supplier is capable of delivering the requested crude oil or petroleum products, the ERA would issue a priority rating to DOD complying in whole or in part with the DOD request. When a supplier receives a priority-rated supply order from DOD, it would be required to fill that order regardless of its other supply commitments. The proposed rules would be used only for crude oil and petroleum products not subject to allocation controls under the Emergency Petroleum Allocation Act (EPAA). Products subject to EPAA controls would be allocated to the Defense Department under those controls.

DATES: Comments by December 31, 1979, 4:30 p.m., requests to speak by November 28, 1979, 4:30 p.m.; Hearing Date: December 6, 1979, 9:30 a.m., and continued if necessary at 9:30 a.m., at the same location on the following day.

ADDRESSES: All comments to: Public Hearing Management, Docket No. ERA-R-79-50, Department of Energy, Room 2313, 2000 M Street, NW., Washington, D.C. 20461. Requests to speak: Public Hearing Management, Docket No. ERA-R-79-50. Department of Energy, Room 2313, 2000 M Street, NW., Washington, D.C. 20461. Hearing location: 2000 M Street, NW., Room 2105, Washington, D.C. 20461..

FOR FURTHER INFORMATION CONTACT:

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

William Webb (Office of Public Information), Economic Regulatory Administration, Room B110, 2000 M Street, NW., Washington, D.C. 20461, (202) 634-2170.

Stanley Vass (Office of Petroleum Allocation Regulations), Economic Regulatory Administration, Room 2310A, 2000 M Street, NW., Washington, D.C. 20461, (202) 254-7477.

Peter Schaumberg (Office of General Counsel), Department of Energy, Room 6A-127, 1000 Independence Avenue, SW., Washington, D.C. 20585, (202) 252-6754.

SUPPLEMENTARY INFORMATION:

I. Background.
II. ERA Authority to Require Priority Supply.
A. DPA vs EPAA Authority.
B. Implementation of the DPA.
III. Proposed Priority Supply Procedures.
A. DOD Application for Rated Order.
B. ERA Evaluation of DOD Request for a Priority Rating.
C. Priority-Rated Supply Order.
1. Issuance.
2. Effect on Existing Contracts.
3. Violations and Sanctions.
D. Contract Requirements.
E. Recording and Reporting Requirements.
IV. Comment Procedures.
A. Written Comments.
B. Public Hearings.
V. Additional Matters.

I. Background

Section 101(a) of the Defense Production Act of 1950 ("DPA"), 50 U.S.C. App. § 2071, provides in pertinent part as follows:

> The President is hereby authorized (1) to require that performance under contracts or orders (other than contracts of employment) which he deems necessary or appropriate to promote the national defense shall take priority over performance under any other contract or order, and, for the purpose of assuring such priority, to require acceptance and performance of such contracts or orders in preference to other contracts or orders by any person he finds to be capable of their performance, and (2) to allocate materials and facilities in such manner, upon such conditions, and to such extent as he shall deem necessary or appropriate to promote the national defense.

This authority, with respect to energy resources, originally was vested in the Department of Interior ("DOI") by Executive Order 10480 (18 FR 4939, Aug. 18, 1953), as amended. The DOI implemented section 101(a) of the DPA by adopting regulations for the mandatory priority supply of crude oil and petroleum products. (38 FR 30572, Nov. 6, 1973). Following the establishment of the Department of Energy ("DOE"), this authority was delegated to the Secretary of Energy by Executive Order 12038 (43 FR 4957, Feb. 7, 1978), which amended Executive Order 10480, and Executive Order 11790 (39 FR 23785, June 27, 1974), and subsequently has been delegated by the Secretary to the Administrator of the Economic Regulatory Administration ("ERA"). (See Amendment No. 1 to DOE Delegation Order No. 0204-4.)

II. ERA Authority to Require Priority Supply

A. DPA vs EPAA Authority

Several factors currently exist that increase the possibility that suppliers of certain petroleum products to the Department of Defense ("DOD") may determine to limit or terminate existing supply relationships with DOD. For example, approximately 60 suppliers, of which 45 are relatively small refiners, historically provide DOD with its naphtha base jet fuel (JP-4) requirements. DOD is the only large volume customer in the U.S. for this product, and under current market conditions it may be more profitable for some of the larger suppliers to produce and sell other petroleum products. By virtue of an energy action submitted to the Congress in 1976, JP-4 is exempt from the ERA Mandatory Petroleum Allocation and Price Regulations in 10 CFR Chapter II, Parts 210, 211, and 212, issued under authority of the Emergency Petroleum Allocation Act ("EPAA"), Pub. L. 93-159, as amended. Thus, suppliers are no longer bound under the supplier/purchaser relationship rule, prescribed in § 211.9, to supply DOD with this fuel. Accordingly, DOD's current suppliers of JP-4 could alter their refinery yield fractions to produce greater volumes of higher revenue products and lesser volumes of JP-4. A similar result could occur with kerosene base jet fuel (JP-5) and aviation gasoline, which were exempted from allocation and price controls effective February 26, 1979. These products are used primarily for commercial airline and general aviation purposes, but are used by the military also for carrier-based jets and other purposes. DOD is also a major user of middle distillates such as heating oil and diesel fuel, which products were decontrolled in 1976.

The ERA has authority under the EPAA to reimpose controls on products currently exempt from ERA allocation

and price regulations, to adjust refinery yields to require refiners to produce more of a particular product and under certain circumstances to assign purchasers new suppliers of a particular product. However, the EPAA is generally used to effect these actions with respect to specific products on a regional or national level, rather than on a firm-by-firm basis or for the benefit of particular customers. It is arguably preferable to utilize the authority provided in section 101(a) of the DPA as the basis for directing the priority supply of crude oil or petroleum products to DOD under circumstances in which the supply is necessary or appropriate to promote the national defense.

These proposed regulations would be applicable on a broad basis to all crude oil and refined petroleum products to provide ERA with as much flexibility as possible. It is ERA's current intention, however, to use the EPAA as the exclusive mechanism for allocating crude oil and petroleum products subject to controls thereunder and ordinarily to utilize these DPA regulations only in the case of crude oil or products that have been exempted from EPAA allocation controls.

B. Implementation of the DPA

Under DPA authority, ERA is authorized to issue priority ratings for DOD and other defense-related contracts which would require that a supplier accept such orders and supply the specified quantities and qualities of petroleum products. Additionally, ERA can issue directives to particular companies requiring that they provide necessary supplies for national defense needs. Such orders may be issued under DPA authority without the reimposition of mandatory allocation or price regulations under the EPAA.

ERA has determined to adopt regulations to provide procedures by which these priority rating orders can be requested and issued. This would enable ERA to act expeditiously and consistently to provide DOD with the necessary relief whenever DOD is unable to obtain necessary supplies of crude oil or petroleum products for national defense-related activities. In addition, these regulations would further notify potential DOD suppliers of the possibility of mandatory priority supply obligations and the procedures associated therewith. Should a supply emergency arise prior to our adoption of these or similar rules proposed herein, ERA is authorized to issue an appropriate priority supply order under the general authority in section 101(a) of the DPA.

The proposed regulations would apply to the priority supply to DOD of crude oil, residual fuel oil, refined petroleum products and lubricants. This proposal would not apply to the supply of natural gas or ethane.

ERA has decided to limit the scope of these proposed regulations to crude oil or petroleum products purchased by DOD for its own use or purchases made by DOD on behalf of other agencies of the Federal Government. DOD is not authorized by these proposed regulations to submit a request for a priority rating for any of its contractors, nor are contractors permitted to submit such requests directly to ERA.

ERA does have authority under the DPA to authorize priority ratings for defense contractors. In extraordinary circumstances DOD may determine that failure to provide crude oil or petroleum products to a defense contractor would have a substantial negative impact on the national defense. ERA could invoke the general DPA authorities to assist that contractor notwithstanding the absence of a specific provision in the proposed regulations authorizing ratings for contractors. DOD has procedures for determining contractor energy shortages in its Instruction No. 4170.9 (May 16, 1978), and we assume that DOD would rely upon these or similar procedures for identifying contractors in need of priority assistance.

We will consider the issue of priorities for defense contractors in a separate action. However, we specifically would like comment on whether these proposed regulations should be expanded to provide procedures for priority supply of petroleum products to defense contractors.

III. Proposed Priority Supply Procedures

A. DOD Application for Rated Order

The priority supply system proposed herein would establish a procedure under which DOD could request ERA to issue a rated order for the priority supply of crude oil or petroleum products to DOD. These procedures could be used whenever DOD is unable to procure or has reason to believe it will be unable to procure crude oil or petroleum products to meet national defense requirements. Under the proposal, when DOD finds that (1) a fuel supply shortage for DOD exists or is anticipated which would adversely affect the national defense and (2) the defense activity for which the fuel is required cannot be postponed until after the fuel supply shortage is likely to terminate, it may submit a written request to ERA for the issuance of a priority-rated supply order directing that DOD be supplied with crude oil or petroleum product on a priority basis. In order for DOD to make the finding of a fuel supply shortage, it is not necessary that there be a general shortage of crude oil or petroleum products. Any circumstance which results in an actual or projected supply shortage for DOD would satisfy the requirements of § 221.31(a) of the proposed regulations. DOD is required to notify the Federal Emergency Management Agency (FEMA) of its findings and request for priority.

Written requests by DOD for priority supply orders would be required to set forth: (1) the quantity and quality of crude oil or petroleum products required to meet national defense requirements; (2) the required delivery dates; (3) the defense-related activity and the supply location for which the crude oil or petroleum product was requested; (4) the current or most recent suppliers of the requested crude oil or petroleum product, and the reason, if known, why such suppliers cannot or will not supply the requested crude oil or petroleum product; (5) the degree to which it is feasible for DOD to use an alternative crude oil or petroleum product in lieu of the type requested, and, where practicable, the efforts that have been made to obtain such alternate; (6) DOD's best estimation as to the duration of the crude oil or petroleum product shortage; (7) DOD's proposed supply source for the requested crude oil or petroleum product, which shall, if practicable, be the historical supplier of such crude oil or product to DOD; and (8) certification that DOD has made the findings that a fuel supply shortage is anticipated which would adversely affect the national defense and that the defense requirement cannot be postponed until after the fuel shortage is likely to terminate.

In those circumstances where the Secretary of Defense or his designee finds, and has so notified the Federal Emergency Management Agency (FEMA), that a fuel supply shortage for DOD exists or is imminent and that compliance with the procedures established by §§ 221.31 and 32 would have a substantial negative impact on the national defense, ERA would be able under proposed § 221.32(d) to authorize an expedited procedure to ensure that DOD receives timely delivery of needed fuel.

Sections 221.31(b) and 221.32(d) of the proposed regulations require DOD to notify FEMA of its request for a priority rating. This requirement affords FEMA an opportunity to exercise its oversight

responsibilities under the DPA. ERA specifically would like comments as to whether the notification provisions are adequate, or whether §§ 221.31(b) and 221.32(d) should require FEMA concurrence in the DOD request.

ERA also would like comment on whether FEMA input on the DOD request is the appropriate mechanism for FEMA involvement in the priority rating process. Commenters are asked to respond whether it would be preferable for FEMA instead to perform its review role in conjunction with ERA at the time that ERA is considering the DOD request.

B. ERA Evaluation of DOD Request for Priority Rating

Under the proposed rules, ERA promptly would review requests for priority ratings to determine whether a sufficient basis existed on which to issue the requested rating and whether the proposed supplier was capable of supplying crude oil or petroleum product in the amounts requested by DOD. This determination would be based upon consideration of several factors, including: (1) whether DOD's national defense needs for crude oil or petroleum products can reasonable be satisfied without exercising the authority specified in these regulations; (2) whether the historical supplier currently is unable or unwilling to supply DOD's crude oil or petroleum product requirements; (3) whether other suppliers are capable of providing the supply; (4) whether the use of an alternate crude oil or petroleum product is economically or practically feasible; and (5) other relevant information.

If ERA determines on the basis of the information including in the request that the priority supply to DOD of crude oil or petroleum products is necessary, ERA would immediately notify the proposed supplier of DOD's request. The proposed supplier would have a period specified in the order, not to exceed fifteen (15) days from the date on which it was notified of DOD's request, to show cause in writing why it could not supply the quantity and quality of crude oil or petroleum products requested. Existing crude oil or petroleum product supply contracts of the proposed supplier with other customers would not alone constitute sufficient cause for not issuing the requested rating. A proposed supplier's current refinery yield fractions also would not alone constitute sufficient cause for not issuing the requested rating.

C. Priority-Rated Supply Order

1. *Issuance*—Following ERA's determination that the proposed supplier or alternate supplier is capable of supplying the requested crude oil or petroleum products, ERA would issue to DOD a priority rating to then be placed by DOD on its supply order to the appropriate supplier. A supplier receiving a priority-rated supply order would supply the quantity and quality of crude oil or petroleum product designated therein to DOD regardless of the supply requirements of other existing contracts not subject to a priority rating, including contracts with DOD. Where supply obligations of the supplier under other priority supply orders create a conflict, ERA would determine, in consultation with DOD and the Federal Emergency Management Agency, the priorities for meeting all such requirements. Where necessary or appropriate to promote the national defense and where for any reason a priority-rated supply order may not be effective, the ERA would also be authorized by the proposed regulations to issue an order directly to a supplier to supply appropriate quantities of crude oil or refined petroleum product to or for the benefit of DOD.

A supplier who receives a priority rating or directive could not use that rating or directive in order to obtain any materials necessary to comply with its supply obligation thereunder.

2. *Effect on Existing Contracts*—The DPA provides that where compliance with a priority-rated order requires a supplier to alter or terminate existing supply contracts, the supplier is not liable for damages or penalties for breach of such contracts, or other damages directly or indirectly related to the supplier's compliance with such order, notwithstanding that such order may thereafter be declared by judicial or other competent authority to be invalid. Accordingly, it is not necessary for the proposed regulations to provide procedures under which the ordered supplier or its customers may recover damages directly or indirectly related to a priority-rated supply order.

Provision is also not made in these proposed regulations for the means by which suppliers that are required to supply crude oil or petroleum product to DOD under a priority order would adjust their other existing supply obligations to account for the supplies provided to DOD. Such adjustments would continue to be subject to the requirements of the Uniform Commercial Code and other applicable laws or contract requirements.

3. *Violations and Sanctions*—Any person who willfully violates any provision of these regulations, or who willfully furnishes false information, would be subject to a fine of not more than $10,000, imprisonment for up to one year, or both. Further, when in the judgment of the Administrator of ERA any person has engaged or is about to engage in any action which would constitute a violation of these regulations, the Administrator may seek an injunction against such action in an appropriate court.

D. Contract Requirements

Under the proposal, no supplier would be allowed to discriminate against orders or contracts to which a priority is assigned by charging higher prices, by imposing terms and conditions for such orders or contracts different from other generally comparable orders or contracts, or by any other means. Contracts involving or arising out of priority-rated supply orders would be subject to all applicable laws and regulations which govern the making of such contracts, including those specified in 10 CFR § 211.26(e).

E. Recording and Reporting Requirements

Suppliers receiving priority-rated orders or directives would be required to maintain, for two years from the date of full compliance with such orders or directives, complete records of all deliveries made in compliance with the orders or directives. Such records would be required to be available for inspection and audit at ERA's request.

IV. Comment Procedures

A. Written Comments

You are invited to participate in this rulemaking by submitting views, data or arguments with respect to the proposal set forth in this Notice. Comments should be submitted to the address indicated in the "ADDRESSES" section of this Notice and should be identified on the outside envelope and on documents submitted with the designation "Defense Production Act Regulations." Fifteen copies should be submitted. All comments received will be available for public inspection in the ERA Office of Public Information, Room B-110, 2000 M Street, N.W., Washington, D.C., between the hours of 8 a.m. and 4:30 p.m., Monday through Friday. Comments should be received by December 31, 1979, 4:30 p.m. in order to be considered.

Any information or data you consider to be confidential must be so identified and submitted in writing, one copy only. We reserve the right to determine the confidential status of the information or data and to treat it according to our determination.

B. Public Hearings

1. *Requesting Opportunity for Oral Statement.* The time and place for the hearing are indicated in the "DATES" and "ADDRESSES" sections of this Notice. If necessary to present all testimony, the hearing will be continued to 9:30 a.m. of the next business day following the first day of the hearing.

Any person may make a written request for an opportunity to make an oral presentation at the hearing. You should provide a phone number where you may be contacted through the day before the hearing.

If you are selected to be heard, you will be so notified by the DOE before 4:30 p.m., November 30, 1979. You must submit 100 copies of your statement before 4:30 p.m., December 5, 1979 to the address given above for requests to speak.

2. *Conduct of the Hearing.* We reserve the right to select the persons to be heard at the hearing, to schedule their respective presentations, and to establish the procedures governing the conduct of the hearing. The length of each presentation may be limited, based on the number of persons requesting to be heard.

An ERA official will be designated to preside at the hearing, which will not be adjudicative in nature. Questions may be asked only by those conducting the hearing. At the conclusion of all initial oral statements, each person who has made an oral statement will be given the opportunity, if he or she so desires, to make a rebuttal statement. The rebuttal statements will be given in the order in which the initial statements were made and will be subject to time limitations.

You may submit questions to be asked of any person making a statement at the hearing. Such questions should be submitted to the address indicated above for requests to speak before 4:30 p.m. on the day prior to the hearing. If at the hearing you decide that you would like to ask a question of a witness, you may submit the question, in writing, to the presiding officer. In any case, the presiding officer will determine whether time limitations permit it to be presented for a response.

Any further procedural rules needed for the proper conduct of the hearing will be announced by the presiding officer.

Transcripts of the hearing will be made and the entire record of the hearing, including the transcripts, will be retained and made available for inspection at the ERA Office of Public Information, Room B-110, 2000 M Street, N.W., Washington, D.C. between the hours of 8 a.m. and 4:30 p.m., Monday through Friday. Any person may purchase a copy of the transcript from the reporter.

In the event that it becomes necessary for us to cancel the hearing, we will make every effort to publish advance notice in the Federal Register of such cancellation. Moreover, we will give actual notice to all persons scheduled to testify at the hearing. However, it is not possible to give actual notice of cancellations or changes to persons not identified to us as participants. Accordingly, persons desiring to attend the hearing are advised to contact DOE on the last working day preceding the date of the hearing to confirm that it will be held as scheduled.

V. Additional Matters

As required by section 7(a)(1) of the Federal Energy Administration Act of 1974 (Pub. L. 93-275), a copy of this Notice has been submitted to the Administrator of the Environmental Protection Agency (EPA). The Administrator does not forsee these actions having an unfavorable impact on the quality of the environment as related to the duties and responsibilities of the EPA.

We currently are reviewing the effects of these proposals on the quality of the human environment and will perform any environmental analysis required by the National Environmental Policy Act (NEPA, 32 U.S.C. 4321 *et seq.*) and the applicable DOE regulations for compliance with NEPA.

ERA has determined that this proposed rulemaking is not subject to the provisions of Executive Order No. 12044 on Improving Government Regulations (43 FR 12661, March 24, 1978), pursuant to the provisions in section 6 of that Executive Order which except regulations issued with respect to military function of the United States and regulations related to Federal Government procurement.

Pursuant to the requirements of section 404(a) of the Department of Energy Organization Act ("DOE Act," Pub. L. 95-91), this proposed rule has been referred, concurrently with the issuance hereof, to the Federal Energy Regulatory Commission for a determination as to whether the proposed rule might significantly affect a function within the Commission's jurisdiction under sections 402 (a)(1), (b) and (c)(1) of the DOE Act. The Commission will have until December 31, 1979, the scheduled close of public comment period on the proposal, to make such determination.

(Emergency Petroleum Allocation Act of 1973, Pub. L. 93-159, as amended, Pub. L. 93-511, Pub. L. 94-99, Pub. L. 94-133, Pub. L. 94-163, and Pub. L. 94-385; Federal Energy Administration Act of 1974, Pub. L. 93-275, as amended, Pub. L. 94-332, Pub. L. 94-385, Pub. L. 95-70, and Pub. L. 95-91; Energy Policy and Conservation Act, Pub. L. 94-163 as amended, Pub. L. 94-385, and Pub. L. 95-70; Department of Energy Organization Act, Pub. L. 95-91; E.O. 12009, 42 FR 46267; Defense Production Act, Pub. L. 82-774, as amended; E.O. 10480 (18 FR 4939); E.O. 12038 (43 FR 4957); E.O. 11790 (39 FR 23785)).

In consideration of the foregoing, Chapter II, Title 10 of the Code of Federal Regulations, is proposed to be amended by adding a new Part 221 as set forth below.

Issued in Washington, D.C., on October 26, 1979.

David J. Bardin,

Administrator, Economic Regulatory Administration.

1. Subchapter A of Chapter II, Title 10 of the *Code of Federal Regulations* is amended to add a new Part 221 as follows:

PART 221—PRIORITY SUPPLY OF CRUDE OIL AND PETROLEUM PRODUCTS UNDER THE DEFENSE PRODUCTION ACT

Subpart A—General

Sec.
221.1 Scope.
221.2 Applicability.

Subpart B—Exclusions

221.11 Natural gas and ethane.

Subpart C—Definitions

221.21 Definitions.

Subpart D—Administrative Procedures and Sanctions

221.31 Requests by DOD.
221.32 Evaluation of DOD request.
221.33 Order.
221.34 Effect of order.
221.35 Contractual requirements.
221.36 Records and reports.
221.37 Violations and sanctions.

Authority.—Defense Production Act, 50 U.S.C. App. 2061 *et seq.*, E.O. 10480 (18 F.R. 4939, Aug. 18, 1953) as amended by E.O. 12038 (43 FR 4957, Feb. 7, 1978), and E.O. 11790 (39 FR 23785, June 27, 1974)

Subpart A—General

§ 221.1 Scope.

This Part sets forth the procedures to be utilized by the Economic Regulatory Administration of the Department of Energy and the Department of Defense whenever the priority supply of crude oil and petroleum products is necessary or appropriate to meet national defense needs. The procedures available in this Part are intended to supplement but not to supplant other regulations of the ERA regarding the allocation of crude oil,

residual fuel oil and refined petroleum products.

§ 221.2 Applicability.

This Part applies to the mandatory supply of crude oil, residual fuel oil, refined petroleum products (including liquefied petroleum gases) and lubricants to the Department of Defense for its own use or for purchases made by the Department of Defense on behalf of other Federal Government agencies.

Subpart B—Exclusions

§ 221.11 Natural gas and ethane.

The supply of natural gas and ethane are excluded from this Part.

Subpart C—Definitions

§ 221.21 Definitions.

For purposes of this Part—

"Directive" means an official action taken by ERA which requires a named person to take an action in accordance with its provisions.

"DOD" means the Department of Defense, including Military Departments and Defense Agencies, acting through either the Secretary of Defense or the designee of the Secretary.

"ERA" means the Economic Regulatory Administration of the Department of Energy.

"National defense" means programs for military and atomic energy production or construction, military assistance to any foreign nation, stockpiling and space, or activities directly related to any of the above.

"Person" means any individual, corporation, partnership, association or any other organized group of persons, and includes any agency of the United States Government or any other government.

"Priority-rated supply order" means any delivery order for crude oil or petroleum products issued by DOD bearing a priority rating issued by ERA under this Part.

"Supplier" means any person other than the DOD which supplies, sells, transfers, or otherwise furnishes (as by consignment) crude oil or petroleum product to any other person.

Subpart D—Administrative Procedures and Sanctions

§ 221.31 Requests by DOD.

(a) When DOD finds that (1) a fuel supply shortage for DOD exists or is anticipated which would have a substantial negative impact on the national defense, and (2) the defense activity for which fuel is required cannot be postponed until after the fuel supply shortage is likely to terminate, DOD may submit a written request to ERA for the issuance to it of a priority rating for the supply of crude oil and petroleum products.

(b) Not later than the transmittal date of its request to ERA, DOD shall notify the Federal Emergency Management Agency that it has requested a priority rating from ERA.

(c) Requests from DOD shall set forth the following: (1) the quantity and quality of crude oil or petroleum products determined by DOD to be required to meet national defense requirements; (2) the required delivery dates; (3) the defense-related activity and the supply location for which the crude oil or petroleum product is to be delivered; (4) the current or most recent suppliers of the crude oil or petroleum product and the reasons, if known, why the suppliers will not supply the requested crude oil or petroleum product; (5) the degree to which it is feasible for DOD to use an alternate product in lieu of that requested and, if such an alternative product can be used, the efforts which have been made to obtain the alternate product; (6) the period during which the shortage of crude oil or petroleum products is expected to exist; (7) the proposed supply source for the additional crude oil or petroleum products required, which shall, if practicable, be the historical supplier of such crude oil or product to DOD; and (8) certification that DOD has made each of the findings required by paragraph (a) of this section.

§ 221.32 Evaluation of DOD request.

(a) Upon receipt of a request from DOD for a priority rating as provided in § 221.31, it shall be reviewed promptly by ERA. The ERA will assess the request in terms of (1) the information provided under § 221.31; (2) whether DOD's national defense needs for crude oil or petroleum products can reasonably be satisfied without exercising the authority specified in this Part; (3) the capability of the proposed supplier to supply the crude oil or petroleum product in the amounts required; (4) the known capabilities of alternative suppliers; (5) the feasibility to DOD of converting to and using a product other than that requested; and (6) any other relevant information.

(b) The ERA promptly shall notify the proposed supplier of DOD's request for a priority rating specified under this Part. The proposed supplier shall have a period specified in the notice, not to exceed fifteen (15) days from the date it is notified of DOD's request, to show cause in writing why it cannot supply the requested quantity and quality of crude oil or petroleum products. ERA shall consider this information in determining whether to issue the priority rating.

(c) If acceptance by a supplier of a rated order would create a conflict with another rated order of the supplier, it shall include all pertinent information regarding such conflict in its response to the show cause order provided for in paragraph (b) of this section, and ERA, in consultation with DOD and the Federal Emergency Management Agency shall determine the priorities for meeting all such requirements.

(d) ERA may waive some or all of the requirements of § 221.31 or this section where the Secretary of Defense or his designee certifies, and has so notified the Federal Emergency Management Agency, that a fuel shortage for DOD exists or is imminent and that compliance with such requirements would have a substantial negative impact on the national defense.

§ 221.33 Order.

(a) *Issuance*—If ERA determines that issuance of a priority rating for a crude oil or refined petroleum product is necessary to provide the crude oil or petroleum products needed to meet the national defense requirement established by DOD, it shall issue such a rating to DOD for delivery of specified qualities and quantities of the crude oil or refined petroleum products on or during specified delivery dates or periods. In accordance with the terms of the order, DOD may then place such priority rating on a supply order.

(b) *Compliance*—Each person who receives a priority-rated supply order pursuant to this Part shall supply the specified crude oil or petroleum products to DOD in accordance with the terms of that order.

(c) *ERA directives*—Notwithstanding any other provisions of this Part, where necessary or appropriate to promote the national defense ERA is authorized to issue a directive to a supplier of crude oil or petroleum product requiring delivery of specified qualities and quantities of such crude oil or petroleum products to DOD at or during specified delivery dates or periods.

(d) *Use of ratings by suppliers*—No supplier who receives a priority-rated supply order or directive issued under the authority of this section may use such priority order or directive in order to obtain materials necessary to meet its supply obligations thereunder.

§ 221.34 Effect of order.

Defense against claims for damages. No person shall be liable for damages or penalties for any act or failure to act resulting directly or indirectly from

compliance with any ERA authorized priority-rated supply order or ERA directive issued pursuant to this Part, notwithstanding that such priority-rated supply order or directive thereafter be declared by judicial or other competent authority to be invalid.

§ 221.35 Contractual requirements.

(a) No supplier may discriminate against an order or contract on which a priority rating has been placed under this Part by charging higher prices, by imposing terms and conditions for such orders or contracts different from other generally comparable orders or contracts, or by any other means.

(b) Contracts with priority ratings shall be subject to all applicable laws and regulations which govern the making of such contracts, including those specified in 10 CFR § 211.26(e).

§ 221.36 Records and reports.

(a) Each person receiving an order or directive under this Part shall keep for at least two years from the date of full compliance with such order or directive accurate and complete records of crude oil and petroleum product deliveries made in accordance with such order or directive.

(b) All records required to be maintained shall be made available upon request for inspection and audit by duly authorized representatives of the ERA.

§ 221.37 Violations and sanctions.

(a) Any practice that circumvents or contravenes the requirements of this Part or any order or directive issued under this Part is a violation of the regulations provided in this Part.

(b) Criminal Penalties. Any person who willfully performs any act prohibited, or willfully fails to perform any act required by this Part or any order or directive issued under this Part shall be subject to a fine of not more than $10,000 for each violation or imprisoned for not more than one year for each violation, or both.

(c) Whenever in the judgment of the Administrator of ERA any person has engaged or is about to engage in any acts or practices which constitute or will constitute a violation of any provision of these regulations, the Administrator may make application to the apropriate court for an order enjoining such acts or practices, or for an order enforcing compliance with such provision.

[FR Doc. 79-33900 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

FEDERAL TRADE COMMISSION

16 CFR Part 13

[Docket 7845]

Arthur Murray, Inc.; Show Cause Order With Analysis To Aid Public Comment; Correction

In FR Doc. 79-3410-01-DM, appearing at page 58747 in the issue of Thursday, October 11, 1979, the following changes should be made:

1. On page 58747, third column, ninth line, "of the public" should be changed to "of the purchasing public".
2. On page 58748, second column, under roman numeral IV, No. 2, fifth line, "respond" is changed to read "respondent".
3. On page 58749, first column, fourth line, "franchises" should be changed to read "franchisees".
4. On page 58749, first column, second complete paragraph, No. 2, "a right to a pro rata refund" should be changed to read "a right to a full refund".

BILLING CODE 1505-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 292

[Docket No. RM79-55]

Small Power Production and Cogeneration—Rates and Exemptions; Correction

October 30, 1979.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Erratum Notice.

SUMMARY: This notice contains a correction to § 292.108(b) of the Commission's proposed regulations in Docket No. RM79-55, (44 FR 61190, October 24, 1979).

FOR FURTHER INFORMATION CONTACT: Adam Wenner, Executive Assistant to the Associate General Counsel, Federal Energy Regulatory Commission, 825 North Capitol St., N.E., Washington, D.C. 20426, (202) 357-8171.

SUPPLEMENTARY INFORMATION: Note the following correction in the Commission's proposed rule, entitled "Small Power Production and Cogeneration—Rates and Exemptions," issued October 22, 1979 (44 FR 61190, October 24, 1979):

(1) At 44 FR 61204 in the second sentence paragraph (b) of § 292.108, "Costs of Interconnection," insert after "to" and before "those" the following: "the difference between the interconnection costs and".

The corrected sentence should read, "These costs are limited to the difference between the interconnection costs and those costs which the purchasing utility would incur if it did not make such purchases but instead generated an equivalent amount of energy itself or purchased an equivalent amount of electric energy from other sources."

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-34044 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL 1350-7]

Approval and Promulgation of Implementation Plans—Ohio; Receipt

AGENCY: U.S. Environmental Protection Agency.

ACTION: Notice of Receipt and Availability.

SUMMARY: This notice is to announce receipt and availability for public review of proposed revisions to specific portions of the State Implementation Plan (SIP) for Ohio.

Under the requirements of Part D of the Clean Air Act, the State of Ohio on July 27, 1979, submitted to the U.S. Environmental Protection Agency (USEPA) proposed revisions to its SIP. These proposed revisions are designed to implement new measures for decreasing the ambient concentrations of carbon monoxide (CO) and ozone (03) in the areas designated as not attaining the National Ambient Air Quality Standards (NAAQS) for these pollutants. The October 5, 1978 Federal Register (43 FR 46015) contains a listing of areas in Ohio not meeting National Ambient Air Quality Standards for CO and ozone.

A Notice of Proposed Rulemaking describing the proposed revisions and USEPA's intended rulemaking action will be published in the Federal Register at a later date.

DATES: See Supplementary Information.

ADDRESSES: The submittal may be examined during normal business hours at the following USEPA offices:

Public Information Reference Unit, Library Systems Branch, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, D.C. 20460.

U.S. Environmental Protection Agency, Region V, Air Programs Branch, 230 South Dearborn Street, Chicago, Illinois 60604.

In addition the revisions may be examined at the offices of the:

Ohio Environmental Protection Agency, 361 West Broad Street, Columbus, Ohio 43215.

WRITTEN COMMENTS SHOULD BE SENT TO: Ms. Maxine Borcherding, State Implementation Plan Coordinator, Region V, Air Programs Branch, U.S. Environmental Protection Agency, 230 South Dearborn Street, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Ms. Maxine Borcherding, State Implementation Plan Coordinator, U.S. Environmental Protection Agency, Region V, Air Programs Branch, 230 South Dearborn Street, Chicago, Illinois 60604, (312) 886-6052.

SUPPLEMENTARY INFORMATION: USEPA is currently reviewing these proposed revisions to the Ohio SIP. At the completion of this review a notice will be published in the Federal Register proposing rulemaking action on these proposed revisions.

All interested persons are advised that the proposed revisions are available for review at the locations listed above. The proposed rulemaking notice referred to above will announce the last day for public comment. This public comment period will extend for not less than 30 days from the date of publication in the Federal Register of USEPA's proposed rulemaking action.

Dated: October 22, 1979.

John McGuire,

Regional Administrator.

[FR Doc. 79-34000 Filed 11-1-79; 8:45 am]

BILLING CODE 6560-01-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of the Secretary

41 CFR Parts 3-1 and 3-7

Procurement; Contract Clauses

AGENCY: Department of Health, Education, and Welfare.

ACTION: Proposed rule.

SUMMARY: It is the policy of the Department of Health, Education, and Welfare that all meetings, seminars, conferences, and other events sponsored or held by the Department will be accessible to persons with disabilities. As a result, the Office of the Secretary, Department of Health, Education, and Welfare is proposing to amend its procurement regulations to include procedures and a contract clause to assure minimum accessibility standards when the Department contracts for the provision of facilities, materials, accommodations, or other services in connection with a meeting, seminar, conference, or other event.

DATE: Comments must be received on or before December 17, 1979.

Any person or organization wishing to submit data, views, or comments pertaining to the proposed amendment may do so by filing them in duplicate with the individual at the address listed below.

ADDRESS: Send comments to Hal G. Hubachek, Division of Procurement Policy and Regulations Development, Office of Grants and Procurement, OASMB-OS, Room 539H, Hubert H. Humphrey Building, Department of Health, Education, and Welfare, Washington, D.C. 20201.

FOR FURTHER INFORMATION CONTACT: Hal G. Hubachek, Division of Procurement Policy and Regulations Development, Office of Grants and Procurement (202-245-6347).

Dated: October 23, 1979.

E. T. Rhodes,

Deputy Assistant Secretary for Grants and Procurement.

1. Under Subpart 3-1.3, General Policies, of Part 3-1, General, the following section is added, and the table of contents for Part 3-1 is amended to add the following:

* * * * *

Subpart 3-1.3—General Policies

* * * * *

Sec. 3-1.356 Accessibility of meetings, conferences, and seminars to persons with disabilities.

Subpart 3-1.3—General Policies

* * * * *

§ 3-1.356 Accessibility of meetings, conferences, and seminars to persons with disabilities.

(a) It is the policy of HEW that all meetings, seminars, conferences, and other events will be accessible to individuals with disabilities. For the purposes of this policy accessibility is defined as both physical access to meeting, conference, and seminar sites, and aids and services to enable individuals with sensory disabilities to fully participate in meetings, conferences, and seminars.

The policy is applicable to all procurements where the statement of work requires the contractor to conduct conferences, meetings, or seminars that are open to the public or involve HEW personnel, but not to ad hoc meetings that may be necessary or incidental to contract performance.

(b) The contracting officer shall be responsible for including the clause described in § 3-7.5026 in every solicitation and resulting contract when the statement of work requires the contractor to conduct meetings, conferences, or seminars.

(c) The project officer shall be responsible for obtaining, reviewing, and approving the contractor's plan, which is to be submitted in response to paragraph (a) of the clause described in § 3-7.5026. The project officer, prior to approving the plan, shall consult with the Office of Facilities Engineering, or the Office of Regional Operations for Facilities Engineering and Construction in the region where the meeting, conference, or seminar is to be held, to assure that the contractor's plan meets the accessibility requirements of the clause.

2. Under Subpart 3-7.50, Special Contract Clauses, of Part 3-7, Contract Clauses, the following section is added, and the table of contents for Part 3-7 is amended to add the following:

* * * * *

Subpart 3-7.50—Special Contract Clauses

* * * * *

Sec.

3-7.5026 Accessibility of meetings, conferences, and seminars to persons with disabilities.

Subpart 3-7.50—Special Contract Clauses

* * * * *

§ 3-7.5026 Accessibility of meetings, conferences, and seminars to persons with disabilities.

The following clause is to be used in accordance with § 3-1.356

Accessibility of Meetings, Conferences, and Seminars to Persons With Disabilities

The Contractor agrees as follows:

(a) *Planning.* The Contractor will develop a plan to assure that any meeting, conference, or seminar held pursuant to this contract will meet or exceed the minimum accessibility standards set forth below. This plan shall include a provision for ascertaining the number and types of disabled individuals planning to attend the meeting, conference, or seminar. This plan shall be submitted to the project officer for approval prior to initiating action.

(b) *Facilities.* Any facility to be utilized for meetings, conferences, or seminars in performance of this contract shall be accessible to persons with disabilities. The Contractor shall determine, by an on-site inspection if

necessary, that the following minimum accessibility requirements are met, or suitable modifications are made to meet these requirements, before the meeting:

(1) *Parking.* (i) Where parking is available on or adjacent to the site, one 12' wide space must be set aside for the car of each mobility impaired attendee. The space need not be permanently striped but may be temporarily marked by signs, ropes, or other means satisfactory to carry out this provision.

(ii) Where parking is not available on or adjacent to the site, valet parking or other alternative means to assist a person who has a mobility impairment may be used. Alternative means must be satisfactory in the judgment of the Government project officer.

(2) *Entrances.* (i) "Entrances" shall include at least one accessible entrance from street/sidewalk level, and at least one accessible entrance from any available parking facility.

(ii) The entrance shall be level or accessible by ramp with an incline that allows independent negotiation by a person in a wheelchair. In general, the slope of the incline shall be no more than 1" rise per foot of ramp length (1:12").

(iii) Entrance doorways (jamb to jamb) shall be at least 32" in width and capable of operation by persons with disabilities. Revolving doors, regardless of foldback capability, will not meet this requirement.

(3) *Meeting Rooms.* (i) Meeting room access from the main entrance area must be level or at an independently negotiable incline (approximately 1:12") and/or served by elevators from the main entrance level. All elevators shall be capable of accommodating a wheelchair 29" wide by 45" long.

(ii) Meeting rooms shall be on one level or, if on different levels, capable of being reached by elevators or by ramps that can be independently negotiated by a person in a wheelchair. Doorways (jamb to jamb) to all meeting rooms shall be at least 32" in width.

(iii) The interior of the meeting room shall be on one level or ramped so as to be independently negotiable for a person in a wheelchair.

(iv) Stages, speaker platforms, etc. which are to be used by persons in wheelchairs must be accessible by ramps or lifts. When used, the ramps may not necessarily be independently negotiable if space does not permit. However, any slope over 1:12" must be approved by the project officer. Each case is to be judged on its own merit.

(v) If a meeting room with fixed seating is utilized, seating arrangements for persons in wheelchairs shall be made so that these persons are accommodated into the group rather than isolated on the perimeter of the group.

(4) *Restrooms.* (i) Restrooms shall have level access, signs indicating accessibility, and doorways (jamb to jamb) at least 32" wide.

(ii) Sufficient turning space within restrooms shall be provided for independent use by a person in a wheelchair 29" wide by 45" long. A space 60" by 60" or 63" by 56" is acceptable by standard; other layouts will be accepted if it can be demonstrated that they are usable as indicated.

(iii) There will be a restroom for each sex with at least one toilet stall capable of accommodating a wheelchair 29" wide by 45" long (by standard, the minimum is 3'-0" by 4'-8") with outswinging doors or privacy curtains. Wall mounted or free standing grab bars are required.

(iv) When separate restrooms have been set up for mobility impaired persons, they shall be located adjacent to the regular restrooms and shall be fully accessible.

(5) *Eating Facilities.* (i) Eating facilities in the meeting facility must be accessible under the same general guidelines as are applied to meeting rooms.

(ii) If the eating facility is a cafeteria, the food service area (cafeteria line) must allow sufficient room for independent wheelchair movement and accessibility to food for persons in wheelchairs.

(6) *Overnight Facilities.* If overnight accommodations are required:

(i) Sufficient accessible guest rooms to accommodate each attendee who is disabled shall be located in the facility where the meeting, conference, or seminar is held, or in a facility housing the other attendees which is conveniently located nearby, whichever is satisfactory to the project officer.

(ii) Overnight facilities shall provide for the same minimum accessibility requirements as the facility utilized for the meeting, conference, or seminar. In addition, guest room access from the main entrance area shall be level, ramped at an independently negotiable incline (1:12"), and/or served by elevators capable of accommodating a wheelchair 29" wide by 45" long.

(iii) Doorways (jamb to jamb) to guest rooms, including the doorway to the bathroom, shall be at least 32" wide.

(iv) Bathrooms shall have wall mounted or free standing grab bars at the tub and water closet.

(v) Guest rooms for persons with a disability shall be provided at the same rate as a guest room for other attendees.

(c) *Provision of Services for Sensory Impaired Attendees.* (1) The Contractor, in planning the meeting, shall prepare an announcement(s) and other material(s) indicating that services will be made available to sensory impaired persons attending the meeting, if requested within three (3) days of the date of the meeting, conference, or seminar. The announcement(s) and other material(s) shall indicate that sensory impaired persons may contact a specific person(s), at a specific address and phone number(s) to make their service requirements known. Phone number(s) shall include a teletype number for the hearing impaired.

(2) The Contractor shall provide, at no cost to the individual, those services required by persons with sensory impairments to assure their complete participation in the meeting, conference, or seminar.

(3) As a minimum, when requested in advance, the Contractor shall provide the following services:

(i) For hearing impaired persons, note takers or trained interpreters. Provisions will also be made for volume controlled phone lines and, if necessary, transportation to teletype equipment to enable hearing impaired individuals to receive and send meeting related calls. Also, the meeting rooms will be adequately lighted for signing by interpreters to be easily seen.

(ii) For vision impaired persons, readers and/or cassette materials, as necessary, to enable full participation. Also, meeting rooms will be adequately lighted.

(iii) Agenda and other conference material translated into a usable form for visually and hearing impaired individuals. This will be available to them upon arrival.

(4) The Contractor is responsible for making every effort to ascertain the number of sensory impaired individuals who plan to attend the meeting, conference, or seminar. However, if it can be determined that there will be no sensory impaired persons (deaf and/or blind) in attendance, the provision of those services under paragraph (c) for the nonrepresentative group, or groups, is not required.

[FR Doc. 79-33930 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-12-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

Federal Insurance Administration

44 CFR Part 67

[Docket No. FI-5460]

Proposed Flood Elevation Determinations for the Village of Louisville, Cass County, Nebr.; Under the National Flood Insurance Program; correction

AGENCY: Federal Insurance Administration, FEMA.

ACTION: Correction of proposed rule.

SUMMARY: This document corrects a proposed rule on base (100-year) flood elevations that appeared on page 44 FR 27179 of the Federal Register of May 9, 1979.

EFFFECTIVE DATE: May 9, 1979.

FOR FURTHER INFORMATION CONTACT: Mr. R. Gregg Chappell, National Flood Insurance Program, Room 5150, 451 Seventh Street, SW., Washington, D.C. 20410, 202-426-1460 or Toll Free Line 800-424-8872.

The following:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Mill Creek	0.04 mile downstream of Second Street.	1,035
	1.27 mile upstream of Sixth Street.	1,066
	1.36 mile upstream of Sixth Street.	1,069
Tributary to Mill Creek	0.296 mile upstream from Elm Street.	1,083
	0.418 mile upstream from Elm Street.	1,093

Should Be Corrected To Read:

Mill Creek	0.04 mile downstream of Second Street.	1,036
	1.09 mile upstream of Sixth Street.	1,066
	1.38 mile upstream of Sixth Street.	1,069
Tributary to Mill Creek	0.305 mile upstream from Elm Street.	1,083
	0.425 mile upstream from Elm Street.	1,093

(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); Executive Order 12127, 44 FR 19367; and delegation of authority to Federal Insurance Administrator, 44 FR 20963)

Issued: September 7, 1979.

Gloria M. Jimenez,

Federal Insurance Administrator.

[FR Doc. 79-33970 Filed 11-1-79; 8:45 am]

BILLING CODE 6718-03-M

44 CFR Part 67

[Docket No. FI-5313]

Revision of Proposed Flood Elevation Determinations for the Town of Derry, Rockingham County, N.H.; Under the National Flood Insurance Program

AGENCY: Federal Insurance Administration, FEMA.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are solicited on the proposed base (100-year) flood elevations listed below for selected locations in the Town of Derry, Rockingham County, New Hampshire.

Due to recent engineering analysis, this proposed rule revises the proposed determinations of base (100-year) flood elevations published in 44 FR 20213 on April 4, 1979, and in the *Derry News*, published on or about April 5, 1979, and April 12, 1979, and hence supersedes those previously published rules.

DATES: The period for comment will be ninety (90) days following the second publication of this notice in a newspaper of local circulation in the above-named community.

ADDRESSES: Maps and other information showing the detailed outlines of the flood-prone areas and the proposed flood elevations are available for review at Office of the Building Inspector, Town Offices, 48 East Broadway, Derry, New Hampshire.

Send comments to: Mr. Donald Bentley, Chairman, Board of Selectmen, Town of Derry, Town Offices, 48 East Broadway, Derry, New Hampshire 03038.

FOR FURTHER INFORMATION CONTACT: Mr. R. Gregg Chappell, National Flood Insurance Program, 202-755-5581 or Toll Free Line (800) 424-8872, Room 5148, 451 Seventh Street, SW., Washington, D.C. 20410.

SUPPLEMENTARY INFORMATION: Proposed base (100-year) flood elevations are listed below for selected locations in the Town of Derry, New Hampshire, 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 44 CFR 67.4(a)).

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).

These modified elevations will also be used to calculate the appropriate flood insurance premium rates for new buildings and their contents and for the second layer of insurance on existing buildings and their contents.

The proposed base (100-year) flood elevations are:

Source of flooding	Location	#Depth in feet, above ground, *elevation in feet (NGVD)
Beaver Brook	Interstate Highway 93 75 feet upstream from centerline.	*236
	Boston and Maine Railroad 50 feet upstream from centerline.	*244
	East Derry Road 50 feet upstream from centerline.	*251
	Lower Beaver Lake Dam 100 feet downstream from centerline.	*285
Shields Brook	Boston and Maine Railroad (First crossing) 50 feet upstream from centerline.	*264
	Folsom Road 40 feet upstream from centerline.	*276
	Boston and Maine Railroad (second crossing) 75 feet upstream from centerline.	*291
	Street A 50 feet upstream from centerline.	*307
	Brewster Road 10 feet upstream from centerline.	*352
	Scobie Pond Road 50 feet upstream from centerline.	*359
	Londonderry Turnpike 75 feet upstream from centerline.	*379
Hornes Brook	Florence Street 10 feet upstream from centerline.	*241
	West Broadway 20 feet upstream from centerline.	*247
	Maple Street 10 feet upstream from centerline.	*253
Tributary O	Unnamed Road 10 feet upstream from centerline.	*239
Tributary E	Chester Road 10 feet upstream from centerline.	*293
	Tsienneto Road 10 feet upstream from centerline.	*294
Tributary F	Beaver Lake Road 20 feet upstream from centerline.	*296
	Back Chester Road 20 feet upstream from centerline.	*32
Tributary G	Rockingham Road 25 feet upstream from centerline.	*265
	Sunset Avenue (second crossing) 25 feet upstream from centerline.	*280
	Windham Road (second crossing) 60 feet downstream from centerline.	*302
	Windham Road (second crossing) 10 feet upstream from centerline.	*314
Drew Brook	Collets Grove Road (First crossing) 50 feet upstream from centerline.	*208
	Drew Road 75 feet upstream from centerline.	*211
Taylor Brook (including Ballard Pond).	North Shore Road 20 feet upstream from centerline.	*214
	Island Pond Road (first crossing) 50 feet upstream from centerline.	*222
	Lower Ballard Pond Dam 20 feet downstream from centerline.	*242
	Lower Ballard Pond Dam 10 feet upstream from centerline.	*255
	Upper Ballard Pond Dam 10 feet upstream from centerline.	*258

Source of flooding	Location	#Depth in feet, above ground, *elevation in feet (NGVD)
	Island Pond Road (third crossing) 20 feet upstream from centerline.	*263
Tributary H	Abandoned Railroad Bed 50 feet upstream from centerline.	*224
	Hampstead Road 40 feet upstream from centerline.	*266
Cunningham Brook	Abandoned Railroad Bed 25 feet upstream from centerline.	*219
	Hampstead Road 25 feet downstream from centerline.	*296
	Hampstead Road 20 feet upstream from centerline.	*300
Adams Pond	Adams Pond Dam upstream face.	*327
Beaver Lake	300 feet northwest of intersection of Beaver Lake Avenue and Pond Road.	*290
Lower Beaver Lake	Lower Beaver Lake Dam upstream face.	*289
Island Pond	300 feet northeast of intersection of Stickney Road and Escumbuit Avenue.	*207

(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); Executive Order 12127, 44 FR 19367; and delegation of authority to Federal Insurance Administrator, 44 FR 20963)

Issued: September 14, 1979.

Gloria M. Jimenez,

Federal Insurance Administrator.

[FR Doc. 79-33971 Filed 11-1-79; 8:45 am]

BILLING CODE 6718-03-M

44 CFR Part 67

[Docket No. FI-5603]

National Flood Insurance Program; Proposed Flood Elevation Determinations; correction

AGENCY: Federal Insurance Administration, FEMA.

ACTION: Correction to propose rule for the Borough of Tremont, Schuylkill County, Pennsylvania.

SUMMARY: The notice published on June 28, 1979, at 44 FR 37640 in the Federal Register duplicating the location of "North Pine Street—Upstream" under Good Spring Creek was a clerical error. It should be listed a single time with a corresponding elevation of 778 feet.

FOR FURTHER INFORMATION CONTACT: Mr. Robert G. Chappell, National Flood Insurance Program, (202) 426–1460 or Toll Free Line (800) 424–8872, (In Alaska and Hawaii call Toll Free Line (800) 424–9080), Room 5150, 451 Seventh Street SW., Washington, D.C. 20410.

(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); Executive Order 12127, 44 FR 19367; and delegation of authority to Federal Insurance Administrator, 44 FR 20963)

Issued: October 4, 1979.

Gloria M. Jimenez,

Federal Insurance Administrator.

[FR Doc. 79-33972 Filed 11-1-79; 8:45 am]

BILLING CODE 6718-03-M

44 CFR Part 67

[Docket No. FI-2885]

Proposed Flood Elevation Determinations for Town of Lyndon, Caledonia County, Vt., Under the National Flood Insurance Program; Correction

AGENCY: Federal Insurance Administration, FEMA.

ACTION: Correction of proposed rule.

SUMMARY: This document corrects a proposed rule on base (100-year) flood elevations that appeared on page 25441 of the Federal Register of May 17, 1977.

EFFECTIVE DATE: May 17, 1977.

FOR FURTHER INFORMATION CONTACT: Mr. R. Gregg Chappell, National Flood Insurance Program, (202) 426–1460 or Toll Free Line (800) 424–8872, Room 5148, 451 Seventh Street SW., Washington, D.C. 20410.

The following corrections are made:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Passumpsic River	Canada Pacific Railroad Bridge.	689
	U.S. Route 5—75 feet upstream from centerline.	707
	Center Street	708
	U.S. Route 5—100 feet downstream from centerline.	709
	Vermont Route 114—100 feet downstream from centerline.	711
	Canada Pacific Railroad Bridge.	716
	Vermont Route 114—25 feet downstream from centerline.	717
	Town Highway 36	718
	Town Highway 40	741
	Vermont Route 114	752
Calendar Brook	U.S. Route 4—475 feet upstream from centerline.	735
Hawkins Brook	Town Highway 69—275 feet upstream from centerline.	687
	Town Highway 6—100 feet downstream from centerline.	706
Millers Run	Interstate Highway 91	714
	Town Highway 31	718
Wheelock Branch Brook.	Town Highway 1	708
	Cross Street—150 feet upstream from centerline.	709

(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); Executive Order 12127, 44 FR 19367; and delegation of authority to Federal Insurance Administrator, 44 FR 20963)

Issued: August 29, 1979.

Gloria M. Jimenez,

Federal Insurance Administrator.

[FR Doc. 79-33973 Filed 11-1-79; 8:45 am]

BILLING CODE 6718-03-M

44 CFR Part 67

[Docket No. FI-4613]

Revision of Proposed Flood Elevation Determinations for the Town of Rumford, Oxford County, Maine; Under the National Flood Insurance Program

AGENCY: Federal Insurance Administration, FIA.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are solicited on the proposed base (100-year) flood elevations listed below for selected locations in the Town of Rumford, Oxford County, Maine.

Due to recent engineering analysis, this proposed rule revises the proposed determinations of base (100-year) flood elevations published in 43 FR 47209 on November 13, 1978, and in the *Lewiston Daily-Sun*, published on or about October 5, 1978, and October 6, 1978, and hence supersedes those previously published rules.

DATES: The period for comment will be ninety (90) days following the second publication of this notice in a newspaper of local circulation in the above-named community.

ADDRESSES: Maps and other information showing the detailed outlines of the flood-prone areas and the proposed flood elevations are available for review at Town Office, Rumford, Maine.

Send comments to: Mr. Howard White, Chairman, Board of Selectmen, Town of Rumford, Town Office, Rumford, Maine 04276.

FOR FURTHER INFORMATION CONTACT: Mr. R. Gregg Chappell, National Flood Insurance Program, (202) 755–5581 or Toll Free Line (800) 424–8872, Room 5148, 451 Seventh Street SW., Washington, D.C. 20410.

SUPPLEMENTARY INFORMATION: Proposed base (100-year) flood elevations are listed below for selected locations in the Town of Rumford, Maine, 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 44 CFR 67.4(a)).

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).

These modified elevations will also be used to calculate the appropriate flood insurance premium rates for new buildings and their contents and for the second layer of insurance on existing buildings and their contents.

The proposed base (100-year) flood elevations are:

Source of flooding	Location	Elevation in feet, national geodetic vertical datum
Androscoggin River	Ridlonville Bridge—100 feet upstream from centerline.	*436
	Rumford Avenue footbridge—50 feet upstream from centerline.	*441
	Chisholm Bridge—40 feet upstream from centerline.	*460
	Morse Bridge—20 feet upstream from centerline.	*495
	High Bridge—50 feet upstream from centerline.	*612
	Martin Bridge—20 feet upstream from centerline.	*626
Swift River	Red Bridge—20 feet upstream from centerline.	*441
	Confluence with Scotty Brook.	*452

(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; Executive Order 12127, 44 FR 19367; and delegation of authority to Federal Insurance Administrator, 44 FR 20963)

Issued: August 29, 1979.

Gloria M. Jimenez,

Federal Insurance Administrator.

[FR Doc. 79-33967 Filed 11-1-79; 8:45 am]

BILLING CODE 6718-03-M

44 CFR Part 67

[Docket No. FI-5545]

Revision of Proposed Flood Elevation Determinations for the Unincorporated Areas of Johnson County, Kans.; Under the National Flood Insurance Program

AGENCY: Federal Insurance Administration, FEMA.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are solicited on the proposed base (100-year) flood elevations listed below for selected locations in the Unincorporated Areas of Johnson County, Kansas.

Due to recent engineering analysis, this proposed rule revises the proposed determinations of base (100-year) flood elevations published in 44 FR 34159 on June 14, 1979, and in the *Olathe Daily News* published on or about June 20, 1979, and June 27, 1979, and hence supersedes those previously published rules.

DATES: The period for comment will be ninety (90) days following the second publication of this notice in a newspaper of local circulation in the above named community.

ADDRESSES: Maps and other information showing the detailed outlines of the flood-prone areas and the proposed flood base (100 year) elevations are available for review at the County Court House, Olathe, Kansas. Send comments to: Mr. John J. Frankie, Chairman, County Commissioners, Johnson County, County Court House, Olathe, Kansas 66061.

FOR FURTHER INFORMATION CONTACT: Mr. R. Gregg Chappell, National Flood Insurance Program, (202) 426–1460 or Toll Free Line (800) 424–8872 (in Alaska and Hawaii call Toll Free Line (800) 424–9080), Room 5150, 451 Seventh Street SW., Washington, D.C. 20410.

SUPPLEMENTARY INFORMATION: Proposed base (100-year) flood elevations are listed below for selected locations in the Unincorporated Areas of Johnson County, Kansas, 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 44 CFR 67.4(a)).

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).

These modified elevations will also be used to calculate the appropriate flood insurance premium rates for new buildings and their contents and for the second layer of insurance on existing buildings and their contents.

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

Source of flooding	Location	Elevations in feet, national geodetic vertical datum
Kansas River	Downstream county boundary.	766
	About 0.5 mile downstream of the Atchison, Topeka & Santa Fe Railway.	772
	About 0.9 mile upstream of the Atchison, Topeka & Santa Fe Railway.	778
	Just downstream of Wyandotte Street bridge.	790
	About 3.0 miles upstream of Wyandotte Street bridge.	795
	Upstream county boundary	798
Kill Creek	Just upstream of Old State Highway 10.	790
	At City of DeSoto southern corporate limits.	792
Blue River	About 1.3 miles downstream of Kenneth Road.	867
	Just upstream of Kenneth Road.	874
	About 1.9 miles upstream of Kenneth Road.	881
	Just upstream of Missouri Pacific Railroad.	886
	Just downstream of Metcalf Avenue.	897
	Just downstream of U.S. Highway 69.	901
Martin Creek	At confluence of Santa Fe Lake Tributary.	959
	Just upstream of U.S. Highway 56.	966
	About 1,100 feet upstream of Edgerton North Road.	987

(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; Executive Order 12127, 44 FR 19367; and delegation of authority to Federal Insurance Administrator, 44 FR 20963)

Issued: September 14, 1979.

Gloria M. Jimenez,

Federal Insurance Administrator.

[FR Doc. 79-33966 Filed 11-1-79; 8:45 am]

BILLING CODE 6718-03-M

44 CFR Part 67

[Docket No. FI-5387]

Proposed Flood Elevation Determinations for the Town of Watertown, Middlesex County, Mass., Under the National Flood Insurance Program; Correction

AGENCY: Federal Insurance Administration, FEMA.

ACTION: Correction of proposed rule.

SUMMARY: This document corrects a proposed rule on base (100-year) flood elevations that appeared on page 44 FR 25880 of the Federal Register of May 3, 1979.

EFFECTIVE DATE: May 3, 1979.

FOR FURTHER INFORMATION CONTACT: Mr. R. Gregg Chappell, National Flood Insurance Program, (202) 426–1460 or Toll Free Line 800–424–8872, Room 5150,

451 Seventh Street, SW., Washington, D.C. 20410.

The following:

Source of flooding	Location	Elevation in feet (national geodetic vertical datum)
Charles River	0.30 miles downstream of Bridge Street.	16

Should be corrected to read:

Charles River	0.2 mile downstream of Bridge Street.	16

(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); Executive Order 12127, 44 FR 19367; and delegation of authority to Federal Insurance Administrator, 44 FR 20963)

Issued: September 4, 1979.

Gloria M. Jimenez,

Federal Insurance Administrator.

[FR Doc. 79-33968 Filed 11-1-79; 8:45 am]

BILLING CODE 6718-03-M

44 CFR Part 67

[Docket No. FI-5104]

Proposed Flood Elevation Determinations for Annexed Areas in the City of Glendive, Dawson County, Montana, Under the National Flood Insurance Program

AGENCY: Federal Insurance Administration, FEMA.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are solicited on the proposed base (100-year) flood elevations listed below for selected locations in the annexed areas of the City of Glendive, Dawson County, Montana.

Due to recent annexations, this proposed rule augments the proposed determinations of base (100-year) flood elevations published in 44 FR 7162 on Tuesday, February 6, 1979, and in *The Ranger Review* on or about February 1, 1979, February 8, 1979, and on July 19, 1979, and hence adds to those previously published rules.

DATES: The period for comment will be ninety (90) days following the second publication of this notice in a newspaper of local circulation in the above-named community.

ADDRESSES: Maps and other information showing the detailed outlines of the flood-prone areas and the proposed flood elevations for the entire community including the annexed areas are available for review at the City Hall, 300 South Merill, Glendive, Montana.

Send comments to: Mayor L. C. Allen, City of Glendive, City Hall, Box 780, Glendive, Montana 59330.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Krimm, National Flood Insurance Program, (202) 755–5581 or Toll Free Line (800) 424–8872, Room 5270, 451 Seventh Street, S.W., Washington, D.C. 20410.

SUPPLEMENTARY INFORMATION: Proposed base (100-year) flood elevations are listed below for selected locations in the annexed areas of the City of Glendive, Montana, 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 44 CFR 67.4(a)).

These base (100-year) flood elevations in addition to those published previously 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).

These additional elevations will also be used to calculate the appropriate flood insurance premium rates for new building and their contents and for the second layer of insurance on existing buildings and their contents.

The additional proposed base (100-year) flood elevations are:

Source of flooding	Location	Eelvation in feet, national geodetic vertical datum
Yellowstone River	The corner of the corporate limits formed by the low water mark of the Yellowstone River and the North section line of Section 24, T16N, R55E (Approximately 800 feet west of the north end of the County Fairgrounds).	2060
	Approximately 3000 feet west along Bell Street from its intersection with Clough Street, then 1000 feet southwest along an unnamed road.	2068

(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); Executive Order 12127, 44 FR 19367; and delegation of authority to Federal Insurance Administrator, 44 FR 20963)

Issued: August 24, 1979.

Gloria M. Jimenez,

Federal Insurance Administrator.

[FR Doc. 79-33969 Filed 11-1-79; 8:45 am]

BILLING CODE 6718-03-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Social Security Administration

45 CFR Part 405

Aid to Families With Dependent Children; Calculating Reduction in Federal Financial Participation for Incorrect Payment by States After September 1980

Corrections

In FR Doc. 79.29693 appearing at page 55318 in the issue for Tuesday, September 25, 1979; make the following corrections:

1. On page 55318, third column, in the second line of the section heading for § 205.42, insert "("before" FFP)".

2. On page 55319, second column, sixth line of paragraph (f), the word "to" after "State" should read "for" and in the twelfth line of that same paragraph, the word "taget" should read "target"; and in the fourth full paragraph beginning with the word "Therefore", in the third line of that paragraph, insert the following after "4 percent": "(0.4 times 10 percent, for the first 6-month period) plus 5.4 percent".

3. On page 55319, third column, fourth line from the bottom, the word "of" should read "to".

BILLING CODE 1505-01-M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

45 CFR Part 1152

Nondiscrimination on the Basis of Age; Extension of Comment Period

AGENCY: National Endowment for the Arts.

ACTION: Notice to extend comment period.

SUMMARY: The National Endowment for the Arts published proposed regulations under the Age Discrimination Act of 1975, 42 U.S.C. 6101 et seq. in the Federal Register, October 2, 1979, 44 FR 56725, (1979). The notice stated that comments regarding the proposed regulations were to be submitted to the agency on or before November 15, 1979. It has been brought to our attention that the comment period specified in the proposed regulations would not afford

the public at least 60 days to comment in accordance with Executive Order 12044. Consequently, the period for public comment has been extended to December 15, 1979. Comments regarding National Endowment for the Arts proposed Age Discrimination Act regulations, 44 FR 56725, (1979) are invited from other Federal agencies and the public.

DATE: Comments should be received on or before December 15, 1979.

ADDRESSES: Comments should be submitted in writing to Susan Liberman, Assistant to the General Counsel, National Endowment for the Arts, 2401 E Street NW, Washington, D.C. 20506.

FOR FURTHER INFORMATION CONTACT: Garrett M. Johnson, Office of the General Counsel, National Endowment for the Arts, 2401 E Street NW, Washington, D.C. 20506, 202/634-6588.

Dated: October 30, 1979.

Livingston L. Biddle, Jr.,

Chairman, National Endowment for the Arts.

[FR Doc. 79-33959 Filed 11-1-79; 8:45 am]

BILLING CODE 7537-01-M

INTERSTATE COMMERCE COMMISSION

49 CFR Part 1056

Transportation of Household Goods in Interstate and Foreign Commerce; Review of the Regulation of Carriers

AGENCY: Interstate Commerce Commission.

ACTION: Setting this matter for informal conferences.

SUMMARY: The Interstate Commerce Commission is responsible for supervising the operations of all household goods carriers engaged in interstate and foreign commerce to assure that consumers are being provided a reasonable and adequate service. To accomplish this regulatory responsibility, the Commission has adopted and published regulations which appear in 49 CFR 1056. A series of informal conferences is being conducted to provide a forum where representatives of the public and industry may review with the Commission's staff the application and responsiveness of the regulations and consider ways that the regulatory supervision may be made more effective. The first informal conference was held in Washington, D.C. on September 27, 1979. Additional conferences will be conducted on the following dates in the cities at the addresses listed.

The conferences will commence at 9:00 a.m. on each date listed.

DATES: The conferences will be held on November 13-14, 27-28, 1979, and December 11-12, 1979, and January 8-9 and 15-16, 1980.

ADDRESSES: The conferences will be held at the following locations:

November 13-14, 1979

6 World Trade Center, U.S. Custom House, Room 770, New York, NY 10048

November 27-28, 1979

Los Angeles County Courthouse, Courtroom 217, 111 North Hill Street, Los Angeles, CA 90012

December 11-12, 1979

Hillsborough County Board of Education Bldg., Main Floor Auditorium, 901 East Kennedy Blvd., Tampa, FL 33601

January 8-9, 1980

Everett McKinley Dirksen Federal Bldg., Room 204A, 219 South Dearborn Street, Chicago, IL 60604

January 15-16, 1980

Interstate Commerce Commission, Hearing Room C, 12th & Constitution Ave. NW., Washington, D.C. 20423

FOR FURTHER INFORMATION CONTACT: Joel E. Burns, Director, Bureau of Operations, Interstate Commerce Commission, Washington, D.C. 20423, (202) 275-7849.

SUPPLEMENTARY INFORMATION:

The regulation of the transportation of household goods is one of the major responsibilities of the Interstate Commerce Commission. Each year over a million shipments are transported by the household goods carriers operating under the regulatory supervision of the Commission. The responsiveness of the industry to the needs of shippers who must rely on the industry for safe, efficient transportation is a matter of continued concern to the Commission.

The regulations appearing in 49 CFR 1056 are intended to protect the interests of the shippers and to assure the availability of a reasonable and adequate service. Representatives of the industry frequently question the necessity and wisdom of various requirements of the regulations and generally maintain that absolute compliance presents an unnecessary regulatory burden. Consumer representatives just as frequently maintain that the regulations do not provide enough protection for individual consumers not familiar with transportation. In recognition of these differing opinions, the Commission's staff will meet with representatives of the industry and consumers in a series of informal conferences to review the present regulations and to consider alternative methods of assuring that the service being provided by the industry results in: (1) the consumer being informed with a reasonable degree of certainty of the probable costs of a move prior to the move; (2) the providing of a service on the dates or between the dates agreed to by the carrier and shipper; (3) the providing of the service at a fair and reasonable cost to the shipper; and, (4) the reasonable and timely handling and disposition of shipper claims for loss, damage or inconvenience.

Topics for discussion at each conference will include but not be limited to: (1) The need for household goods shippers to be given pre-move information about moving. (2) Identification of the problems confronting the industry in meeting reasonable dispatch obligations. How can reasonable dispatch performances be improved? (3)The development of an industry rate structure which would provide for the furnishing of different levels of service. Are full-service, standard and budget rates and levels of service feasible? (4) What can be done to improve the efficiency and reliability of shipment weighing? (5) Review of the shipping documents now in use in the industry. How can they be improved? Simplified? Eliminated? (6) The relationship between carriers and agents. How does this relationship impact on the providing of a reasonable and adequate service? (7) Procedures employed by the industry and the Commission to respond to shipper complaints. How can these procedures be made more efficient?

Dated: October 26, 1979.

By the Commission: Chairman O'Neal.

Agatha L. Mergenovich,

Secretary.

FR Doc. 79-33913 Filed 11-1-79; 8:45 am]

BILLING CODE 7035-01-M

49 CFR Part 1301

[Ex Parte No. 346 (Sub-No. 3)]

Rail General Exemption Authority; Long- and Short-Haul Transportation

AGENCY: Interstate Commerce Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Commission proposes, pursuant to 49 U.S.C. 10505, to exempt certain categories of rail rates from the long-and-short haul and aggregate-of-intermediate provisions of 49 U.S.C. 10726 [1]. The purpose of the proposal is to

[1] Formerly section 12(1)(b) and section 4 of the Interstate Commerce Act.

conserve both carrier and Commission resources by exempting rates that would otherwise qualify for relief from the prohibitions of section 10726 had an application for relief been filed with the Commission.

DATES: Interested persons may submit written comments on the proposed rules on or before January 2, 1980.

ADDRESS: An original and 10 copies, if possible, of any comments should be sent to: Room 5356, Interstate Commerce Commission, Washington, D.C. 20423.

FOR FURTHER INFORMATION CONTACT: Martin E. Foley, (202) 275-7348.

SUPPLEMENTARY INFORMATION: The provisions of 49 U.S.C. 10505 provide that the Commission may, after opportunity for a proceeding, grant an exemption for a person, class of person, or a transportation or service from all or any part of the IC Act in matters related to rail carriers. In order to grant such an exemption, the Commission must find that compliance with a provision of the Act: (1) is not necessary to carry out the transportation policy of section 10101; (2) would be an unreasonable burden on a person, class of person, or interstate or foreign commerce; and (3) would serve little or no useful public purpose.

We are therefore instituting this proceeding to determine whether or not certain categories of rail rates should be exempted from the long-and-short-haul and aggregate-of-intermediate provisions of 49 U.S.C. 10726.

Over the last two decades many innovations in rail transportation pricing have occurred due to changing transportation conditions. When shippers can generate sufficient volume of traffic, and when warranted, rail carriers have been receptive to the shipping community's needs by gearing their pricing system to reflect changing transportation conditions. This has resulted in the establishment of rates predicated on multiple-car shipments, unit train shipments, annual volume shipments and international rail/water shipments.[2] Economic conditions similar to those giving rise to these various types of volume-related rates are also likely to exist in the case of rail contract rates, which have recently been recognized by the Commission as offering significant potential transportation benefits.[3]

Generally, transportation conditions at intermediate points over the short tariff routes are rarely the same; that is to say traffic from or to less distant points is usually not sufficient to support a rate level that would be reasonably compensatory, and that would at the same time clear the long-and-short-haul prohibition of § 10726. Accordingly, the carriers must apply to the Commission for authority to depart from the long-and-short haul provisions in order to maintain rates on the kind of traffic here under consideration that are lower for the longer distance than rates for the shorter distance, even though like conditions may not prevail at higher-rated intermediate points. See *Coal from Illinois, Indiana, and Kentucky to Illinois and Indiana*, 308 I.C.C. 673.

For the most part these applications are not contested and for the most part, they are routinely granted. Obviously, this places a needless and wasteful financial burden upon the carriers, and taxes Commission resources which would be better utilized in more critical areas of responsibility.

The same may be said of the aggregate-of-intermediate provisions of section 10726. During the past several years the Commission received only a very limited number of applications for relief from those provisions. All involved single-car rates and all were granted without protest. No applications were received that requested relief for rates under consideration here.[4] As a matter of fact, the chances of such violations occurring are remote, if not nonexistent, since like traffic, insofar as the rates here under consideration, is not involved. Cf. *Carnation Company* v. *Southern Pacific Company*, et al., 269 I.C.C. 470.

In general increase proceedings the railroads routinely request relief from § 10726. Shippers in recent years have not indicated any significant opposition to the granting of the requested relief. Technical departures from § 10726 result from general increases because of variations in the increases proposed in different rate territories and differences in the percentage increases taken by individual lines with respect to specific commodities. Relief from section 10726 has been granted by the Commission in conjunction with all authorized general increases. Cf. Ex Parte No. 123, *In the Matter of Increases in Rates, Fares, and Charges*, 226 I.C.C. 41, 139-140.

The Railroad Revitalization and Regulatory Reform Act of 1976 (Public Law No. 94-210) and the Commission's regulations provide for the filing of special categories of rates, such as demand sensitive rates (49 CFR 1109.10), separate rates for distinct rail service (49 CFR 1109.15), and incentive rates for capital investment (49 CFR 1109.20). While the Commission has not experienced any substantial activity in these areas of rate filings, they appear to be the kind that are likely candidates for exemption under § 10505 since conditions at potentially higher rated intermediate points would not appear to be the same, and as such would not warrant the filing of applications on a case-by-case basis. The same would appear to be true with respect to the aggregate-of-intermediate provisions of section 10726 since these kinds of rates are specially designed for a specific purpose, hence they should not be used in combination with other rates to construct an aggregate-of-intermediate rates that would normally defeat the through single-factor rate.

As matters now stand carriers who want a rate exempted have the burden of making a "special case" under the provisions of section 10726 by filing an application for relief, subject to protest and the possibility that the Commission will withold relief pending an investigation. See *Intermountain Rate Cases*, 234 U.S.C. 476, 485-86. If the procedure proposed in this notice is adopted, shippers or other interested parties would no longer have the right to protest exemptions of the rate; however, they would still be able to file a verified complaint (49 CFR 1100.40) requesting the suspension and/or investigation of any rate proposed under the exemption. To insure that shippers and other interested parties are made aware of their right, we propose to require that all rates proposed under the exemption bear a notation that shippers or other interested parties may exercise their right to file a verified complaint under 49 CFR 1100.40.

In this proceeding the Commission is specifically considering exempting the following categories of rates and charges from the provisions of section 10726:

Multiple car
Unit train
Annual volume
International rail/water shipments
Contract rates
Rail general increase
Demand Sensitive rates

[2] International rail/water rates are commonly referred to as mini-bridge or micro-bridge traffic, which differs substantially from domestic TOFC and COFC traffic because of sheer volume and lower transportation cost as a result of less handling. See Ex Parte No. 261, *In the Matter of Tariffs Containing Joint Rates and Through Routes for the Transportation of Property Between Points in the United States and Points in Foreign Countries*. 337 I.C.C. 625, et seq.

[3] See Ex Parte No. 358-F, *Change of Policy, Railroad Contract Rates*; 361 I.C.C. 205, and Ex Parte No. 364—Notice of Proposed Change in Policy, Railroad—*Freight Forwarder Contract Rates* (44 FR 33714 June 12, 1979).

[4] Generally, relief from aggregate-of-intermediate is granted on the basis that rates for which relief is sought, are depressed rates for the purpose of meeting competition from other modes of transportation.

Separate rates for distinct rail service
Incentive rates for capital investment

Moreover, in view of the protection that would be provided to shippers by the notation requirement described above, we are also considering whether any other categories of rail transportation, or rail transportation in general, should be exempted from the provisions of section 10726. Parties should address the effect of the "limited scope" language of Section 10505(a) on these considerations.

This notice of proposed rulemaking is issued pursuant to section 553 of the Administrative Procedure Act (5 U.S.C. 553) and section 10321 of the Interstate Commerce Act.

It does not appear that this proposal will significantly affect either the quality of the human environment or conservation of energy resources.

Dated: October 11, 1979.

By the Commission, Chairman O'Neal, Vice Chairman Stafford, Commissioners Gresham, Clapp, Christian, Trantum, Gaskins and Alexis.

Agatha L. Mergenovich,

Secretary.

Appendix

Proposed Rule

We propose to amend Chapter X, Subchapter D, of Title 49 of the Code of Federal Regulations, as follows:

PART 1301—LONG- AND SHORT-HAUL AND AGGREGATE OF INTERMEDIATE RATES—RAILROADS

By the addition of a new section, as follows:

§ 1301.86 Exemption.

The provisions of §§ 1301.11 through 1301.85 do not apply in connection with the following categories of rail rates or charges:

Multiple car
Unit train
Annual volume
International rail/water shipments
Contract rates
Rail general increase
Demand Sensitive rates
Separate rates for distinct rail service
Incentive rates for capital investment

Any rates or charges established pursuant to this section shall be made subject to, or in some manner bear reference to, substantially the following statement:

Rates or charges subject hereto are filed pursuant to 49 CFR 1301.86, and are exempt from the provision of 49 U.S.C. 10726; however, anyone objecting to the rates or charges on other grounds may file a verified complaint pursuant to 49 CFR 1100.40.

[FR Doc. 79-33969 Filed 11-1-79; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 32

Proposed Addition of Lake Nettie National Wildlife Refuge, N. Dak., to List of Open Areas; Big Game Hunting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: The Fish and Wildlife Service proposes to add Lake Nettie National Wildlife Refuge, North Dakota, to the refuge areas open for big game hunting. The Director has received information that this action would be in accordance with the provisions of all laws applicable to the area, would be compatible with the principles of sound wildlife management, would otherwise be in the public interest and that such use is compatible with the major purposes for which the refuge was established. Big game hunting, subject to annual special regulations, will provide additional public recreational opportunity.

DATES: Comments must be received on or before December 3, 1979.

ADDRESS: Comments may be addressed to the Director, (FWS/RF), U.S. Fish and Wildlife Service, Department of the Interior, Washington, D.C. 20240.

FOR FURTHER INFORMATION CONTACT: Ronald L. Fowler, Division of Refuge Management, U.S. Fish and Wildlife Service, Washington, D.C. 20240. Telephone 202-343-4305.

SUPPLEMENTARY INFORMATION: Ronald L. Fowler is the primary author of this proposed rulemaking. Areas within the National Wildlife Refuge System are closed to hunting until officially opened by rulemaking. The Director may open refuge areas to hunting upon a determination that such use is compatible with the major purposes for which such areas were established and that funds are available for the development, operation and maintenance of the permitted forms of recreation. This action will be in accordance with provisions of all laws applicable to the area, will be compatible with the principles of sound wildlife management and will otherwise be in the public interest. It is the purpose of this proposed rulemaking to seek public input regarding the opening of the above cited refuge to the hunting of migratory game birds. Pursuant to the requirements of section 102(2)(C) of the National Environmental Policy Act of 1969, 42 U.S.C. 4332(2)(C), an environmental assessment has been prepared on this proposal and is available for public inspection and copying at room 2024, Department of the Interior, 18th and C Streets, NW., Washington, D.C. 20240, or by mail, addressing the Director at the address above. The policy of the Department of Interior is, whenever practicable, to afford the public an opportunity to participate in the rulemaking process. Accordingly, interested persons may submit written comments, suggestions, or objections regarding the proposed amendment. All relevant comments will be considered by the Department prior to the issuance of a final rulemaking.

Note.—The Department of the 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.

Accordingly, it is proposed to amend 50 CFR Part 32 by the addition of Lake Nettie National Wildlife Refuge in § 32.31 as follows:

§ 32.31 List of open areas; big game.

* * * * *

North Dakota

* * * * *

Lake Nettie National Wildlife Refuge

* * * * *

Dated: October 29, 1979.

Robert S. Cook,

Acting Director, Fish and Wildlife Service.

[FR Doc. 79-34051 Filed 11-1-79; 8:45 am]

BILLING CODE 4310-55-M

Notices

Federal Register
Vol. 44, No. 214
Friday, November 2, 1979

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.

CIVIL AERONAUTICS BOARD

[Order 79-10-172; Dockets 31290, 35523, and 36151]

Air Transport Association of America and Braniff Airways, Inc.; Order

Establishment of the interim standard industry fare level.

Petition For Reconsideration of Order 79-7-190 Filed in Behalf of Certain Carriers by Air Transport Association of America.

Petition For A Fuel Adjustment Charge by Braniff Airways, Inc.

Adopted by the Civil Aeronautics Board at its office in Washington, D.C. on the 25th day of October, 1979.

By Order 79-8-184, the Board established its current interim Standard Industry Fare Level (SIFL), reflecting the Airline Deregulation Act of 1978 (ADA), Public Law 95-504. In summary, the ADA set deadlines and policies for deregulation of the economic aspects of interstate air transportation, culminating, among other things, with the dissolution of the Board's discretion to prescribe fares in domestic and overseas markets. The Board must compute a "standard industry fare level" based upon the fare level in effect on July 1, 1977, and periodically update the SIFL by increasing or decreasing it by the percentage change in operating costs per available seat mile (ASM) for interstate and overseas transportation combined. Once computed, the SIFL becomes the benchmark for measuring the statutory zone of reasonableness. Subsequent to our initial determination of the SIFL, we announced our intention of revising the level every two months, for a two-month period, based on the latest 4 months of reported fuel data. (Order 79-7-190).

September fuel costs are now available and indicate an increase in average price per gallon of 3.75 cents over August to 67.14 cents. Applying our methodology to calendar year 1978 financial data and September fuel costs, with fuel projected to December 1, 1979, the midpoint of our projection period, at the rate of 4.36 cents per gallon increase each month, raises the SIFL 3.7 percent over the level effective September 1, 1979.[1] The average monthly fuel escalation produced by our formula is greater than the August-September increase because the formula continues to give weight to the 6.51 cent escalation recorded in June-July. (See Appendix) [2]

The Board wishes to take this opportunity to clarify its position on the implementation of these increases on short notice. The Board's policy of granting carriers short notice for increases applies to those increases which are within the Congressionally ordained zone of reasonableness and where there is no controversy as to the lawfulness of the charges. This relaxation of our requirements for advance notice to permit carriers to more quickly implement tariff changes is intended to remove regulatory obstacles to a more competitive and dynamic pricing system. We believe these changes will offer significant long term benefits to the public by allowing carriers' pricing options to more closely approximate those available to unregulated industries.

We wish to remind carriers, however, that our current policy is purely discretionary. Likewise, it is for each individual carrier to decide whether to implement a fare increase on short notice, but it is clearly their obligation to adequately notify their agents and others of the impending price changes. The spirit of deregulation, we think, clearly places the principal burden on carriers and their agents to accommodate their respective needs in these situations. We are, of course, prepared to do our part insofar as our statute permits, but we would be mistaken if we allowed the industry to evade its responsibilities in this respect. Following the last increase in the SIFL, the Board was deluged by an intolerable number of complaints from travel agents and consumers about allegedly chaotic conditions in the industry, as some carriers rushed to implement increased fares with minimal or no effort to coordinate their efforts with their agents. We will be monitoring events closely as this Order becomes effective. Any repetition of the previous situation would cause us to reconsider our short notice policy.

We will also dismiss two petitions outstanding in connection with the timeliness and methodology for constructing the SIFL—Petition of Braniff Airways, Inc., For a fuel Adjustment Charge, Docket 36151, and Petition for Reconsideration of Order 79-7-190, Docket 35523, filed by the Air Transport Association of America (ATA). Essentially, these two petitions request that the Board rely on a shorter projection period for the SIFL to permit the carriers to increase fares more often to compensate for the rapidly escalating price of fuel. The Board's reply is clearly stated in this and the previous SIFL Order (79-8-184) where the Board, in fact, altered the time periods within which it calculated the SIFL to reflect fuel price increases.

Accordingly, pursuant to the Federal Aviation Act of 1958, and particularly section 1002:

1. We set the Standard Industry Fare Level effective November 1, 1979 as follows:

Terminal Charge: $22.54. Plus .1233/mile (0-500 miles); plus .0940/mile (501-1,500 miles); plus .0904/mile (over 1,500 miles).

2. We will dismiss the Petition of Braniff Airways, Inc. for a Fuel Adjustment Charge, in Docket 36151, and the Petition for Reconsideration of Order 79-7-190 filed by the Air Transport Association of America in Docket 35523.

This order will be published in the Federal Register.

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[1] See the following table:

Trunk and Local Service Carrier Scheduled Service Fuel Price

[In cents]

Month	Price	Change from previous month
June	52.49	2.77
July	59.00	6.51
August	63.39	4.39
September	67.14	3.75

Our latest methodology projects future fuel prices based on the average change in price during the most recent four months. In this case we projected forward an average increase of 4.36 cents per month for two and one-half months (to December 1); then added this 10.90 cent increase to the September price—projecting a 78.04 cent per gallon cost on December 1.

[2] Filed with the original.

By the Civil Aeronautics Board.

Phyllis T. Kaylor,

Secretary.

All Members concurred except Member O'Melia who filed the following concurring in part and dissenting in part statement:

I have said before in Order 79-8-184, August 31, 1979, and Order 79-7-190, July 30, 1979, and I repeat again, the Board's delay in taking favorable action on the Braniff and ATA petitions has denied the carriers fare increases to which they were entitled under the specific terms of the new Act.

Richard J. O'Melia.

[FR Doc. 79-34012 Filed 11-1-79; 8:45 am]

BILLING CODE 6320-01-M

Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart Q of the Board's Procedural Regulations

Notice is hereby given that, during the week ended October 26, 1979 CAB has received the applications listed below, which request the issuance, amendment, or renewal of certificates of public convenience and necessity or foreign air carrier permits under Subpart Q of 14 CFR 302.

Answers to foreign permit applications are due 28 days after the application is filed. Answers to certificate applications requesting restriction removal are due within 14 days of the filing of the application. Answers to conforming applications in a restriction removal proceeding are due 28 days after the filing of the original application. Answers to certificate applications (other than restriction removals) are due 28 days after the filing of the application. Answers to conforming applications or those filed in conjunction with a motion to modify scope are due within 42 days after the original application was filed. If you are in doubt as to the type of application which has been filed, contact the applicant, the Bureau of Pricing and Domestic Aviation (in interstate and overseas cases) or the Bureau of International Aviation (in foreign air transportation cases).

Subpart Q Applications

Date filed	Docket No.	Description
Oct. 19, 1979	32707	Lineas Aereas Costarricenses, S.A. (LACSA), c/o Robert D. Paplin, Squire, Sanders & Dempsey, 21 Dupont Circle, N.W., Washington D.C. 20036. Amendment No. 2 to the application of Lineas Aereas Costarricenses, S.A. (LACSA) to add the following: Amend Paragraph 6 to read as follows: "6. The routes to be covered by the amended permit for which application is hereby made are as follows: Between the terminal point San Jose, Costa Rica, the intermediate points Managua, Nicaragua; Cayman Islands, British West Indies; San Andres, Colombia, San Salvador, El Salvador; San Pedro de Sula, Honduras; Guatemala City, Guatemala; Punta Cancun, Mexico City, Merida, and Cozumel, Mexico; Kingston, Jamaica, and the coterminal points Miami, Florida; New Orleans, Louisiana; and Los Angeles, California." LACSA requests that the amended permit authorize it to provide scheduled and non-scheduled foreign air transportation of persons, property, and mail over the above-described route. Answers due on November 16, 1979.
Oct. 19, 1979	36932	Toronto Airways Limited d.b.a. Torontair, c/o Lee M. Hydeman, Hydeman, Mason & Goodell, 1220 19th Street, N.W., Washington, D.C. 20036. Application of Toronto Airways, Ltd. d.b.a. Torontair pursuant to Section 402 of the Act requesting the Board for a foreign carrier permit authorizing it to provide scheduled foreign air transportation of persons and property between Kingston, Ontario, Canada, and Syracuse, New York, using small aircraft. Answers due November 16, 1979.
Oct. 22, 1979	36942	British Caledonian Airways Limited, c/o Leonard N. Bebchick, Martin, Whitfield, Smith & Bebchick, 1701 Pennsylvania Avenue, N.W., Suite 1102, Washington, D.C. 20006. Application of British Caledonian Airways Limited requests the Board pursuant to Subpart Q of the Act for the amendment and renewal of its foreign air carrier permit issued pursuant to Order 78-7-166 so as to grant it the additional route authority to serve Dallas/Fort Worth, Texas, and to renew its existing authority to serve Bangor, Maine. Answers due on November 19, 1979.
Oct. 24, 1979	36972	Braniff Airways, Inc., Braniff World Headquarters, Braniff Boulevard, Dallas/Fort Worth Regional Airport, Dallas, Texas 75261. Application of Braniff Airways, Inc., under Subpart Q pursuant to Section 401(e)(7)(B) of the Act requesting an amendment to its certificate of public convenience and necessity for Route 9 to remove the one-stop restriction on Braniff's authority in the Boston-Dallas/Fort Worth market. Conforming answers and applications are due November 7, 1979.
Oct. 24, 1979	36974	American Airlines, Inc., P.O. Box 61616, Dallas/Fort Worth Airport, Texas 75261. Application of American Airlines, Inc., under Subpart Q requesting an issuance of a certificate of public convenience and necessity authorizing it to engage in scheduled foreign air transportation of persons, property and mail over the following route: Between the coterminal points Honolulu, Hawaii, Seattle, Wash., Los Angeles and San Francisco, Calif., Chicago, Ill., Detroit, Mich., Dallas/Fort Worth and Houston, Tex., Boston, Mass., New York, N.Y., Newark, N.J., Baltimore, Md., Washington, D.C., Miami and Tampa, Fla., New Orleans, La., and San Juan, P.R., intermediate points in Mexico, British Honduras, Honduras, Nicaragua, Guatemala, El Salvador, Costa Rica, Panama, Colombia, Venezuela, Ecuador, Peru, Bolivia, Paraguay, Uruguay, Brazil, Chile and Argentina, and the terminal point Buenos Aires, Argentina. Answers are due November 7, 1979.

Subpart Q Applications—Continued

Date filed	Docket No.	Description
Oct. 24, 1979	36977	DHL Airways, Inc., c/o Herbert A. Rosenthal, Hausman and Rosenthal, 1747 Pennsylvania Ave., N.W., Washington, D.C. 20006. Application of DHL Airways, Inc., under Subpart Q and pursuant to Section 401 of the Act request the Board for issuance of an amended certificate of public convenience and necessity authorizing it to engage in foreign air transportation of persons, property and mail over the following route: Between the coterminal points Boston, Mass.; New York/Newark, N.J.; Baltimore, Md.; Washington, D.C.; Miami and Tampa, Fla.; San Juan, P.R.; New Orleans, La.; Houston, Texas; Chicago, Ill.; Detroit, Mich.; Los Angeles/Long Beach/Ontario and San Franciso/Oakland, Calif.; Seattle, Wash.; and Honolulu, Hawaii, on the other hand, and the coterminal points Mexico City, Mexico; Guatemala City, Guatemala; San Jose, Costa Rica; Panama City, Panama; Medellin, Cartegena, Cali and Bogota, Colombia; Caracas, Venezuela; Quito and Guayaquil, Ecuador; Lima, Peru; La Paz, Bolivia; Santiago, Chile; Asuncion, Paraguay; Rio De Janiero, Brazil; Montevideo, Uruguay, and Buenos Aires, Argentina, on the other. Answers due on November 7, 1979.
Oct. 25, 1979	36981	USAir, Inc., Washington National Airport, Washington, D.C. 20001. Application of USAir, Inc., under Subpart Q, pursuant to Section 401 of the Act and Part 201 of the Economic Regulations requesting the Board for amendment of its certificate of public convenience and necessity for Route 97 so as to authorize USAir to engage in scheduled nonstop air transportation of persons, property and mail between Kansas City, Missouri, on the one hand, and New York and Buffalo, New York, Philadelphia and Pittsburgh, Pennsylvania, on the other hand, by amending USAir's certificate for Route 97 to include a new segment as follows: Between the terminal point Kansas City, Missouri, and the alternate terminal points New York (JFK), New York (LaGuardia) and Buffalo, New York, Philadelphia and Pittsburgh, Pennsylvania. Conforming answers and applications due November 22, 1979.
Oct. 26, 1979	36993	Trans World Airlines, Inc., 605 Third Avenue, New York, New York 10016. Application of Trans World Airlines, Inc., under Subpart Q requesting that the Board amend its certificate of public convenience and necessity for Route 2 by adding a new segment which would authorize service between the alternate terminal point Chicago, Illinois, and the terminal point Madison, Wisconsin. Conforming answers and applications are due November 23, 1979.
Oct. 26, 1979	36994	Trans World Airlines, Inc., 605 Third Avenue, New York, New York 10016. Application of Trans World Airlines, Inc., under Subpart Q requesting the Board amend its certificate of public convenience and necessity for Route No. 2 by adding a new segment which would authorize service between the terminal point Peoria, Illinois, and the alternate terminal points Chicago (O'Hare), Illinois, Kansas City, and St. Louis, Missouri. Conforming answers and applications are due November 23, 1979.

Phyllis T. Kaylor,
Secretary.

[FR Doc. 79-34010 Filed 11-1-79; 8:45 am]
BILLING CODE 6320-01-M

[Docket 30356]

Transcontinental Low-Fare Route Proceeding (Air U.S., Air Transport Associates, Standard Airways, and United States Overseas Airlines—Remanded); Assignment of Proceeding

This proceeding is hereby assigned to Administrative Law Judge Henry M. Switkay. Future communications should be addressed to Judge Switkay.

Dated at Washington, D.C., October 29, 1979.

Joseph J. Saunders,
Chief Administrative Law Judge.

[FR Doc. 79-34011 Filed 11-1-79; 8:45 am]
BILLING CODE 6320-01-M

COMMISSION ON CIVIL RIGHTS

Illinois 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 Illinois Advisory Committee (SAC) of the Commission will convene at 10:00 am and will end at 3:00 pm, on November 26, 1979, at 230 South Dearborn Street, Room 3280, Chicago, Illinois 60604.

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 a report from National SAC Conference held in Washington, D.C.; and discussion of the Chicago Desegregation Report.

This meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, D.C., October 29, 1979.

John I. Binkley,
Advisory Committee Management Officer.

[FR Doc. 79-33993 Filed 11-1-79; 8:45 am]
BILLING CODE 6335-01-M

Michigan Advisory Committee Agenda and Notice of Open Meeting; Amendment

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 Michigan Advisory Committee (SAC) of the Commission originally scheduled at the Howard Johnson Hotel, G3129 Miller Road, Flint, Michigan 48507, has been changed.

The meeting now will be held at Genosee County Community Action Agency, Board Room—Sections 2 & 3, 301 Dryden Building, 601 South Saginaw Street, Flint, Michigan 48602. The time and date will remain the same.

Dated at Washington, D.C., October 29, 1979.

John I. Binkley,
Advisory Committee Management Officer.

[FR Doc. 79-33996 Filed 11-1-79; 8:45 am]
BILLING CODE 6335-01-M

Missouri 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 conference of the Missouri Advisory Committee (SAC) of the Commission will convene at 1:00 pm and will end at 3:00 pm, on November 29–30, 1979, at the Holiday Inn-City Center, 1301 Wyandette Street, Kansas City, Missouri 64105.

Persons wishing to attend this open meeting should contact the Committee Chairperson, or the Central States Regional Office of the Commission, 911 Walnut Street, Kansas City, Missouri 64106.

The purpose of this conference is to plan the program activities of the advisory committee during fiscal 1981.

This meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, D.C., October 29, 1979.

John I. Binkley,

Advisory Committee Management Officer.

[FR Doc. 79-33995 Filed 11-1-79; 8:45 am]

BILLING CODE 6335-01-M

South Carolina 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 South Carolina Advisory Committee (SAC) of the Commission will convene at 11:00 a.m. and will end at 3:00 p.m., on November 27, 1979, at the Carolina Townhouse, Deauville Conference Room #4, 1615 Gervais Street, Columbia, South Carolina 29201.

Persons wishing to attend this open meeting should contact the Committee Chairperson, or the Southern Regional Office of the Commission, 75 Piedmont Avenue NE., Atlanta, Georgia 30303.

The purpose of this meeting is a press conference to release staff report on follow-up of study, Equality in Municipal Services in Mullins, South Carolina. Sac will then plan SAC project for fiscal 1980. There will also be a report of the SAC Chairperson's conference in October.

This meeting will be conducted pursuant to the provisions of the rules and regulations of the Commission.

Dated at Washington, D.C., October 29, 1979.

John I. Binkley,

Advisory Committee Management.

[FR Doc. 79-33994 Filed 11-1-79; 8:45 am]

BILLING CODE 6335-01-M

DEPARTMENT OF COMMERCE

(Department Organization Order 20-11; Transmittal 463)

Appeals Board; Authority and Functions

Effective Date: October 12, 1979.

Subject: This order effective October 12, 1979 supersedes the material appearing at 40 FR 17771 of April 22, 1975.

Section 1. Purpose

.01 This Order prescribes the authority and functions of the Appeals Board for the Department of Commerce.

.02 This revision: (1) reflects the transfer of all but a few pending contract appeals to Interior (paragraph 3.01); (2) removes from the authority and functions of the Appeals Board appeals relating to orders, regulations, or administrative sanctions taken pursuant to Section 402 of the Federal Property and Administrative Services Act of 1949, as amended, and the Export Administration Act of 1979, which appeals shall hereafter be handled within the Industry and Trade Administration; and (3) removes gender indicative language from the order.

Section 2. General

The Appeals Board for the Department of Commerce, initially established on August 18, 1953, by Department Order 106 of that date, and which serves as an impartial body to consider certain appeals from the public, is continued within the Office of the Assistant Secretary for Administration. It shall be composed of a chairperson and other members as may be designated by the Assistant Secretary for Administration and approved by the Secretary.

Section 3. Authority and Functions

.01 The Appeals Board is authorized to consider and decide appeals by contractors from decisions made by contracting officers under contracts which provide for such an appeal to the Secretary, and which have not been delegated or assigned to the Department of Interior Board of Contract Appeals.

.02 The Appeals Board is also authorized to consider and decide appeals by persons affected by:

a. Any order, regulation, or administrative action issued pursuant to the authority delegated to the Secretary under the Defense Production Act of 1950, as amended, (50 U.S.C. App. 2061 *et seq.*), or

b. Other administrative actions taken pursuant to law and referred to the Board by appropriate authority.

.03 Decisions by the Appeals Board on appeals arising under paragraphs .01 and .02 of this section shall be final within the Department.

.04 No member may act for the Appeals Board or participate in a decision on appeal if the member has otherwise been directly involved in the administration of the contract, regulation, or other subject matter of the appeal.

.05 The Chairperson of the Appeals Board is authorized to issue rules governing the handling of appeals.

Savings Provision

All outstanding delegations, regulations, orders and other actions issued by or relating to the Appeals Board shall remain in effect until amended or revoked by proper authority.

Juanita M. Kreps,

Secretary of Commerce.

Elsa A. Porter,

Assistant Secretary for Administration.

[FR Doc. 79-34015 Filed 11-1-79; 8:45 am]

BILLING CODE 3510-17-M

[Department Organization Order 10-1 Amdt. 4; Transmittal 464]

Assistant Secretary for Science and Technology; Delegation of Authority

Effective Date: October 18, 1979.

Subject: This order effective October 18, 1979 further amends the materials appearing at 41 FR 18536 of May 5, 1976, 41 FR 26593 of June 28, 1976, 42 FR 40963 of August 12, 1977, and 43 FR 39167 of September 1, 1978.

Department Organization Order 10-1 dated April 9, 1976 is hereby further amended as shown below. The purpose of this amendment is to delegate to the Assistant Secretary for Science and Technology the authority to waive the requirements of those Federal Information Processing Standards which authorize the Secretary to waive such requirements, and to issue interpretative guidelines concerning the waiver provisions of all such standards.

Section 3. Delegation of Authority

a. A new subparagraph .01i. is added to read as follows:

"i. Exercise the functions of the Secretary of Commerce under provisions in Federal Information Processing Standards authorizing the Secretary to waive compliance with requirements of the standards. The Assistant Secretary is also delegated authority to issue interpretative guidelines concerning the waiver provisions of the standards."

b. Paragraph .03 is revised to read as follows:

".03 The Assistant Secretary may delegate authorities except for subparagraph i. of paragraph .01 above and the the authority to issue or approve regulations. Further, redelegation of other authorities in subparagraphs c., d., g., and h. of paragraph .01 above shall be limited to the Deputy Assistant Secretaries provided herein."

Juanita M. Kreps,

Secretary of Commerce.

Elsa A. Porter,

Assistant Secretary for Administration.

[FR Doc. 79-34014 Filed 11-1-79; 8:45 am]

BILLING CODE 3510-17-M

[Department Organization Order 25-5B; Amdt. 4; Transmittal 462]

National Oceanic and Atmospheric Administration; Delegation of Authority

Effective date: September 27, 1979.

Subject: This order effective September 27, 1979 further amends the materials appearing at 43 FR 51438 of November 3, 1978, 44 FR 3303 of January 16, 1979, 44 FR 15522 of March 14, 1979, and 44 FR 24623 of April 26, 1979.

Department Organization Order 25-5B, dated October 16, 1978, is hereby further amended as shown below. The purpose of this amendment is to (1) change the title of the Assistant Administrator for Administration to the Assistant Administrator for Management and Budget, and (2) transfer the Office of Program Evaluation and Budget from the immediate Office of the Administrator to the Assistant Administrator for Management and Budget.

1. Section 8. Office of Program Evaluation and Budget

Section 8. is deleted. In pen and ink, renumber the existing Sections 9. through 14. as 8. through 13., respectively.

2. Section 10. Assistant Administrator for Administration

a. The title, opening paragraph, and paragraph .01 of the renumbered Section 10. are revised to read as follows:

"Section 10. Assistant Administrator for Management and Budget

"The Assistant Administrator for Management and Budget shall provide administrative management support services and the means of management control over program and budget operations and program evaluation for all components of NOAA, except for elements of such services that appropriate components are directed to provide for themselves, exercise functional supervision over such decentralized services, and provide advise and guidance on the utilization of NOAA resources. To carry out these responsibilities, the Assistant Administrator shall have and direct the following units.

".01 The *Office of the Assistant Administrator* shall formulate and execute the basic policies of the Office of Management and Budget."

b. In pen and ink renumber the existing paragraphs .03 through .07 as .04 through .08 and add a new paragraph .03 to read as follows:

".03 The *Office of Program Evaluation and Budget* shall provide NOAA with the means of management control over program and budget operations and program evaluations, and shall coordinate Management by Objectives activities. This Office, through the Assistant Administrator for Management and Budget, shall be the focal point for contacts with the Department and the Office of Management and Budget in these areas. The Office shall specifically be responsible for the planning and management of the annual NOAA Program review; the consolidation and integration of program guidance developed by the Assistant Administrators; the coordination and development of issue studies, Zero Base Budget material, and other supporting documentation required in the program/budget cycle; the development of the NOAA budget; the allocation and budgetary control of funds; the review and monitoring of fiscal plan execution; the design and implementation of program impact and efficiency evaluations; and the coordination of Departmental and OMB requirements and reporting activities necessary to the operation of the Office."

3. The organization chart, Exhibit 1, attached to this amendment, supersedes the organization chart dated March 23, 1979. A copy of the organization chart is on file with the original of this document in the Office of the Federal Register.

Richard A. Frank,

Administrator, National Oceanic and Atmospheric Administration.

Approved:

Elsa A. Porter,

Assistant Secretary for Administration.

[FR Doc. 79-34016 Filed 11-1-79; 8:45 am]

BILLING CODE 3510-17-M

Industry and Trade Administration

Numerically Controlled Machine Tool Technical Advisory Committee; Partially Closed 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 Numerically Controlled Machine Tool Technical Advisory Committee will be held on Tuesday, November 27, 1979, at 10:00 a.m. in Room 3708, Main Commerce Building, 14th Street and Constitution Avenue, N.W., Washington, D.C.

The Numerically Controlled Machine Tool Technical Advisory Committee was initially established on January 3, 1973. On December 20, 1974, January 13, 1977, and August 28, 1978, the Assistant Secretary for Administration approved the recharter and extension of the Committee, pursuant to Section 5(c)(1) of the Export Administration Act of 1969, as amended, 50 U.S.C. App. Sec. 2404(c)(1) and the Federal Advisory Committee Act.

The Committee advises the Office of Export Administration with respect to questions involving (A) technical matters, (B) worldwide availability and actual utilization of production of technology, (C) licensing procedures which affect the level of export controls applicable to numerically controlled machine tools, including technical data or other information related thereto, and (D) exports of the aforementioned commodities and technical data subject to multilateral controls in which the United States participates including proposed revisions of any such multilateral controls.

The Committee meeting agenda has six parts:

General Session

(1) Opening remarks by the Chairman.

(2) Presentation of papers or comments by the public.

(3) Continued discussion of accuracy parameters for numerically controlled machine tools.

(4) Review of information regarding foreign availability of numerically controlled technology obtained at the recent European machine tool show.

(5) New business.

Executive Session

(6) Discussion of matters properly classified under Executive Order 11652 and 12065, dealing with the U.S. and COCOM control program and strategic criteria related thereto.

The General Session of the meeting will be open to the public and a limited number of seats will be available. To the extent time permits members of the public may present oral statements to the Subcommittee. Written statements may be submitted at any time before or after the meeting.

With respect to agenda item (6), the Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on September 6, 1978, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended by Section 5(c) of the Government In The Sunshine Act, P.L. 94-409, that the matters to be discussed in the Executive Session should be exempt from the provisions of the Federal Advisory Committee Act relating to open meetings and public participation therein, because the Executive Session will be concerned with matters listed in 5 U.S.C. 552b(c)(1). Such matters are specifically authorized under criteria established by

an Executive Order to be kept secret in the interests of the national defense or foreign policy. All materials to be reviewed and discussed by the Committee during the Executive Session of the meeting have been properly classified under Executive Order 11652 or 12065. All Committee members have appropriate security clearances.

The complete Notice of Determination to close meetings or portions thereof of the series of meetings of the Numerically Controlled Machine Tool Technical Advisory Committee and of any Subcommittees thereof, was published in the Federal Register on October 25, 1978 (43 FR 49828)

Copies of the minutes of the General Session will be available by calling Mrs. Margaret Cornejo, Policy Planning Division, Office of Export Administration, U.S. Department of Commerce, Washington, D.C. 20230, telephone: A/C 202-377-2583.

For further information contact Mrs. Cornejo either in writing or by phone at the address or number shown above.

Dated: October 30, 1979.

Kent N. Knowles,

Director, Office of Export Administration, Bureau of Trade Regulation, U.S. Department of Commerce.

[FR Doc. 79-34046 Filed 11-1-79; 8:45 am]

BILLING CODE 3510-25-M

Maritime Administration

[Docket No. S-649]

Farrell Lines Inc.; Application

Notice is hereby given that Farrell Lines Incorporated (Farrell), by letter dated October 26, 1979, has made the following application in connection with its proposed 20-year operating-differential subsidy contract:

(a) For transfer and interchange privileges:

1. The transfer of C4-S-58a and C4-S-64a breakbulk ships of Operating-Differential Subsidy Contract No. MA/MSB-352, and C3-S-38a, C3-S46a, and C3-S-46b breakbulk ships of Operating-Differential Subsidy Contract No. FMB-87, among Farrell's services on Trade Route Nos. 10, 14-1, 15-A, and 18, and the renewal of Farrell's existing authority to interchange (substitute) the above-named vessels among the above-named trade routes.

2. The transfer and interchange (substitution) of C6-S-85a containerships of Operating-Differential Subsidy Contract No. MA/MSB-352, and C5-S-73b containerships and C5-S-78a Ro/Ro containership's of Operating-Differential Subsidy Contract No. FMB-87 among Farrell's services on Trade Route Nos. 5-7-8-9, 10, 12, 15-A, and 16.

(b) For vessel non-limitation as to number:

1. The right to operate vessels without limitation as to number in the proposed service on Trade Route No. 5-7-8-9, subject to the minimum/maximum number of voyages applied for.

As used in this Notice, the term "interchange" means the approximately simultaneous substitution of vessesls. The term "transfer" means removal of a vessel from one service and placement into another.

Interested persons may inspect this application in the Office of the Secretary, Maritime Subsidy Board, Room 3099B, Department of Commerce Building, 14th and E Streets NW., Washington, D.C. 20230.

Any person, firm, or corporation having an interest in such application who desires to offer views and comments thereon for consideration by the Maritime Subsidy Board should submit them in writing, in triplicate, to the Secretary by the close of business on November 12, 1979.

The Maritime Subsidy Board will consider such views and comments and take such action with respect thereto as may be deemed appropriate.

(Catalog of Federal Domestic Assistance Program No. 11.504 Operating-Differential Subsidies (ODS))

By Order of the Maritime Subsidy Board.

Dated: October 26, 1979.

Robert J. Patton, Jr.,

Secretary.

[FR Doc. 79-34048 Filed 11-1-79; 8:45 am]

BILLING CODE 3510-15-M

[Docket No. S-650]

Ogden Leader Transport, Inc., Application

Notice is hereby given that Ogden Leader Transport, Inc., 280 Park Avenue, New York, New York 10017, has filed an application dated August 17, 1979, with the Maritime Subsidy Board (the Board) pursuant to Title VI of the Merchant Marine Act, 1936, as amended (the Act), for an operating-differential subsidy contract, to expire December 31, 1979, unless extended, to operate the SS Ogden Leader, 37,807 deadweight tons, in the carriage of bulk raw and processed agricultural commodities in the foreign commerce of the United States (U.S.) from ports in the U.S. to ports in the Union of Soviet Socialist Republics (U.S.S.R.), or other permissible ports of discharge. Dry and liquid bulk cargoes may be carried from the U.S.S.R. and other foreign ports inbound to U.S. ports during voyages subsidized for carriage of export bulk raw and processed agricultural commodities to the U.S.S.R., or other permissible ports of discharge.

Full details concerning the U.S.-U.S.S.R. export bulk raw and processed agricultural commodities subsidy program, including terms, conditions and restrictions upon both the subsidized operators and vessels, appear in Title 46 of the Code of Federal Regulations, Part 294.

For purposes of section 605(c) of the Act, it should be assumed that should the Board grant the requested approval, the vessel named above will engage in the described trade, on a full-time basis, during the indicated time period. Under such approval, each voyage must be approved for subsidy assistance prior to its commencement, and the Board will act on such request(s) as an administrative matter for which there is no requirement for further section 605(c) notice(s).

Any person having an interest in the granting of the application and who would contest a finding by the Board that the service now provided by vessels of U.S. registry for the carriage of cargoes previously specified is inadequate, must on or before November 30, 1979, notify the Board's Secretary, in writing, of his interest and of his position, and file a petition for leave to intervene in accordance with the Board's Rules of Practice and Procedure (46 CFR 201). Each such statement of interest and petition to intervene shall state whether a hearing is requested under section 605(c) of the Act, and, with as much specificity as possible, the facts that the intervenor would undertake to prove at such hearing.

In the event a hearing under section 605(c) of the Act is ordered to be held with respect to the subject application, the purpose of such hearing will be to receive evidence relevant to (1) whether the application herein described, with respect to the vessel to be operated in an essential service and serviced by citizens of the U.S., would be in addition to the existing service or services, and if so, whether the service already provided by vessels of U.S. registry is inadequate, and (2) whether in the accomplishment of the purposes and policy of the Act additional vessels should be operated thereon.

If no request for hearing and petition for leave to intervene is received within the specified time, or if the Board determines that petitions for leave to intervene filed within the specified time do not demonstrate sufficient interest to warrant a hearing, the Board will take such actions as may be deemed appropriate.

(Catalog of Federal Domestic Assistance Program No. 11.504 Operating-Differential Subsidy (ODS))

Dated: October 30, 1979.

Robert J. Patton, Jr.,

Secretary.

[FR Doc. 79-34078 Filed 11-1-79; 8:45 am]

BILLING CODE 3510-15-M

Performance Review Board; Establishment and Membership

This notice announces the establishment by the Assistant Secretary for Maritime Affairs, as Appointing Authority for the Senior Executive Service at MarAd, of the MarAd Performance Review Board (PRB) and the appointment of the initial members.

The purpose of the PRB is to review performance agreements, performance appraisals and ratings, recommendations for certain personnel actions and other related material, and to make appropriate recommendations to the Appointing Authority concerning such matters as will assure the fair and equitable treatment of senior executives and the organization of which they are members and instill in the minds of such senior executives confidence in the integrity, competence and impartiality of the PRB.

The names, titles and terms of the members of the PRB who have been appointed, are set out below:

Mr. James S. Dawson, Secretary, Maritime Administration/Maritime Subsidy Board (Retired), Term-1 year

Mr. Thomas A. King, Eastern Region Director, Maritime Administration, New York, N.Y., Term-2 years

Mr. C. G. Caras, General Counsel, Maritime Administration, Washington, D.C. 20230, Term-Continuous as long as in current position.

Mr. John J. Nachtsheim, Assistant Administrator for Shipbuilding and Ship Operations, Maritime Administration, Washington, D.C. 20230, Term-Continuous as long as in current position.

Mr. Marvin Pitkin, Assistant Administrator for Commercial Development, Maritime Administration, Washington, D.C. 20230, Term-Continuous as long as in current position.

Mr. Wallace T. Sansone, Assistant Administrator for Maritime Aids, Maritime Administration, Washington, D.C. 20230, Term-Continuous as long as in current position.

Mr. Russell F. Stryker, Assistant Administrator for Policy and Administration, Maritime Administration, Washington, D.C. 20230, Term-Continuous as long as in current position.

Ms. Myra R. Wells, Director, Office of Personnel, Maritime Administration, Washington, D.C. 20230. will serve as non-voting Executive Secretary to the PRB.

Persons desiring any further information about the PRB or its membership may contact Ms. Myra R. Wells, Director, Office of Personnel, Maritime Administration, Washington, D.C. 20230, (202) 377-3616.

Dated: October 26, 1979.

Robert J. Patton, Jr.,

Secretary.

[FR Doc. 79-34050 Filed 11-1-79; 8:45 am]

BILLING CODE 3510-15-M

[Docket No. S-648]

Rio Grande Transport, Inc.; Application

Notice is hereby given that Rio Grande Transport, Inc., 280 Park Avenue, New York, New York 10017, has filed an application dated September 28, 1979, with the Maritime Subsidy Board (the Board) pursuant to Title VI of the Merchant Marine Act, 1936, as amended (the Act), for an operating-differential subsidy contract, to expire December 31, 1979, unless extended, to operate the SS OGEN CHARGER, 37,807 deadweight tons in the carriage of bulk raw and processed agricultural commodities in the foreign commerce of the United States (U.S.) from ports in the U.S. to ports in the Union of Soviet Socialist Republics (U.S.S.R.), or other permissible ports of discharge. Dry and liquid bulk cargoes may be carried from the U.S.S.R. and other foreign ports inbound to U.S. ports during voyages subsidized for carriage of export bulk raw and processed agricultural commodities to the U.S.S.R., or other permissible ports of discharge.

Full details concerning the U.S.-U.S.S.R. export bulk raw and processed agricultural commodities subsidy program, including terms, conditions and restrictions upon both the subsidized operators and vessels, appear in Title 46 of the Code of Federal Regulations, Part 294.

For purposes of section 605(c) of the Act, it should be assumed that should the Board grant the requested approval, the vessel named above will engage in the described trade, on a full-time basis, during the indicated time period. Under such approval, each voyage must be approved for subsidy assistance prior to its commencement, and the Board will act on such request(s) as an administrative matter for which there is no requirement for further section 605(c) notice(s).

Any person having an interest in the granting of the application and who would contest a finding by the Board that the service now provided by vessels of U.S. registry for the carriage of cargoes previously specified is inadequate, must on or before November 30, 1979, notify the Board's Secretary, in writing, of his interest and of his position, and file a petition for leave to intervene in accordance with the Board's Rules of Practice and Procedure (46 CFR 201). Each such statement of interest and petition to intervene shall state whether a hearing is requested under section 605(c) of the Act, and, with as much specificity as possible, the facts that the intervenor would undertake to prove at such hearing.

In the event a hearing under section 605(c) of the Act is ordered to be held with respect to the subject application, the purpose of such hearing will be to receive evidence relevant to (1) whether the application herein described, with respect to the vessel to be operated in an essential service and serviced by citizens of the U.S., would be in addition to the existing service or services, and if so, whether the service already provided by vessels of U.S. registry is inadequate, and (2) whether in the accomplishment of the purposes and policy of the Act additional vessels should be operated thereon.

If no request for hearing and petition for leave to intervene is received within the specified time, or if the Board determines that petitions for leave to intervene filed within the specified time do not demonstrate sufficient interest to warrent a hearing, the Board will take such actions as may be deemed appropriate.

(Catalog of Federa Domestic Assistance Program No. 11.504 Operating-Differential Subsidy (ODS))

Dated: October 26, 1979.

Robert J. Patton, Jr.,

Secretary.

[FR Doc. 79-34094 Filed 11-1-79; 8:45 am]

BILLING CODE 3510-15-M

Office of Federal Statistical Policy and Standards

Standard Occupational Classification; Proposed Revisions

AGENCY: Office of Federal Statistical Policy and Standards, Department of Commerce.

ACTION: Notice of Proposed revision of the Standard Occupational Classification.

SUMMARY: This document proposes changes in the Standard Occupational Classification (SOC)

Introduction

The proposed changes to the SOC were developed in the process of incorporating the SOC into the 1980 Census of Population. Only those changes which were identified in that

process were considered in this revision. A brief indication of each revised group is listed, usually indicated by a change in the title. The SOC Manual must be referred to in order to determine the original title and content of each occupational group. The manual is available from the Government Printing Office, S/N 041-001-00153-1, Price $8.25. Associated changes in the description and examples of job titles will be developed and published in a supplement after the review period.

Proposed Changes

The major change is an effort to provide more skill level distributions, especially in the broader groups. Other changes were made to recognize occupational groups that are expected to be large enough for separate identification in the Census of Population.

A supplement to the Standard Occupational Classification Manual will be published after the comments are considered.

ADDRESS: Send comments to Milo O. Peterson, Chairman, Occupational Classification Committee, Office of Federal Statistical Policy and Standards, U.S. Department of Commerce, Washington, D.C. 20230 by December 3, 1979. All comments, materials, questions, etc., in response to this proposal will be available for public inspection during normal business hours, 8:30 a.m. to 5:00 p.m., in Room 200, 2001 "S" Street, NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Milo Peterson, Office of Federal Statistical Policy and Standards, U.S. Department of Commerce, Washington, D.C. 20230, Telephone (202) 673-7977.

Note.—The Department of Commerce has determined that this proposal is not a significant regulation requiring preparation of a regulatory analysis under Executive Order No. 12044.

Courtenay M. Slater,

Chief Economist for the Department of Commerce.

Occupational Classification Committee Recommendations for Revisions of the SOC

Unit Group 1136 is moved to new Minor Group 137.

Minor Group 139 is split into a redefined original group and administrative services managers are merged into new Minor Group 137.

Minor Group 144 is split into two groups 1443—Purchasing Agents and Buyers, Farm Products and 1444—Purchasing Agents, NEC.

Unit Group 432 is split into one unit group in Minor Group 144 retitled Buyers, Wholesale and Retail Trade, except Farm Products and the rest combined in new unit group 1443.

A new Minor Group 147—Inspectors and Regulatory Officers is created with 4 unit groups.

Unit Group 1171 is moved into new Minor Group 147.

Unit Group 1172 is moved into new Minor Group 147.

Existing Minor Group 147 is made a Unit Group 1475.

Unit Group 618 is moved (as a unit group) into new Minor Group 147.

Minor Group 303 is further divided into five groups:
3031 Inhalation Therapists,
3032 Occupational Therapists,
3033 Physical Therapists,
3034 Speech Therapists,
3039 Therapists, Not Elsewhere Classified.

Unit Group 2232 is split into two unit groups 2231—Medical Science Teachers, and Unit Group 2232 is retitled as Health Specialties Teachers, Not Elsewhere Classified.

Minor Group 331 is further divided into two groups 3312—Editors and 3313—Reporters.

Minor Group 645 is moved into Major Group 39.

Parts of Unit Groups 4516 and 4518 are moved to Unit Groups in Major Group 40 to correspond with the move of Unit Groups 4683 and 4665.

Minor Group 411—Sales Engineers is a new group created from the Unit Groups of Major Group 16.

Unit Group 4146 is split into two unit groups, 4146—Salespersons, Garments and Textile Products and 4151—Salespersons, Shoes.

Unit Group 4665 is moved into Minor Group 414-5.

Unit Group 4683 is moved into Minor Group 414-5.

Unit Group 4259 is moved into Minor Group 414-5.

Minor Group 439 is split into two Minor Groups 438—Auctioneers and 439—Sales Related Occupations, Not Elsewhere Classified.

Minor Groups 414-5 and 416 are moved into Major Group 42, which is retitled Sales Occupations, Personal Goods and Services.

Minor Groups 422 and 425 except 4259 are moved to Major Group 41.

Major Group 41 is retitled Sales Occupations, Business Goods and Services.

The Clerical Occupations Division is retitled Administrative Support Occupations, including Clerical.

Unit Group 4622 is moved to Minor Group 461 and Typists is added to the title.

Minor Group 462 is deleted.

Unit Group 4624 is moved to Minor Group 479 and retitled Data-Entry Keyers.

Unit Group 4623 is moved to Minor Group 465.

Unit Group 4784 is merged into Unit Group 4693.

Minor Groups 471 and 486 are combined and titled Financial Records Processing Occupations.

Minor Groups 472 and 473 are combined and titled Mail and Message Distributing Occupations.

Unit Group 4747 is retitled Samplers.

Unit Group 4786 is moved to Minor Group 479.

Unit Group 4682 is moved to Minor Group 479, eliminating Minor Group 468.

Unit Group 4692 is moved to Minor Group 479.

Unit Group 4695 is moved to Minor Group 479.

Minor Group 479 is retitled Administrative Support Occupations, Not Elsewhere Classified.

Unit Group 4747 is retitled Samplers.

Major Group 53 is moved to the beginning of Service Occupations.

Major Group 50 is deleted by moving Minor Group 501 to Major Group 51, and Unit Groups 5021, 5024, and 5025 into Minor Groups 521, 524, and 525-6 respectively.

Unit Group 5133 is moved to Minor Group 512.

Unit Groups 5012 and 5013 are changed to reflect the move of Unit Group 5133.

Unit Group 5252 is retitled Hairdressers and Cosmetologists.

Division—Mechanics and Repairers is moved to before Construction and Extractive Occupations.

Minor Group 712, Major Group 72, Major Group 79 and a new Unit Group made up of a part of Minor Group 711 are made into a new division Precision Production Occupations following Construction and Extractive Occupations.

Minor Group 793 is retitled Power Plant and Systems Operators and split into 2 Unit Groups, 7931—Stationary Engineers and 7932—Power Plant and Systems Operators, except Stationary Engineers.

Unit Group 7234 is deleted, by creating a new unit group—7235 Furniture Finishers in Minor Group 723 and combining the rest with Unit Group 7239.

Unit Groups 7443 and 7643 are split into redefined original groups and a new Unit Group 7243—Precision Printing Press Operators.

Unit Group 7249 is split into a redefined original group and 7244—Bookbinders.

Unit Group 7223 is split into a redefined original group and photoengravers are merged into a retitled Unit Group 7242—Lithographers and Photoengravers.

Unit Group 7241 is combined into a retitled Unit Group 7442—Typesetters and Compositers.

Unit Group 7259 is split into two unit groups 7256—Apparel and Fabric Patternmakers and a redefined 7259.

Unit Group 7263 is split into two Unit Groups 7268—Photographic Process Workers and redefining 7263 to exclude them. (Plus one DOT from 7249)

Unit Group 7671 is deleted (DOT's to 795 & 794) (the number is reused later).

Unit Group 7679 is split into two Unit Groups 7671—Photographic Developing Machine Operators and redefining 7679.

Minor Group 433 is moved to Minor Group 641 as a unit group.

Minor Group 679 is moved to the beginning of Division—Material Handlers, Equipment Cleaners and Laborers.

Minor Group 619 is moved to Division—Material Handlers, Equipment Cleaners, and Laborers (following Minor Group 679).

Minor Group 769 is moved to Division—Material Handlers, Equipment Cleaners, and Laborers (following Minor Group 619).

Minor Group 779 is moved to Division—Material Handlers, Equipment Cleaners, and Laborers (following Minor Group 769).
Minor Group 672 is moved to Division—Material Handlers, Equipment Cleaners and Laborers (following Minor Group 826).
Division—Material Handlers, Equipment Cleaners, and Laborers is retitled Handlers, Equipment Cleaners, Helpers, and Laborers.
A new Major Group (80) is created for Supervisors in the new Division—Handlers, Equipment Cleaners, Helpers, and Laborers (these would come from Supervisor Groups in the five (old) preceding Divisions).
Minor Group 649 is deleted wit a part going to Minor Group 826 and the rest to Minor Group 846.
Minor Group 659 is deleted with a part going to 846 and the rest to 6519.
Parts of the unit groups of Minor Group 619 are moved to Major Group 81.
The high-level aggregated groups listed on page 9 of the Manual are changed by substituting 'sales and administrative support' for 'clerical, sales, and related' in group 2. Group 5 is split into two groups, 5-Precision Production, Craft, and Repair and 6-Operators, Fabricators and Laborers.

[FR Doc. 79-33920 Filed 11-1-79; 8:45 am]
BILLING CODE 3510-07-M

COUNCIL ON ENVIRONMENTAL QUALITY

Publication of Fourth Progress Report on Agency Implementing Procedures Under the National Environmental Policy Act

AGENCY: Council on Environmental Quality, Executive Office of the President.

ACTION: Information Only: Publication of Fourth Progress Report on Agency Implementing Procedures Under the National Environmental Policy Act.

SUMMARY: In response to President Carter's Executive Order 11991, on November 29, 1978, the Council on Environmental Quality issued regulations implementing the procedural provisions of the National Environmental Policy Act ("NEPA"). (43 FR 55978–56007; 40 CFR 1500–08) Section 1507.3 of the regulations provides that each agency of the Federal Government shall have adopted procedures to supplement the regulations by July 30, 1979. The Council has indicated to Federal agencies its intention to publish progress reports on agency efforts to develop implementing procedures under the NEPA regulations. The purpose of these progress reports, the fourth of which appears below, is to provide an update on where agencies stand in this process and to inform interested persons of when to expect the publication of proposed procedures for their review and comment.

FOR FURTHER INFORMATION CONTACT: Nicholas C. Yost, General Counsel, Council on Environmental Quality, 722 Jackson Place, N.W., Washington, D.C. 20006; 202–395–5750.

Fourth Progress Report on Agency Implementing Procedures Under the National Environmental Policy Act

At the direction of President Carter (Executive Order 11991), on November 29, 1978, the Council on Environmental Quality issued regulations implementing the procedural provisions of the National Environmental Policy Act ("NEPA"). These regulations appear at Volume 43 of the Federal Register, pages 55978–56007 and in forthcoming revisions to Volume 40 of the Code of Federal Regulations, Sections 1500–1508. Their purpose is to reduce paperwork and delay associated with the environmental review process and to foster environmental quality through better decisions under NEPA.

Section 1507.3 of the NEPA regulations provides that each agency of the Federal government shall adopt procedures to supplement the regulations. The purpose of agency "implementing procedures," as they are called, is to translate the broad standards of the Council's regulations into practical action in Federal planning and decisionmaking. Agency procedures will provide government personnel with additional, more specific direction for implementing the procedural provisions of NEPA, and will inform the public and State and local officials of how the NEPA regulations will be applied to individual Federal programs and activities.

In the course of developing implementing procedures, agencies are required to consult with the Council and to publish proposed procedures in the Federal Register for public review and comment. Proposed procedures must be revised as necessary to respond to the ideas and suggestions made during the comment period. Thereafter, agencies are required to submit the proposed final version of their procedures for 30 day review by the Council for conformity with the Act and the NEPA regulations. After making such changes as are indicated by the Council's review, agencies are required to promulgate their final procedures. Although CEQ's regulations required agencies to publish their procedures by July 30, a number of Federal agencies did not meet this deadline.

The Council published its first progress report on agency implementation procedures on May 7, 1979, its second progress report on July 23, 1979 and its third progress report on September 26, 1979. (44 FR 26781–82; 44 FR 43037–38; 44 FR 55408–55410.) The fourth progress report appears below. The Council hopes that concerned members of the public will review and comment upon agency procedures to insure that the reforms required by President Carter and by the Council's regulations are implemented. Agencies preparing implementing procedures are listed under one of the following four categories:

Category No. 1: Final Procedures Have Been Published

This category includes agencies whose final procedures have appeared in the Federal Register.

Central Intelligence Agency, 44 FR 45431 (Aug. 2, 1979).
Department of Agriculture, 44 FR 44802 (July 30, 1979):
- Animal and Plant Health Inspection Service, 44 FF 50381 (Aug. 28, 1979) [correction: 44 FR 51272 (Aug. 31, 1979)]
- Forest Service, 44 FR 44716 (July 30, 1979)
- Soil Conservation Service, 44 FR 50576 (Aug. 29, 1979)

Department of Defense, 44 FR 46841 (Aug. 9, 1979)
Department of Transportation, 44 FR 56420 (Oct. 1, 1979)
Environmental Protection Agency, (at the Federal Register)
Export-Import Bank, 44 FR 50810 (Aug. 30, 1979)
International Communications Agency, 44 FR 45489 (Aug. 2, 1979)
Marine Mammal Commission, 44 FR 52637 (Sept. 11, 1979)
National Aeronautics and Space Administration, 44 FR 44485 (July 30, 1979) [correction: 44 FR 49650 (Aug. 24, 1979)]
Overseas Private Investment Corporation, 44 FR 51385 (Aug. 31, 1979) [NEPA Procedures are contained in this agency's procedures implementing Executive Order 12114.]

Category No. 2: Proposed Procedures Have Been Established

This category includes agencies whose proposed procedures have appeared in the Federal Register. Those agencies whose final procedures are expected within 30 days are marked with a single asterisk (*); those expected within 60 days by a double asterisk (**).

ACTION, 44 FR 60110 (Oct. 18, 1979)
Advisory Council on Historic Preservation, 44 FR 40653 (July 12, 1979)*
Agency for International Development, 44 FR 56378 (Oct. 1, 1979)
Civil Aeronautics Board, 44 FR 45637 (Aug. 3, 1979)
Department of Agriculture:
- Agriculture Stabilization and Conservation Service, 44 FR 44167 (July 27, 1979) [correction: 44 FR 45631 (Aug. 3, 1979)]
- Rural Electrification Administration, 44 FR 28363 (May 15, 1979)*

Department of Defense:
Department of the Air Force, 44 FR 44118 (July 26, 1979)*
Department of the Army, Corps of Engineers, 44 FR 38292 (June 29, 1979)*
Department of Commerce: National Oceanic and Atmospheric Administration, 44 FR 60779 (Oct. 22, 1979)
Department of Energy, 44 FR 42136 (July 18, 1979): Federal Energy Regulatory Commission, 44 FR 50052 (Aug. 27, 1979)*
Department of Housing and Urban Development: Community Development Block Grant Program 44 FR 45568 (Aug. 2, 1979)*
Department of the Interior, 44 FR 40436 (July 10, 1979)*:
Bureau of Reclamation, 44 FR 47627 (Aug. 14, 1979)
Heritage Conservation and Recreation Service, 44 FR 49523 (Aug. 23, 1979)
Department of Justice, 44 FR 43751 (July 26, 1979)*:
Drug Enforcement Agency, 44 FR 43754 (July 26, 1979)*
Immigration and Naturalization Service, 44 FR 43754 (July 26, 1979)*
Bureau of Prisons, 44 FR 43753 (July 26, 1979)*
Department of State, (at the Federal Register)
Department of Transportation:
Coast Guard, 44 FR 59306 (Oct. 15, 1979)
Federal Aviation Administration, 44 FR 32094 (June 4, 1979)*
Federal Highway Administration, 44 FR 59438 (Oct. 15, 1979)
Federal Railroad Administration, 44 FR 40174 (July 9, 1979)*
Urban Mass Transportation Administration, 44 FR 59438 (Oct. 15, 1979)
Department of the Treasury, 44 FR 39692 (July 6, 1979)*
Federal Communications Commission, 44 FR 38913 (July 3, 1979)**
Federal Maritime Commission, 44 FR 29122 (May 18, 1979)
Federal Trade Commission, 44 FR 42712 (July 20, 1979)
General Services Administration, 44 FR 33485 (June 11, 1979)*: Public Buildings Program, 44 FR 27473 (May 10, 1979)
International Boundary and Water Commission (U.S. Section). 44 FR 61665 (Oct. 26, 1979)
National Capitol Planning Commission, 44 FR 33185 (June 8, 1979)*
National Science Foundation, 44 FR 46901 (Aug. 9, 1979)**
Pennsylvania Avenue Development Corporation, 44 FR 45925 (Aug. 6, 1979)
Postal Service, 44 FR 36991 (June 25, 1979) [Addition—44 FR 52262 (Sept. 7, 1979)]*
Small Business Administration, 44 FR 45002 (July 31, 1979)*
Tennessee Valley Authority, 44 FR 39679 (July 6, 1979)*
Veterans Administration, 44 FR 48281 (Aug. 17, 1979)*
Water Resources Council, 44 FR 43749 (July 26, 1979)**

Category No. 3: Anticipate Publication of Proposed Procedures by Nov. 16, 1979

This category includes agencies that are expected to publish proposed procedures in the Federal Register by Nov. 16, 1979.

Department of Agriculture: Science and Education Administration
Department of Health, Education, and Welfare: Food and Drug Administration
Department of Housing and Urban Development
Department of Labor
Federal Emergency Management Agency
Nuclear Regulatory Commission

Category No. 4: Publication of Proposed Procedures Delayed Beyond Nov. 16, 1979

This category includes agencies that are *not* expected to publish proposed procedures in the Federal Register by Nov. 16, 1979.

Appalachian Regional Commission
Arms Control and Disarmanment Agency
Community Services Administration
Consumer Product Safety Commission
Department of Agriculture: Farmers Home Administration
Department of Commerce: Economic Development Administration
Department of Defense:
Department of the Army
Department of the Navy
Defense Logistics Agency
Department of the Interior:
Bureau of Indian Affairs
Bureau of Land Management
Bureau of Mines
Fish and Wildlife Service
Geological Survey
National Park Service
Office of Surface Mining Reclamation and Control
Department of Justice: Law Enforcement Assistance Administration
Department of Transportation:
National Highway Traffic Safety Administration
Saint Lawrence Seaway Corporation
Farm Credit Administration
Federal Deposit Insurance Corporation
Federal Home Loan Bank Board
Federal Reserve System
Federal Savings and Loan Insurance Corporation
Interstate Commerce Commission
METRO
National Credit Union Administration
Securities and Exchange Commission

The development of agency implementing procedures is a critical stage in Federal efforts to reform the NEPA process. These procedures must, of course, be consistent with the Council's regulations and provide the means for reducing paperwork and delay and producing better decisions in agency planning and decisionmaking.

Interested persons will have the opportunity to make their suggestions for improving agency procedures when they are published in the Federal Register in proposed form. Broad public participation at this crucial juncture could go a long way toward ensuring that the goals of the NEPA regulations are widely implemented in the day-to-day activities of government.

October 30 1979.

Nicholas C. Yost,

General Counsel.

[FR Doc 79-34022 Filed 11-1-79; 8:45 am]

BILLING CODE 3125-01-M

THE COMMISSION OF FINE ARTS

Appearance of Washington, D.C.; Meeting

The Commission of Fine Arts will next meet in open session on Tuesday, December 11, 1979, at 10:00 a.m. in the Commission's offices at 708 Jackson Place, N.W., Washington, D.C. 20006 to discuss various projects affecting the appearance of Washington, D.C.

Inquiries regarding the agenda and requests to submit written or oral statements should be addressed to Mr. Charles H. Atherton, Secretary, Commission of Fine Arts, at the above address.

Dated in Washington, D.C., October 29, 1979.

Charles H. Atherton,

Secretary.

[FR Doc. 79-34008 Filed 11-1-79; 8:45 am]

BILLING CODE 6330-01-M

COMMITTEE FOR PURCHASE FROM THE BLIND AND OTHER SEVERELY HANDICAPPED

Procurement List 1979; Addition

AGENCY: Committee for Purchase from the Blind and Other Severely Handicapped.

ACTION: Addition to Procurement List.

SUMMARY: This action adds to Procurement List 1979 a service to be provided by workshops for the blind and other severely handicapped.

EFFECTIVE DATE: November 2, 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 May 18, 1979 the Committee for Purchase from the Blind and Other Severely Handicapped published a notice (44 F.R. 29136) of proposed addition to Procurement List 1979, November 15, 1978 (43 F.R. 53151).

After consideration of the relevant matter presented, the Committee has determined that the service listed below is suitable for procurement by the Federal Government under 41 U.S.C. 46-48c, 85 Stat. 77.

Accordingly, the following service is hereby added to Procurement List 1979:

SIC 0782

Grounds Maintenance, Mare Island Housing Areas:
Coral Sea Village, Bldg. 301D-4
Farragut South, Bldg. 302D-3
Farragut Central, Bldg. 303E-3
Farragut North
Mare Island Naval Shipyard, Vallejo, California.

E. R. Alley, Jr.,

Acting Executive Director.

[FR Doc. 79-33997 Filed 11-1-79; 8:45 am]

BILLING CODE 6820-33-M

Procurement List 1979; Proposed Addition

AGENCY: Committee for Purchase from the Blind and Other Severely Handicapped.

ACTION: Proposed Addition to Procurement List.

SUMMARY: The Committee has received a proposal to add to Procurement List 1979 a commodity to be produced by workshops for the blind and other severely handicapped.

COMMENTS MUST BE RECEIVED ON OR BEFORE: December 5, 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 addition, all entities of the Federal Government will be required to procure the commodity listed below from workshops for the blind or other severely handicapped.

It is proposed to add the following commodity to Procurement List 1979, November 15, 1978 (43 FR 53151):

Class 7530

Pad, Writing Paper, 7530-00-239-8479 (GSA National Capital Region)

E. R. Alley, Jr.,

Acting Executive Director.

[FR Doc. 79-33993 Filed 11-1-79; 8:45 am]

BILLING CODE 6820-33-M

DEPARTMENT OF DEFENSE

Corps of Engineers; Department of the Army

Intent To Prepare a Draft Environmental Impact Statement (DEIS) for Denison Dam (Lake Texoma) Restudy on the Red River, Okla., and Tex.

AGENCY: US Army Corps of Engineers, DOD, Tulsa District.

ACTION: Notice of Intent to Prepare a Draft Environmental Impact Statement (DEIS).

SUMMARY: 1. The primary purpose of our study is to determine if the Lake Texoma project should be modified to satisfy existing and predicted water resource problems and needs including flood control, water supply, hydropower, recreation, and fish and wildlife.

2. Reasonable Alternatives: Evaluation included various alternatives to change the lake level and to add different numbers of generators, conversion of power storage to water supply or irrigation, construction of additional recreation facilities and no action.

3. Corps Scoping Process:

a. Public Involvement: A comprehensive public involvement program was developed as a means of disseminating information and soliciting public views. A variety of techniques including formal public meetings, public workshops, and the local news media were employed to involve the Federal, State, and local agencies, citizen committees, organizations, and the interested public in the planning studies.

b. Significant Issues Requiring In-Depth Analysis: None.

c. Assignments: US Fish and Wildlife Service is preparing a Fish and Wildlife Coordination Act Report.

d. Environmental Review and Consultation Requirements: The draft environmental impact statement will be circulated for review and all comments will be incorporated into the final environmental impact statement.

4. Scoping meeting will not be held.

5. Estimated date when the DEIS will be available: November 1979.

ADDRESS: Mr. Buell O. Atkins, Chief, Environmental Resources Branch, US Army Corps of Engineers, Tulsa District, PO Box 61, Tulsa, OK 74121, (918) 581-7857, FTS 736-7857.

Dated: October 25, 1979.

Robert G. Bening,

Colonel, CE, District Engineer.

[FR Doc. 79-33906 Filed 11-1-79; 8:45 am]

BILLING CODE 3710-39-M

DEPARTMENT OF ENERGY

Economic Regulatory Administration

Receipt of Petitions for Temporary Public Interest Exemptions for Use of Natural Gas by Existing Powerplants Under the Powerplant and Industrial Fuel Use Act of 1978 and Proposed Order Granting the Temporary Exemptions; Correction

AGENCY: Economic Regulatory Administration, Department of Energy.

ACTION: Correction to 44 FR 60792, October 22, 1979.

SUMMARY: This notice will serve to correct 44 FR 60792 published on October 22, 1979. The table which appears on page 60793 has been amended; specifically the figures in the column indentified as: *Max. Quantity of Oil Displaced Barrels/per day,* have been revised as follows:

Petitioner generating station	Unit identification	Maximum quantity of oil displaced barrels/per day	Type of oil displaced	Coal displaced
Portland General Electric Co. (Bethel)	CT 1	49	Distillate	No
Rochester Public Utilities (Cascade Creek)	No. 1	57.5	Distillate	No
Nebraska Public Power District (Ogallala)	No. 1	52	Distillate	No
(Bluffs)	No. 2	2.7	Distillate	No
Savannah Electric & Power Company (Port Wentworth).	CT 1	54.8	Distillate	No
(Boulevard)	CT 1, CT 2, and CT 3	213.7	Distillate	No
Board of Public Utilities, City of McPherson (Municipal Plant).	GT 1, GT 2, and GT 3	468.5	Distillate	No
The Washington Water Power Company (Northeast Combustion Turbine).	CT 1	65.8	Distillate	No
Tri-State Generation & Transmission Association, Inc. (Republican River).	CT 1, CT 2, and CT 3	342.5	Distillate	No
(Burlington)	CT 1 and CT 2	243.8	Distillate	No.
City of Crete Utilities Department (Crete)	No. 1	32.9	Distillate	No

Issued in Washington, D.C., on October 26, 1979.

Robert L. Davies,

Acting Assistant Administrator, Office of Fuels Conversion, Economic Regulatory Administration.

[FR Doc. 79-33901 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

Western Area Power Administration

Fort Peck-Havre 161-kV Electrical Transmission Line, Montana; Intent To Prepare an Environmental Impact Statement

Notice is hereby given that in accordance with the National Environmental Policy Act of 1969 (NEPA), the Western Area Power Administration (Western) has commenced preparation of an environmental impact statement (EIS) to assess the environmental implications of a proposed Western action to reconstruct the Fort Peck-Havre 161-kV electrical transmission line. The proposed action would be located in Montana in the counties of McCone, Valley, Phillips, Blaine and Hill; and would generally follow the Milk River and U.S. Highway 2 for 188 miles between Fort Peck and Havre.

The existing Fort Peck-Havre 161-kV transmission line was constructed in 1935 and is the major west side transmission connection for the Fort Peck powerplant. It provides service to Federal and non-Federal loads along its route.

The existing 44-year old line is of wood pole H-frame construction and the poles are in advanced stages of shell rot. The poles are dangerous to climb, subject to repeated failures and require high maintenance costs. The line was initially designed and constructed under minimum design criteria making it the source of excessive radio noise. It is also susceptible to lightning strikes because of the absence of overhead ground wires, causing an excessive number of voltage irregularities and power outages.

A number of environmental and local issues have been identified. These issues include the possibilities of locating structures within floodplains or wetlands, encroachment onto the Bowdoin National Wildlife Refuge, impacting Federal or State listed or proposed threatened or endangered species or critical habitats, esthetic impacts, crossing irrigated or irrigable agricultural land, crossing the Fort Belknap Indian Reservation, and causing an adverse effect on historic or cultural properties that are included in or eligible for inclusion in the National Register.

Alternatives currently planned to be assessed in the EIS include the no action alternative, rebuilding the existing line at the existing voltage, upgrading the line to 230-kV in the existing right-of-way, and upgrading to 230-kV in a new right-of-way to the south which would avoid the irrigated land and river crossings.

It is planned that four scoping meetings will be held. They will be held at Glasgow, Malta, Chinook and Havre, Montana. A separate public notice of the meetings will be issued to Federal, State, and local agency officials and the general public when the exact locations and dates have been finalized.

The draft EIS is tentatively scheduled to be released to the public for review and comment during January 1981. The final EIS is tentatively scheduled for release during July 1981.

All interested agencies, organizations, and persons are invited to submit questions on the proposed project and comments and suggestions on the proposed scope of the EIS, including issues and alternatives, and comments and suggestions for consideration in the preparation of the draft EIS. Questions, comments and suggestions should be submitted to Gary W. Frey, Environmental Manager, Western Area Power Administration, Department of Energy, P.O. Box 3402, Golden, Colorado 80401 (telephone 303-231-1527). Comments and suggestions should be submitted to Mr. Frey on or before November 16, 1979. Upon completion of the draft EIS, its availability will be announced in the Federal Register at which time public comments will again be solicited.

Issued in Golden, Colo., October 19, 1979.

For the Department of Energy, Western Area Power Administration.

Robert L. McPhail,

Administrator.

[FR Doc. 79-33903 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

Economic Regulatory Administration

ADA Resources, Inc.; Action Taken on Consent Order

ACTION: Economic Regulatory Administration, Department of Energy.

ACTION: Notice of Action taken and opportunity for comment on Consent Order.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) announces action taken to execute a Consent Order and provides an opportunity for public comment on the Consent Order and on potential claims against the refunds deposited in an escrow account established pursuant to the Consent Order.

DATES: Effective date: October 16, 1979. Comments by: December 3, 1979.

ADDRESS: Send comments to: Wayne I. Tucker, District Manager of Enforcement, Southwest District Office, Department of Energy, P.O. Box 35228, Dallas, Texas 75235.

FOR FURTHER INFORMATION CONTACT: Wayne I. Tucker, District Manager of Enforcement, Southwest District Office, Department of Energy, P.O. Box 35228, Dallas, TX 75235 [phone] 214/767-7745.

SUPPLEMENTARY INFORMATION: On October 16, 1979, the Office of Enforcement of the ERA executed a Consent Order with Ada Resources, Inc. of Houston, TX. Under 10 CFR 205.199J(b), a Consent Order which involves a sum of less than $500,000 in the aggregate, excluding penalties and interest, becomes effective upon its execution.

Because the DOE and ADA Resources, Inc. wish to expeditiously resolve this matter as agreed and to avoid delay in the payment of refunds, the DOE has determined that it is in the public interest to make the Consent Order with Ada Resources, Inc. effective as of the date of its execution by the DOE and Ada Resources, Inc.

I. The Consent Order

Ada Resources, Inc. (formerly doing business as Ada Oil Company), with its home office in Houston, Texas, is a firm engaged in the resale of petroleum products, and is subject to the Mandatory Petroleum Price and Allocation Regulations at 10 CFR, Parts 210, 211, 212. To resolve certain civil actions which could be brought by the Office of Enforcement of the Economic Regulatory Administration as a result of its audit of Ada Resources, Inc.'s sales as a reseller of petroleum products, the Office of Enforcement, ERA, and ADA Resources, Inc. entered into a Consent Order, the significant terms of which are as follows:

1. The periods covered by the audit were November 1, 1973, through June 30, 1974, for sales of natural gasoline, butane and bunker "C" fuel, and November 1, 1973, through August 31, 1974, for sales of motor gasoline, No. 2 diesel fuel, kerosene and aviation fuel.

2. Ada Resources, Inc. improperly applied the provisions of 10 CFR 212.93 (6 CFR 150.359 prior to January 15, 1974) when determining the prices to be charged for its petroleum products, and as a consequence certain of its customers were overcharged on some of their purchases.

3. Ada Resources, Inc. agrees to refund to the DOE $100,000, including interest, within 30 days of the effective date of the Consent Order, October 16, 1979.

4. The provisions of 10 CFR 205.199J, including the publication of this Notice, are applicable to the Consent Order.

II. Dispostion of Refunded Overcharges

In this Consent Order, Ada Resources, Inc. agrees to refund, in full settlement of any civil liability with respect to actions which might be brought by the Office of Enforcement, ERA, arising out of the transactions specified in I.1 above, the sum of $100,000 within 30 days of the effective date of this Consent Order. Refunded overcharges will be in the form of a certified check made payable to the United States Department of Energy and will be delivered to the Assistant Administrator for Enforcement, ERA. These funds will remain in a suitable account pending the determination of their proper disposition.

The DOE intends to distribute the refund amounts in a just and equitable manner in accordance with applicable laws and regulations. Accordingly, distribution of such refunded overcharges requires only those "persons" (as defined at 10 CFR 205.2) who actually suffered a loss as a result of the transactions described in the Consent Order receive appropriate refunds. Because of the petroleum industry's complex marketing system, it is likely that overcharges have either been passed through as higher prices to subsequent purchasers or offset through devices such as the Old Oil Allocation (Entitlements) Program, 10 CFR 211.67. In fact, the adverse effects of the overcharges may have become so diffused that it is a practical impossibility to identify specific, adversely affected persons, in which case disposition of the refunds will be made in the general public interest by an appropriate means such as payment to the Treasury of the United States pursuant to 10 CFR 205.199I(a).

III. Submission or Written Comments

A. *Potential Claimants:* Interested persons who believe that they have a claim to all or a portion of the refund amount should provide written notification of the claim to the ERA at this time. Proof of claims is not now being required. Written notification to the ERA at this time is requested primarily for the purpose of identifying valid potential claims to the refund amount. After potential claims are identified, procedures for the making of proof of claims may be established. Failure by a person to provide written notification of a potential claim within the comment period for this Notice may result in the DOE irrevocably disbursing the funds to other claimants or to the general public interest.

b. *Other Comments:* The ERA invites interested persons to comment on the terms, conditions, or procedural aspects of this Consent Order.

You should send your comments or written notification of a claim to Wayne I. Tucker, District Manager of Enforcement, Southwest District Office, Department of Energy, P.O. Box 35228, Dallas, TX. You may obtain a free copy of this Consent Order by writing to the same address or by calling 214/767-7745.

You should identify your comments or written notification of a claim on the outside of your envelope and on the documents you submit with the designation, "Comments on Ada Resources, Inc. Consent Order." We will consider all comments we receive by 4:30 p.m. local time, on December 3, 1979. You should identify any information or data which, in your opinion, is confidential and submit it in accordance with the procedures in 10 CFR 205.9(f).

Issued in Dallas, TX on the 23rd day of October, 1979.

Wayne I. Tucker,

District Manager of Enforcement, Southwest District Office, Economic Regulatory Administration.

[FR Doc. 79-33926 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

Adams Resources & Energy, Inc.; Action Taken on Consent Order

AGENCY: Economic Regulatory Administration, Department of Energy.

ACTION: Notice of action taken and opportunity for comment on Consent Order.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) announces action taken to execute a Consent Order and provides an opportunity for public comment on the Consent Order and on potential claims against the refunds deposited in an escrow account established pursuant to the Consent Order.

DATES: Effective Date: October 11, 1979.

COMMENTS BY: December 3, 1979.

ADDRESS: Send comments to: Wayne I. Tucker, District Manager of Enforcement, Southwest District Office, Department of Energy, P.O. Box 35228, Dallas, Texas 75235.

FOR FURTHER INFORMATION CONTACT: Wayne I. Tucker, District Manager of Enforcement, Southwest District Office, Department of Energy, P.O. Box 35228, Dallas, Texas 75235—(214) 767-7745.

SUPPLEMENTARY INFORMATION: On October 11, 1979, the Office of Enforcement of the ERA executed a Consent Order with Adams Resources & Energy, Inc. of Houston, Texas. Under 10 CFR 205.199J(b), a Consent Order which involves a sum of less than $500,000 in the aggregate, excluding penalties and interest, becomes effective upon its execution.

I. The Consent Order

Adams Resources & Energy, Inc., with its office located in Houston, is a firm engaged in crude oil production, and is subject to the Mandatory Petroleum Price and Allocation Regulations at 10 CFR, Parts 210, 211, 212. To resolve certain civil actions which could be brought by the Office of Enforcement of the Economic Regulatory Administration as a result of its audit of crude oil sales, the Office of Enforcement, ERA, and Adams Resources & Energy, Inc., entered into a Consent Order, the significant terms of which are as follows:

1. The period covered by the audit was September 1973 through May 1979, and it included all sales of crude oil which were made during that period for the properties listed in the Consent Order.

2. Adams Resources & Energy Inc. improperly applied the provisions of 6 CFR Part 150, Subpart L and 10 CFR Part 212, Subpart D, when determining the prices to be charged for crude oil; and as a consequence, charged prices in excess of the maximum lawful sales price resulting in overcharges to its customers.

3. In order to expedite resolution of the disputes involved, the DOE and Adams Resources & Energy Inc. have agreed to a settlement in the amount of $80,000.00. The refund will be made in three quarterly payments beginning September 30, 1979 and ending on March 31, 1980. A detailed schedule of the refund payments is contained in the Consent Order.

4. The sales of crude oil determined to be in violation were made to several refiners and because the ultimate consumers are not readily identifiable, the refund will be made through the

DOE in accordance with 10 CFR Part 205, Subpart V as provided below.

5. The provisions of 10 CFR 205.199J including the publication of this Notice, are applicable to the Consent Order.

II. Disposition of Refunded Overcharges

In this Consent Order, Adams Resources & Energy Inc. agrees to refund, in full settlement of any civil liability with respect to actions which might be brought by the Office of Enforcement, ERA, arising out of the transactions specified in I.1. above, the sum of $80,000.00 on or before March 31, 1980. Refunded overcharges will be in the form of a certified check made payable to the United States Department of Energy and will be delivered to the Assistant Administrator for Enforcement, ERA. These funds will remain in a suitable account pending the determination of their proper disposition.

The DOE intends to distribute the refund amounts in a just and equitable manner in accordance with applicable laws and regulations. Accordingly, distribution of such refunded overcharges requires that only those "persons" (as defined at 10 CFR 205.2) who actually suffered a loss as a result of the transactions described in the Consent Order receive appropriate refunds. Because of the petroleum industry's complex marketing system, it is likely that overcharges have either been passed through as higher prices to subsequent purchasers or offset through devices such as the Old Oil Allocation (Entitlements) Program, 10 CFR 211.67. In fact, the adverse effects of the overcharges may have become so diffused that it is a practical impossibility to identify specific, adversely affected persons, in which case disposition of the refunds will be made in the general public interest by an appropriate means such as payment to the Treasury of the United States pursuant to 10 CFR 205.199I(a).

III. Submission of Written Comments

A. *Potential Claimants*: Interested persons who believe that they have a claim to all or a portion of the refund amount should provide written notification of the claims to the ERA at this time. Proof of claims is not now being required. Written notification to the ERA at this time is requested primarily for the purpose of identifying valid potential claims to the refund amount. After potential claims are identified, procedures for the making of proof of claims may be established. Failure by a person to provide written notification of a potential claim within the comment period for this Notice may result in the DOE irrevocably disbursing the funds to other claimants or to the general public interest.

B. *Other Comments*. The ERA invites interested persons to comment on the terms, conditions, or procedural aspects of this Consent Order. You should send your comments or written notification of a claim to Wayne I. Tucker, District Manager of Enforcement, Southwest District Office, Department of Energy, P.O. Box 35228, Dallas, Texas 75235. You may obtain a free copy of this Consent Order by writing to the same address or by calling (214) 767-7745.

You should identify your comments or written notification of a claim on the outside of your envelope and on the documents you submit with the designation, "Comments on Adams Resources & Energy, Inc. Consent Order." We will consider all comments we receive by 4:30 p.m., local time, on December 3, 1979. You should identify any information or data which, in your opinion, is confidential and submit it in accordance with the procedures in 10 CFR 205.9(f).

Issued in Dallas, Texas on the 23 day of October, 1979.

Wayne I. Tucker,

District Manager of Enforcement, Southwest District, Economic Regulatory Administration.

[FR Doc. 79-33925 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

Al Brown, Oil Operator; Action Taken on Consent Order

AGENCY: Economic Regulatory Administration, Department of Energy.

ACTION: Notice of action taken and opportunity for comment on Consent Order.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) announces action taken to execute a Consent Order and provides an opportunity for public comment on the Consent Order and on potential claims against the refunds deposited in an escrow account established pursuant to the Consent Order.

DATES: Effective date: October 15, 1979. Comments by December 3, 1979.

ADDRESS: Send comments to: Wayne I. Tucker, District Manager of Enforcement, Economic Regulatory Administration, Department of Energy, P.O. Box 35228, Dallas, Texas 75235.

FOR FURTHER INFORMATION CONTACT: Wayne I. Tucker, District Manager of Enforcement, Economic Regulatory Administration, Department of Energy, P.O. Box 35228, Dallas, Texas 75235. Phone: 214/767-7745.

SUPPLEMENTARY INFORMATION: On October 15, 1979, the Office of Enforcement of the ERA executed a Consent Order with Al Brown, Oil Operator of Houston, Texas. Under 10 CFR 205.199J(b), a Consent Order which involves a sum of less than $500,000 in the aggregate, excluding penalties and interest, becomes effective upon its execution.

I. The Consent Order

Al Brown, Oil Operator (Brown), with its office located in Houston, Texas, is a firm engaged in the production and sale of crude oil, and is subject to the Mandatory Petroleum Price and Allocation Regulations at 10 CFR, Parts 210, 211 and 212. To resolve certain civil actions which could be brought by the Office of Enforcement of the Economic Regulatory Administration as a result of its audit of Brown, the Office of Enforcement, ERA, and Brown entered into a Consent Order, the significant terms of which are as follows:

1. The Consent Order covers sales of crude oil to Sun Oil Company and the Permian Corporation during the period September 1, 1973 through December 31, 1977.

2. The ERA has alleged violations of the ceiling prices for crude oil set forth in 10 CFR, Part 212, Subpart D.

3. Brown admits no liability.

4. The provisions of 10 CFR 205.199J, including the publication of this Notice, are applicable to the Consent Order.

II. Disposition of Refunded Overcharges

In this Consent Order, Brown agrees to refund, in full settlement of any civil liability with respect to actions which might be brought by the Office of Enforcement, ERA, arising out of the transactions specified in I.1. above, the sum of $31,203.15 on or before May 31, 1980. Refunded overcharges will be in the form of a certified check made payable to the United States Department of Energy and will be delivered to the Assistant Administrator for Enforcement, ERA. These funds will remain in a suitable account pending the determination of their proper disposition. The DOE intends to distribute the refund amounts in a just and equitable manner in accordance with applicable laws and regulations. Accordingly, distribution of such refunded overcharges requires that only those "persons" (as defined at 10 CFR 205.2) who actually suffered a loss as a result of the transactions described in the Consent Order receive appropriate refunds. Because of the petroleum industry's complex marketing system, it

is likely that overcharges have either passed through as higher prices to subsequent purchasers or offset through devices such as the Old Oil Allocation (Entitlements) Program, 10 CFR 211.67. In fact, the adverse effects of the overcharges may have become so diffused that it is a practical impossiblility to identify specific, adversely affected persons, in which case disposition of the refunds will be made in the general public interest by an appropriate means such as payment to the Treasury of the United States pursuant to 10 CFR 205.199J(a).

III. Submission of Written Comments

A. *Potential Claimants:* Interested persons who believe that they have a claim to all or a portion of the refund amount should provide written notification of the claim to the ERA at this time. Proof of claims is not now being required. Written notification to the ERA at this time is requested primarily for the purpose of identifying valid potential claims to the refund amount. After potential claims are identified, procedures for the making of proof of claims may be established. Failure by a person to provide written notification of a potential claim within the comment period for this Notice may result in the DOE irrevocably disbursing the funds to other claimants or to the general public interest.

B. *Other Comments:* The ERA invites interested persons to comment on the terms, conditions, or procedural aspects of this Consent Order. You should send your comments or written notification of a claim to Mr. Wayne I. Tucker, Economic Regulatory Administration, Department of Energy, P.O. Box 35228, Dallas, Texas 75235. You may obtain a free copy of this Consent Order by writing to the same address or by calling 214/767-7745.

You should identify your comments or written notification of a claim on the outside of your envelope and on the documents you submit with the designation, "Comments on Al Brown Consent Order". We will consider all comments we receive by 4:30 p.m., local time, on December 3, 1979. You should identify any information or data which, in your opinion, is confidential and submit it in accordance with the procedures in 10 C.F.R. Section 205.9(f).

Issued in Dallas, Texas on the 23rd day of October, 1979.

Wayne I. Tucker,

District Manager of Enforcement.

[FR Doc. 79-33928 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

C & K Petroleum, Inc.; Action Taken on Consent Order

AGENCY: Economic Regulatory Administration, Department of Energy.

ACTION: Notice of action taken and opportunity for comment on Consent Order.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) announces action taken to execute a Consent Order and provides an opportunity for public comment on the Consent Order and on potential claims against the refunds deposited in an escrow account established pursuant to the Consent Order.

DATES: Effective Date: October 16, 1979.

ADDRESS: Send comments to: Wayne I. Tucker, District Manager of Enforcement, Southwest District Office, Department of Energy, P.O. Box 35228, Dallas, Texas 75235.

FOR FURTHER INFORMATION CONTACT: Wayne I. Tucker, District Manager of Enforcement, Southwest District Office, Department of Energy, P.O. Box 35228, Dallas, Texas 75235—(214) 767-7745.

SUPPLEMENTARY INFORMATION: On October 16, 1979, the Office of Enforcement of the ERA executed a Consent Order with C & K Petroleum, Inc. of Houston, Texas. Under 10 CFR 205.199J(b), a Consent Order which involves a sum of less than $500,000 in the aggregate, excluding penalties and interest, becomes effective upon its execution.

I. The Consent Order

C & K petroleum, Inc., with its office located in Houston, Texas, is a firm engaged in crude oil production, and is subject to the Mandatory Petroleum Price and Allocation Regulations at 10 CFR, Parts 210, 211, 212. To resolve certain civil actions which could be brought by the Office of Enforcement of the Economic Regulatory Administration as a result of its audit of crude oil sales, the Office of Enforcement, ERA, and C & K Petroleum, Inc., entered into a Consent Order, the significant terms of which are as follows:

1. The period covered by the audit was September 1973 through March 1979, and it included all sales of crude oil which were made during that period for the properties listed in the Consent Order.

2. C & K Petroleum, Inc. improperly applied the provisions of 6 CFR Part 150, Subpart L and 10 CFR Part 212, Subpart D, when determining the prices to be charged for crude oil, and as a consequence, charged prices in excess of the maximum lawful sales price resulting in overcharges to its customers.

3. In order to expedite resolution of the disputes involved, the DOE and C & K Petroleum, Inc. have agreed to a settlement in the amount of $265,000.00. The refund will be made within 30 days of the effective date of the Consent Order.

4. The sales of crude oil determined to be in violation were made to several refiners and because the ultimate consumers are not readily identifiable, the refund will be made through the DOE in accordance with 10 CFR Part 205, Subpart V as provided below.

5. The provisions of 10 CFR 205.199J, including the publication of this Notice, are applicable to the Consent Order.

II. Disposition of Refunded Overcharges

In this Consent Order, C & K Petroleum, Inc. agrees to refund, in full settlement of any civil liability with respect to actions which might be brought by the Office of Enforcement, ERA, arising out of the transactions specified in I.1. above, the sum of $265,000.00 on or before Refunded overcharges will be in the form of a certified check made payable to the United States Department of Energy and will be delivered to the Assistant Administrator for Enforcement, ERA. These funds will remain in a suitable account pending the determination of their proper disposition.

The DOE intends to distribute the refund amounts in a just and equitable manner in accordance with applicable laws and regulations. Accordingly, distribution of such refunded overcharges requires that only those "persons" (as defined at 10 CFR 205.2) who actually suffered a loss as a result of the transactions described in the Consent Order receive appropriate refunds. Because of the petroleum industry's complex marketing system, it is likely that overcharges have either been passed through as higher prices to subsequent purchasers or offset through devices such as the Old Oil Allocation (Entitlements) Program, 10 CFR 211.67. In fact, the adverse effects of the overcharges may have become so diffused that it is a practical impossibility to identify specific, adversely affected persons, in which case disposition of the refunds will be made in the general public interest by an appropriate means such as payment to the Treasury of the United States pursuant to 10 CFR 205.199I(a).

III. Submission of Written Comments

A. *Potential Claimants:* Interested persons who believe that they have a cliam to all or a portion of the refund

amount should provide written notification of the claim to the ERA at this time. Proof of claims is not now being required. Written notifications to the ERA at this time is requested primarily for the purpose of identifying valid potential claims to the refund amount. After potential claims are identified, procedures for the making of proof of claims may be established. Failure by a person to provide written notification of a potential claim within the comment period for this Notice may result in the DOE irrevocably disbursing the funds to other claimants or to the general public interest.

B. *Other Comments.* The ERA invites interested persons to comment on the terms, conditions, or procedural aspects of this Consent Order. You should send your comments or written notification of a claim to Wayne I. Tucker, District Manager of Enforcement, Southwest District Office, Department of Energy, P.O. Box 35228, Dallas, Texas 75235. You may obtain a free copy of this Consent Order by writing to the same address or by calling (214) 767-7745.

You should identify your comments or written notification of a claim on the outside of your envelope and on the documents you submit with the designation, "Comments on C & K Petroleum, Inc. Consent Order." We will consider all comments we receive by 4:30 p.m., local time on December 3, 1979. You should identify any information or data which, in your opinion, is confidential and submit it in accordance with the procedures in 10 CFR 205.9(f).

Issued in Dallas, Texas on the 23 day of October, 1979.

Wayne I. Tucker,

District Manager for Enforcement, Southwest District, Economic Regulatory Administration.

[FR Doc. 79-33927 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Docket No. RI79-41]

An-Son Corp.; Petition for Special Relief

October 29, 1979.

Take notice that on June 11, 1979, An-Son Corporation (An-Son), 3814 N. Santa Fe, Oklahoma City, Oklahoma, 73118, filed a petition for special relief pursuant to Section 2.76 of the Commission's Rules and Regulations under the Natural Gas Act. An-Son seeks an increase in its rate from 49.9 cent per Mcf to 79 cent per Mcf for the sale of gas from the Barby-Featherstone well in Beaver County, Oklahoma to Northern Natural Gas Company. An-Son states the increase is necessary in order to install compression facilities.

Any person desiring to be heard or to make any protest with reference to said petition should on or before November 19, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426 a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to ask the protestants parties to the proceeding. Any party wishing to become a party to a proceeding, or to participate as a party in any hearing therein, must file a petition to intervene in accordance with the Commission's Rules.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-33930 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CI73-293]

Belco Petroleum Corp., Agent; Petition To Clarify Certificate of Public Convenience and Necessity

October 29, 1979.

Take notice that on September 14, 1979, Belco Petroleum Corporation, Agent ("Belco"), One Dag Hammarskjold Plaza, New York, New York 10017, filed a petition pursuant to Section 1.7 of the Commission's Rules of Practice and Procedure, requesting a modification of the Certificate of Public Convenience and Necessity issued in Opinion No. 659, Docket No. CI73-293.[1] Specifically, Belco requests that (1) the plowback obligation, embodied in Ordering Paragraph (H) be clarified to reflect that the obligation, in keeping with Belco's refund exposure, is limited to the actual revenues Belco has received under the certificate in excess of those which it would have received at the area rate of 26¢ per Mcf; and (2) the period for completing that obligation be extended from ten to 15 years.

Any person desiring to be heard or to make any protest with reference to said application should on or before November 19, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-33931 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

[1] 49 F.P.C. 1154 (1973), on rehearing Opinion No. 659-A, 50 F.P.C. 164 (1973).

[Docket No. EL80-2]

City of Gallup v. Public Service Co. of New Mexico; Notice of Filing

October 29, 1979.

The filing party submits the following:

Take notice that on October 9, 1979, the City of Gallup, New Mexico (City) filed a complaint, a motion for declaratory order, and a motion for an order compelling interconnection by the City, against the Public Service Company of New Mexico (PNM).

The City is bringing this action in order to obtain a fourth point of interconnection for the delivery of electric power and energy from PNM to the City. PNM is contractually obligated to provide all of the power and energy requirements of the City, and the fourth point of interconnection is necessary if the City's electric energy requirements are to be met.

A copy of this filing has been served upon the Public Service Company of New Mexico, the firm of Keleher and McLeod, and the firm of Morgan, Lewis, and Bockius.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). All such petitions or protests should be filed on or before November 23, 1979. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-33932 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP79-485]

Kentucky West Virginia Gas Co.; Application

October 29, 1979.

Take notice that on September 12, 1979, Kentucky West Virginia Gas Company (Kentucky), Second National Bank Building, Ashland, Kentucky 41101, filed in Docket No. CP79-485 an application pursuant to Section 7(b) of the Natural Gas Act for permission and approval to abandon natural gas service to 44 farm-type service taps through which Kentucky delivers gas to Equitable Gas Company (Equitable) for resale to 44 residential and small commercial customers and to amend the order issued on January 20, 1972 in Docket No. CP72-130 pursuant to Section 7(a) of the Natural Gas Act so as to authorize the delivery and sale of additional volumes of natural gas to Prestonsburg City's Utility Commission (Utility Commission) sufficient to provide service to the 44 retail customers whose service would be abandoned, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Prior to June 1953, Kentucky owned and operated gas well Nos. 219, 282, and 409, in Knotley Hollow located in Floyd County, Kentucky. It is stated that gas from these wells was transported through 2-inch connecting line Nos. W-219, W-282, and W-409 to line No. 3 of Kentucky's gathering system. Kentucky provided gas service from said connecting lines to 36 rural homes and small businesses located near the connecting lines and on December 5, 1958, said retail customers were transferred to Equitable by the Kentucky Public Service Commission, and thereafter Kentucky has sold gas to Equitable for resale to said retail customers.

By June 1953, Kentucky states that the three wells were depleted and plugged and the gas supplied to the 36 domestic customers was "backfed" from Kentucky's gathering system through its said line Nos. W-219, W-282, and W-409.

Since 1953, said connecting lines have become extremely corroded, deteriorated and in dangerous condition. Accordingly, Kentucky is requesting authority to abandon service at the 36 farm-type tap delivery points where gas is delivered to Equitable for sale for resale along Line Nos. W-219, W-282, and W-409, and to abandon service to Equitable at 8 additional farm-type taps located between Knotley Hollow and the existing "Emma" service point where Kentucky sells gas to the Utility Commission. Kentucky also requests amendment of the order issued in Docket No. CP72-130 to permit the delivery and sale of sufficient additional gas to the Utility Commission at the "Emma" service point to provide substitute retail gas service for the 44 customers whose service would be abandoned, and in connection therewith, for approval of a new service agreement increasing the maximum annual and daily contract quantities of deliveries at the Prestonsburg Metering Station at Emma to accommodate the gas requirements of said 44 customers for whom the Utility Commission has agreed to provide replacement gas service.

Any person desiring to be heard or to make any protest with reference to said application should on or before November 19, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.70). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on the application to abandon if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate and permission and approval for the proposed abandonment are required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Kenneth F. Plumb,
Secretary.

[FR Doc. 79-33933 Filed 11-1-79; 8:45 am]
BILLING CODE 6450-01-M

[Docket No. CP80-3]

Lone Star Gas Co., a Division of Enserch Corp.; Application

October 29, 1979.

Take notice that on October 1, 1979, Lone Star Gas Company, a Division of Enserch Corporation (Applicant), 301 South Harwood Street, Dallas, Texas 75201, filed in Docket No. CP80-3 an application pursuant to Section 7(c) of the Natural Gas Act and Section 157.7(b) of the Regulations thereunder (18 CFR 157.7(b)) for a certificate of public convenience and necessity authorizing the construction, during the calendar year 1980, and operation of facilities to enable Applicant to take into its certificated main pipeline system supplies of natural gas which would be purchased from producers and other similar sellers thereof, all as more fully set forth in the application on file with the Commission and open to public inspection.

The stated purpose of this budget-type application is to augment Applicant's ability to act with reasonable dispatch in connecting to its pipeline system supplies of natural gas which may become available from various producing areas generally coextensive with its pipeline system or the systems of other pipeline companies which may be authorized to transport gas for the account of or exchange gas with Applicant.

Applicant states that the total cost of the proposed facilities would not exceed $2,000,000 and that the cost of any single project would not exceed $500,000, which cost Applicant proposes to finance from funds currently on hand.

Any person desiring to be heard or to make any protest with reference to said application should on or before November 19, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C., 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party

to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-33934 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP80-19]

Michigan Wisconsin Pipe Line Co.; Application

October 29, 1979.

Take notice that on October 9, 1979, Michigan Wisconsin Pipe Line Company (Mich Wis), One Woodward Avenue, Detroit, Michigan 48226, filed in Docket No. CP80-19 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the transportation of up to 22,500 Mcf of natural gas per day for Tennessee Gas Pipeline Company, a Division of Tenneco Inc. (Tennessee), all as more fully set forth in the application which is on file with the Commission and open for public inspection.

Pursuant to an order issued August 16, 1978 in Docket No. CP78-18, Mich Wis and four other pipeline transmission companies were authorized to construct and operate lateral pipeline facilities connecting the production platform in High Island area Block A-209, offshore Texas with the east leg of the pipeline systems of High Island Offshore System (HIOS) located in High Island area Block A-332, offshore Texas. At the time of issuance of the certificate, Mich Wis was the only applicant having obtained a commitment of gas reserves underlying Block A-309 and, accordingly, was authorized to own a 100 percent interest in the first segment of the lateral line and corresponding percentage interests in the other segments necessary to deliver the Block A-309 gas supplies to HIOS. Mich Wis indicated that it expected to transport the uncommitted gas reserves underlying Block A-309 for such other companies as may require the right to purchase such reserves.

Subsequently, the application indicates that, Tennessee advised Mich Wis that it acquired by a Gas Purchase Contract dated August 6, 1979, the right to purchase the gas production attributable to a previously uncommitted 45 percent interest of Amoco Production Company. To effectuate receipt of the Block A-309 gas supplies, Tennessee has requested Mich Wis provide transportation service for up to 22,500 Mcf of natural gas per day. The proposed point of receipt would be at the Block A-309 production platform and the point of redelivery would be at the interconnection of the Block A-309 lateral line and the aforementioned east leg of HIOS located in High Island area Block A-332, offshore Texas. From the point of redelivery, Tennessee would utilize its entitlement in both HIOS and U-T Offshore System to effectuate receipt of the Block A-309 gas supplies to its own transmission system.

The transportation agreement provides for a contract monthly demand charge of $2.60 per Mcf of contract demand. The term of the agreement is 15 years which would commence on the date of initial deliveries.

Any person desiring to be heard or to make any protest with reference to said application should on or before November 19, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Mich Wis to appear or be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-33935 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP80-6]

Panhandle Eastern Pipe Line Co.; Application

October 29, 1979.

Take notice that on October 1, 1979, Panhandle Eastern Pipe Line Company (Applicant), P.O. Box 1642, Houston, Texas 77001, filed in Docket No. CP80-6 an application pursuant to Section 7(c) of the Natural Gas Act and Section 157.7(b) of the Regulations thereunder (18 CFR 157.7(b)) for a certificate of public convenience and necessity authorizing the construction, during the 12-month period commencing January 1, 1979, and operation of facilities to enable Applicant to take into its certificated main pipeline system natural gas which would be purchased from producers or other similar sellers thereof, all as more fully set forth in the application on file with the Commission and open to public inspection.

The stated purpose of this budget-type application is to augment Applicant's ability to act with reasonable dispatch in connecting to its pipeline system supplies of natural gas which may become available from various producing areas generally conextensive with its pipeline system or the systems of other pipeline companies which may be authorized to transport gas for the account of or exchange gas with Applicant.

Applicant states that the total cost of the proposed gas purchase facilities would not exceed $20,000,000, with no single onshore project to exceed $2,500,000 and no single offshore project to exceed $3,500,000.

Applicant recognizes that the proposed total and single project costs

are in excess of the amounts specified in subparagraphs (1)(i) and (ii) of Section 157.7(b) of the Commission's Regulations but requests cost limits in contemplation of amendments to the regulations permitting such limits. However, Applicant requests waiver of the cost limitations in subparagraphs (1)(i) and (ii) to permit a total and single project cost in excess of the amounts specified thereunder in the event such amendments increasing the cost limits are not duly promulgated.

Any person desiring to be heard or to make any protest with reference to said application should on or before November 19, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-33938 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP70-224]

Sea Robin Pipeline Co.; Petition To Amend

October 29, 1979.

Take notice that on September 21, 1979, Sea Robin Pipeline Company (Sea Robin), P.O. Box 1478, Houston, Texas 77001, filed in Docket No. CP70-224 [1] a petition to amend the order of June 1, 1970, issued in said docket pursuant to Section 7(c) of the Natural Gas Act authorizing an increase in the total contract demand level presently applicable to Columbia Gas Transmission Corporation (Columbia) under Rate Schedule X-3 to 85,000 Mcf per day, all as more fully set forth in the petition to amend which is on file with the Commission and open to public inspection.

Pursuant to a gas transportation agreement between Sea Robin and United Fuel Gas Company (United) dated January 15, 1970, Columbia, successor in interest to United, is reserved up to 100,000 Mcf per day of capacity in Sea Robin's offshore transmission pipeline system, it is stated. Sea Robin indicates that it presently transports approximately 48,400 Mcf per day of gas for Columbia or Columbia's account as provided for in Sea Robin's Rate Schedule X-3, from various delivery points on Sea Robin's system to a point of redelivery to Columbia at the terminus of Sea Robin's system onshore near Erath, Vermilion Parish, Louisiana.

It is stated that Columbia and Sea Robin have entered into an amendment of the transportation agreement dated March 21, 1979, which amends the agreement between the parties dated January 15, 1970, to allow for an increase in Columbia's contract demand to 100,000 Mcf per day. However, Columbia has advised United that it would have only 85,000 Mcf per day of gas available for transportation through the Sea Robin system. Accordingly, Sea Robin requests authorization to transport for Columbia or Columbia's account up to 85,000 Mcf per day. Sea Robin states that service to other customers of Sea Robin would not be affected by the proposals made herein nor would service to Sea Robin's resale customers be affected as well.

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before November 19, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-33937 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

[1] This proceeding was commenced before the FPC. By joint regulation of October 1, 1977 (10 CFR 1000.1), it was transferred to the Commission.

[Docket No. CP79-490]

Southwest Gas Storage Co., and Panhandle Eastern Pipe Line Co.; Application

October 29, 1979.

Take notice that on September 17, 1979, Southwest Gas Storage Company (Southwest), P.O. Box 1348, Kansas City, Missouri 64141, and Panhandle Eastern Pipe Line Company (Panhandle), P.O. Box 1642, Houston, Texas 77001, filed in Docket No. CP79-490 a joint application pursuant to Section 7 of the Natural Gas Act for a certificate of public convenience and necessity authorizing the development and operation of the Borchers North Field (BNF) located in Meade County, Kansas, as an operational gas storage facility, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

It is stated that the BNF is a nearly depleted natural gas field located in Meade County, Kansas. Panhandle is the sole purchaser of gas produced from this field. It is estimated that the original gas in place in the BNF was 70,082,000 Mcf. Applicants state that as of April 1, 1979, the cumulative gas production was 60,159,000 Mcf with remaining recoverable reserves of approximately 6,579,000 Mcf and nonrecoverable gas reserves of 3,344,000 Mcf.

Applicants state that the Morrow Formation has been studied and found to be a well defined closed gas reservoir with essentially no energy derived from water influx, and have concluded that it is well suited to provide the storage service proposed by Southwest herein to Panhandle and other potential storage customers.

Southwest proposes the total reservoir volume for the BNF to be 70,082,000 Mcf with a total top working storage of 35,000,000 Mcf and proposed base

volume of 35,082,000 Mcf. It is asserted that the facilities proposed herein have been designed in order to accommodate a daily injection rate of 300,000 Mcf and withdrawal rate of 350,000 Mcf.

By this application Southwest seeks authorization for the following facilities and operations necessary to develop and perform the storage service proposed herein from the BNF:

(a) To acquire all necessary mineral, royalty, and working interests, and all storage, surface and other rights and interest necessary to develop and operate the BNF as a gas storage facility.

(b) To drill, complete and operate thirty new injection-withdrawal wells and one caprock observation well, together with appurtenant wellhead measuring equipment and other ancillary well completion facilities.

(c) To rework nineteen existing gas wells and provide certain wellhead measuring equipment and other ancillary facilities. Upon reworking, fifteen of these wells would be utilized as injection-withdrawal wells and the remaining four wells would be utilized as observation wells.

(d) To rework and replug nine previously abandoned wells in the field.

(e) To construct and operate a field compressor station to be equipped with 15,000 horsepower of compression, together with all related facilities including yard piping and valves, liquid collection facilities, flow control and measurement and gas cooling towers.

(f) To construct storage gathering lines and facilities within the BNF along with dehydration and cleaning equipment.

(g) To construct the 11.25 miles of 24-inch OD pipeline and related facilities necessary to connect the BNF to Panhandle's existing main line transmission system in Meade County, Kansas, and to establish an interconnection at that point.

(h) To receive 31,738,000 Mcf of natural gas plus compressor fuel required for the injection of such gas from its storage customers for utilization as base or cushion gas for the Borchers North Project with title to such base gas remaining in each of the storage customers providing the base gas.

(i) To hold the base gas provided by the customers for the benefit of such storage customers.

(j) To accept delivery of gas for storage and to withdraw from storage and redeliver to Panhandle in the Winter Period volumes of gas up to 25,000,000 Mcf for testing purposes while the project is being developed.

(k) To accept delivery of gas for storage and to withdraw and redeliver to its storage customers a volume of working storage gas not to exceed 35,000,000 Mcf on an annual basis when the Borchers North Project is fully developed.

(l) To withdraw and redeliver base gas volumes in accordance with Article V of the Gas Storage Agreement with Panhandle dated June 11, 1979.

(m) To maintain a total reservoir content of gas in the Borchers North Project not to exceed 70,100,000 Mcf at a bottom hole reservoir pressure of 2190 psia.

(n) To render natural gas storage service to Panhandle pursuant to the gas storage agreement.

Southwest estimates that the costs required to develop the BNF as a storage facility would be $72,960,000.

Panhandle seeks Commission authorizations for the folloiwng operations, accounting and rate treatment in order to carry out the Borchers North Storage Project:

(a) To deliver base gas aggregating 27,200,000 Mcf (including 6,579,000 Mcf of remaining recoverable reserves), plus compressor fuel required to inject such gas, to Southwest during the development phase of the Borchers North Project. This volume of gas would be utilized by Southwest as the major portion of the cushion or base required for the Borchers North Project.

(b) To record in Account 117, "Gas stored underground Noncurrent" for inclusion in Panhandle's rate base, all base or cushion gas delivered to Southwest by Panhandle during the term of the gas storage agreement dated June 11, 1979, under provisions of the Commission's regulations in effect from time to time for Account 117 or any superseding regulations.

(c) To exercise all rights and obligations under the gas storage agreement.

(d) To deliver to Southwest during the Summer Period and to receive from Southwest in the Winter Period volumes of gas not to exceed 25,000,000 Mcf during the development of the Borchers North Project.

The application states that Southwest would charge Panhandle a rate of 57.24 cents per Mcf for the proposed storage service.

It is indicated that the cost of construction would be initially financed through short-term loans which would be repaid with the proceeds from long-term debt securities of Southwest.

Any person desiring to be heard or to make any protest with reference to said application should on or before November 19, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicants to appear or be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-33308 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP60-94 et al.]

Tennessee Gas Pipeline Co., a Division of Tenneco Inc.; Petition To Amend

October 29, 1979.

Take notice that on October 2, 1979, Tennessee Gas Pipeline Company, a Division of Tenneco Inc. (Tennessee), P.O. Box 2511, Houston, Texas 77001, filed in Docket No. CP60-94 *et al.*, a petition to amend the order of December 28, 1976, as amended on December 13, 1978, issued in said docket pursuant to Section 7(c) of the Natural Gas Act so as to authorize the sale of natural gas to the Connecticut Gas Company (Connecticut) under the terms of a new gas sales contract which provides for changes in daily volume limits by delivery point as set forth in the appendix hereto, all as more fully set forth in the petition which is on file with the Commission and open to public inspection.

Tennessee states that it was granted authorization in Docket No. CP60-94 *et al.*, to serve Connecticut under Tennessee's CD-6 Rate Schedule in lieu of Tennessee's G-6 and GS-6 Rate Schedules and to render such service with revised daily volume limits by delivery point. Accordingly, it is stated, Tennessee is now serving Connecticut under Tennessee's CD-6 Rate Schedule and the terms and conditions of an associated gas sales contract between the parties dated December 13, 1978, which provides for the sale and delivery by Tennessee of a contracted demand of 44,133 Mcf of gas per day. Tennessee states that the total of the daily volume limits at the delivery points exceed Connecticut's contracted demand of 44,133 Mcf per day in order to provide Connnecticut with operational flexibility among delivery points; however, Connecticut is not entitled to take on any day a total of more than 44,133 Mcf at all delivery points.

Connecticut has requested that Tennessee revise the daily volume limits for certain specified delivery points. Tennessee is agreeable to such changes in service to Connecticut and, accordingly, both parties have entered into a precedent agreement which provides for the execution of a new gas sales contract providing for revised daily volume limits by delivery points.

Tennessee states that the proposed sale of gas would not increase or decrease the annual volumetric limitation imposed on Tennessee's system in Opinion Nos. 712 and 712-A for sales to Connecticut. Tennessee also states that the proposed service would have no impact on Tennessee's other customers.

Any person desiring to be heard or to make any protest with reference to said petition should on or before November 19, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Kenneth F. Plumb,
Secretary.

Appendix

Proposed Revision of Daily Volume Limits (Mcf)

Delivery point	Existing daily volume limits	Proposed revised daily volume limit	Net change
1—Torrington	[1]3400	[1]4000	600
2—Winsted	[1]2345	[1]2345	
3—Long Ridge Road Stamford	22000	22000	
4—Stamford Emergency			
5—Norwalk	8000	8000	
6—Derby	18700	15000	(3700)
7—Danbury	9792	9792	
8—Wallingford	5800	8000	2200
Total	70127	69227	(900)

[1] Tennessee has indicated that the existing daily delivery capacity of the Winsted-Torrington lateral is 5335 Mcf.

[FR Doc. 79-33939 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP77-260]

Texas Eastern Transmission Corp.; Petition To Amend

October 29, 1979.

Take notice that on October 9, 1979, Texas Eastern Transmission Corporation (Texas Eastern), P.O. Box 2521, Houston, Texas 77001, filed in Docket No. CP77-260 a petition to amend the order of May 23, 1977, issuing a certificate of public convenience and necessity in the instant docket pursuant to Section 7(c) of the Natural Gas Act by authorizing the construction and operation of facilities for the exchange of natural gas with Natural Gas Pipeline Company of America (Natural), all as more fully set forth in the petition to amend which is on file with the Commission and open for public inspection.

Pursuant to the order issued May 23, 1977, Texas Eastern is authorized to exchange with Natural up to 4,000 dekatherms (dt) equivalent of natural gas per day. It is further authorized to construct and operate a 2-inch tap and valve assembly on its 24-inch line in Colorado County, Texas, and a 2-inch tap and valve assembly on its 16-inch line in Goliad County, Texas, for the receipt of the said natural gas from Natural.

Texas Eastern requests authorization to

(1) Construct an additional two-inch tap and valve assembly on its twenty-four-inch line in Colorado County, Texas, for receipt of 3,000 dt equivalent per day of natural gas from Natural.

(2) Construct a two-inch tap and valve assembly on its sixteen-inch line in Dewitt County, Texas, for the receipt of 2,000 dt equivalent per day of natural gas from Natural, and,

(3) Add the existing interconnection with the Exxon Sarita Gasoline Plant in Kenedy County, Texas, as an exchange point for the delivery of natural gas to Natural.

Texas Eastern would redeliver equivalent volumes to Natural at the existing points of interconnection between the two systems in either Brazoria County, Texas, or Kenedy County, Texas.

Construction of the facilities is estimated to cost $12,400 and Natural would reimburse Texas Eastern for the cost of all facilities to be installed.

Texas Eastern asserts that the construction would increase the volumes of supply to Natural's customers, without requiring it to build additional facilities. Texas Eastern states that it has ample capacity on its system to render the proposed service and its obligations under the exchange agreement would have no significant effect on the operation of its system. Natural has notified Texas Eastern that it must have all necessary approvals for the exchange by November 1, 1979, or it could lose its right to purchase gas quantities from Westland Oil Development Corporation.

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before November 19, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Kenneth F. Plumb,
Secretary.

[FR Doc. 79-33940 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP80-8]

Texas Eastern Transmission Corp.; Application

October 29, 1979

Take notice that on October 1, 1979, Texas Eastern Transmission Corporation (Applicant), P.O. Box 2521, Houston, Texas 77001, filed in Docket No. CP80-8 an application pursuant to Section 7(c) of the Natural Gas Act and Section 157.7(b) of the Regulations thereunder (18 CFR 157.7(b)) for a certificate of public convenience and necessity authorizing the construction, during the calendar year 1980, and operation of facilities to enable Applicant to take into its certificated main pipeline system natural gas which would be purchased from producers or other similar sellers thereof, all as more fully set forth in the application on file with the Commission and open to public inspection.

The stated purpose of this budget-type application is to augment Applicant's ability to act with reasonable dispatch in connecting to its pipeline system supplies of natural gas which may become available from various producing areas generally coextensive with its pipeline system or the systems of other pipeline companies which may be authorized to transport gas for the account of or exchange gas with Applicant.

Applicant states that the total cost of the proposed gas purchase facilities would not exceed $20,000,000, with the cost of any single offshore project not to exceed $3,500,000 and any single onshore project not to exceed $2,500,000. Applicant proposes to finance the cost of the proposed facilities from funds on hand.

Applicant recognizes that the proposed total and single project costs are in excess of the amounts specified in subparagraphs (1) (i) and (ii) of § 157.7(b) of the Commission's Regulations but requests cost limits in contemplation of amendments to the regulations permitting increased limits. However, Applicant requests waiver of the cost limitations in subparagraphs (1) (i) and (ii) to permit a total and single project cost in excess of the amounts specified thereunder in the event such amendments increasing the cost limits are not duly promulgated. Applicant avers that it needs the increases in order to offset the effects of inflation and still be able to maintain an active gas supply program for the benefit of its customers.

Any person desiring to be heard or to make any protest with reference to said application should on or before November 19, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-33941 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP80-13]

Texas Eastern Transmission Corp. and United Gas Pipe Line Co.; Application

October 29, 1979.

Take notice that on October 4, 1979, Texas Eastern Transmission Corporation (Texas Eastern), P.O. Box 2521, Houston, Texas 77001, and United Gas Pipe Line Company (United), P.O. Box 1478, Houston, Texas 77001, (Applicants) filed in Docket No. CP80-13 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the exchange of certain quantities of natural gas, all as more fully set forth in the application on file with the Commission and open to public inspection.

Applicants request authorization to exchange up to 40,000 Mcf of natural gas per day pursuant to an exchange agreement dated August 31, 1979. By the terms of said agreement, Texas Eastern would accept up to 40,000 Mcf of natural gas per day from United[1] at a point of interconnection between a 16-inch lateral pipeline to be constructed, owned and operated by United[2] and Texas Eastern proposes to redeliver a thermally equivalent volume of gas, less fuel and lost and unaccounted for gas, to Trunkline Gas Company (Trunkline) for United's account at existing onshore points of interconnection between the facilities of Texas Eastern and Trunkline in Allen and/or Beauregard Parishes, Louisiana.

In return for Texas Eastern's rendering such service, United proposes to utilize a portion of its capacity in the pipeline system owned by Sea Robin Pipeline Company (Sea Robin) to transport up to 40,000 Mcf of natural gas per day for Texas Eastern.[3] United indicates that it would cause Sea Robin to accept such gas at the producers' platforms in Eugene Island Blocks 333 and 256, offshore Louisiana, and to redeliver equivalent volumes, less fuel and other uses, to Columbia Gas Transmission Corporation (Columbia) for Texas Eastern's account at an existing point of interconnection between the facilities of Sea Robin and Columbia at Erath, Louisiana. United avers that it would utilize the capacity in Sea Robin's system that it has acquired by assignment from Texas Eastern pursuant to a letter agreement dated August 31, 1979, between the parties.

Any person desiring to be heard or to make any protest with reference to said application should on or before November 19, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party

[1] United has contracted to purchase such gas from Getty Oil Company.

[2] United would construct the facility under its current budget authorization.

[3] Texas Eastern, it is indicated, has acquired the right to purchase this gas from Sun Oil Company.

to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicants to appear or be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-33942 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CI79-487]

(October 29, 1979).

Texas Pacific Oil Co.; Application

Take notice that on June 6, 1979, Texas Pacific Oil Company (Texas Pacific), 1700 One Main Place, Dallas, Texas, filed in Docket No CI79-487 an application pursuant to Section 7(c) of the Natural Gas Act, as amended, and Section 2.75 of the Commission's General Policy and Interpretations, *Optional Procedure For Certificating New Producer Sales of Natural Gas,* for a certificate of public convenience and necessity authorizing the sale of natural gas from its interest in Block A-298 Field, High Island Area, Offshore Texas to Michigan Wisconsin Pipeline Company, all as more fully set forth in the application, which is on file with the Commission and open to public inspection.

The contract is for a base period of 15 years. Texas Pacific requests that the Commission issue it a certificate authorizing a rate of $4.00 per Mcf (at 14.73 psia) subject to a Btu adjustment for BTU content above or below 1000 BTU.

Any person desiring to be heard or to make any protest with reference to said application, on or before November 19, 1979, should file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding, or to participate as a party in any hearing therein, must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-33943 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP79-506]

Transcontinental Gas Pipe Line Corp.; Application

October 29, 1979.

Take notice that on September 27, 1979, Transcontinental Gas Pipe Line Corporation (Applicant), P.O. Box 1396, Houston, Texas 77001, filed in Docket No. CP79-506 an application pursuant to Section 7(c) of the Natural Gas Act and Section 157.7(b) of the Regulations thereunder (18 CFR 157.7(b)) for a certificate of public convenience and necessity authorizing the construction, during the period November 21, 1978, through December 31, 1980[1], and operation of facilities to enable Applicant to take into its certified main pipeline system natural gas which would be purchased from producers or other similar sellers thereof, all as more fully set forth in the application on file with the Commission and open to public inspection.

The states purpose of this budget-type application is to augment Applicant's ability to act with reasonable dispatch in connecting to its pipeline system supplies of natural gas which may become available from various producing areas generally coextensive with its pipeline system or the systems of other pipeline companies which may be authorized to transport gas for the account of or exchange gas with Applicant.

Applicant requests waiver of Section 157.7(b)(1) (i) and (ii) of the Regulations in order to permit a total expenditure limitation for the extended period of $27,000,000 with any single onshore project not to exceed $3,200,000, and any single offshore project not to exceed $4,500,000. In the alternative, Applicant requests authorization to construct, during the same time period, gas purchase facilities subject to the cost limitations that are ultimately established by the Commission in Docket No. RM79-37. Applicant states that the proposed facilities would be financed initially from temporary bank loans and company funds, with permanent financing to be arranged as part of an overall financing program.

Applicant indicates that it needs to have its total dollar budget limitation for the period November 21, 1979, through December 31, 1980, set at the highest possible level due to the effect of inflation and increased gas acquisition activity which contribute to the recent increase in Applicant's expenditures for the construction of gas purchase facilities.

Applicant states that the continuing inflation costs, as well as the increase in gas supply acquisition activity that was brought about in large part by the beneficial effects of the Natural Gas Policy Act of 1978, require that Applicant incur greater expenditures for these type facilities than it has in the past.

Any person desiring to be heard or to make any protest with reference to said application should on or before November 19, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with

[1] Applicant requests that the proposed budget authorization extend through December 31, 1980, in order that its subsequent budget-authorization may be issued on a calendar year basis. Transco's current budget authorization expires November 20, 1978.

the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on the application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-33944 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP79-55]

Transwestern Pipeline Co.; Notice of Petition To Amend

October 29, 1979.

Take notice that on September 27, 1979, Transwestern Pipeline Company (Petitioner), P.O. Box 2521, Houston, Texas 77001, filed in Docket No. CP79-55 a petition to amend further the order of January 16, 1979, issued in said docket pursuant to Section 7 of the Natural Gas Act and Section 157.7(b) of the Regulations thereunder (18 CFR 157.7(b)) so as to authorize Petitioner to increase the total cost of facilities constructed under its gas purchase budget-type authorization, all as more fully set forth in the petition which is on file with the Commission and open to public inspection.

Petitioner states that pursuant to the Commission's order of January 16, 1979, it was authorized to construct gas purchase facilities under budget-type authorization for a one-year period commencing January 1979. Petitioner indicates that the order limited the total cost of said facilities to $8,600,000 with no single project to exceed $1,500,000. On August 13, 1979, Petitioner filed a petition to amend the order herein to waive the regulations in order to permit an increase in its allowable costs from $8,600,000 to $12,000,000. It is stated that this request was necessitated by the increase in construction costs caused by inflation and the number of new gas supply sources in Petitioner's gas supply area.

By the subject petition, Petitioner requests that the Commission authorize Petitioner to increase its allowable costs for the calendar year 1979 from the requested increase of $12,000,000 to $13,500,000. Petitioner states the increase would be used for additional gas purchase facilities with any single project constructed with the increase limited to $1,500,000.

Petitioner states that the increase in costs is due to the increase in the number of new gas supply sources in its gas supply area.

Any person desiring to be heard or to make any protest with reference to said petition should on or before November 19, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-33945 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP80-9]

Transwestern Pipeline Co.; Application

October 29, 1979.

Take notice that on October 1, 1979, Transwestern Pipeline Company (Applicant), P.O. Box 2521, Houston, Texas 77001, filed in Docket No. CP80-9 an application pursuant to Section 7(c) of the Natural Gas Act and Section 157.7(b) of the Commission's Regulations thereunder (18 CFR 175.7(b)) for a certificate of public convenience and necessity authorizing the construction, during the calendar year 1980, and operation of facilities to enable Applicant to take into its certificated main pipeline system natural gas which would be purchased from producers or other similar sellers thereof, all as more fully set forth in the application on file with the Commission and open to public inspection.

The stated purpose of this budget-type application is to augment Applicant's ability to act with reasonable dispatch in connecting to its pipeline system supplies of natural gas which may become available from various producing areas generally coextensive with its pipeline system or the systems of other pipeline companies which may be authorized to transport gas for the account of or exchange gas with Applicant.

Applicant states that the total cost of the proposed gas purchase facilities would not exceed $13,000,000 with the cost of no single project to exceed $2,500,000.

Applicant recognizes that the proposed total and single project costs are in excess of the amounts specified in subparagraphs (1) (i) and (ii) of Section 157.7(b) of the Commission's Regulations. Consequently, Applicant requests waiver of the cost limitations in subparagraphs (1) (i) and (ii) in order to permit total and single project costs in excess of the amounts specified thereunder. Applicant avers that it needs the increases in order to offset the effects of inflation and still be able to maintain an active gas supply program for the benefit of its customers.

Any person desiring to be heard or to make any protest with reference to said application should on or before November 19, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 and 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this

application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-33946 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP80-25]

October 29, 1979.

Transwestern Pipeline Co. and Cities Service Gas Co.; Application

Take notice that on October 12, 1979, Transwestern Pipeline Company (Transwestern), P.O. Box 2521, Houston, Texas 77001, and Cities Service Gas Company (Cities Service), First National Center, Oklahoma City, Oklahoma 73125, filed in Docket No. CP80-25 an application pursuant to Section 7 of the Natural Gas Act for a certificate of public convenience and necessity authorizing the exchange of natural gas, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicants request authorization to exchange natural gas pursuant to a gas exchange agreement between the Applicants dated August 9, 1979. Applicants have agreed to exchange gas gathered from 9 wells located in Dewey County, Oklahoma, and Hemphill County, Texas, which are in proximity to Cities Service's facilities.

Under the terms of the agreement, gas volumes produced from the 9 wells which are dedicated to Transwestern would be gathered into Cities Service's system. Cities Service would concurrently reduce the volumes of gas received from Transwestern by an equivalent quantity at the existing delivery point between Cities Service and Transwestern located in Hemphill County, Texas. It is stated that the facilities required to attach the 9 wells to Cities Service's system were constructed under budget-type authorizations granted to Transwestern.

Applicants have provided for the addition of wells and balancing points to the agreement from time to time to provide for other mutually agreeable points of exchange. Accordingly, Applicants request authorization to exchange gas from additional wells and balancing points and agree to file revisions to the gas exchange agreements to show the addition of new wells or the deletion of wells and new balancing points.

Any person desiring to be heard or to make any protest with reference to said application should on or before November 19, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public onvenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicants to appear or be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-33947 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP80-17]

United Gas Pipe Line Co.; Notice of Application

October 29, 1979.

Take notice that on October 9, 1979, United Gas Pipe Line Company (Applicant), P.O. Box 1478, Houston, Texas 77001, filed in Docket No. CP80-17 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the construction and operation of approximately 635 miles of 30-inch pipeline, five compressor stations and appurtenant facilities, all as more fully set forth in the application on file with the Commission and open to public inspection.

Applicant states that this proposed Mid-Continent to Gulf Coast pipeline (Mid-Continent Line) would originate in Moore County, Texas, where it would interconnect with the Four-Way Compressor Station of Colorado Interstate Gas Company. Applicant asserts that from Moore County, the Mid-Continent Line would extend east through the Anadarko Basin, crossing numerous intrastate pipelines in Oklahoma, and would then run southeast to West Monroe, Louisiana, where it would connect with Applicant's existing pipeline facilities.

The five compressor stations which would be constructed by Applicant are:

(1) The Pampa Compressor Station consisting of two 2,400 horsepower units in Roberts County, Texas;

(2) The Thomas Compressor Station consisting of two 1,250 horsepower units in Custer County, Oklahoma;

(3) The Calumet Compressor Station consisting of three 2,400 horsepower units in Canadian County, Oklahoma;

(4) The Chandler Compressor Station consisting of two 2,000 horsepower units in McClain County, Oklahoma;

(5) The Huskey Compressor Station consisting of two 2,400 horsepower units in Choctaw County, Oklahoma.

Applicant states that following installation of the facilities and a nominal build-up period, it anticipates a minimum of 300,000 Mcf of natural gas per day on the average would be available to the Mid-Continent Line: 175,000 Mcf per day from the Anadarko Basin and Oklahoma production and 125,000 Mcf per day from the Overthrust Belt area. It is stated that the Mid-Continent Line would have an initial capacity of 425,000 Mcf per day.

Applicant asserts that the proposed Mid-Continent Line would provide it with access to two major new gas supply areas with great potential for future development: The Deep Anadarko Basin and the Overthrust Belt in the Rocky Mountain area. Moreover, it is stated, the Mid-Continent Line would cross areas in Oklahoma where increased drilling activity has resulted in large surpluses of natural gas and these surpluses are expected to continue into the foreseeable future, given the

presence of an adequate market outlet. The Mid-Continent Line, it is asserted, would provide the means for moving this gas to Applicant's existing pipeline system.

Applicant states that it has been unable to move gas from the Deep Anadarko Basin, the Overthrust Belt and Oklahoma to its system because pipelines in the area both interstate and intrastate, have no spare capacity.

Applicant estimates the cost of facilities to be $385,639,730 which cost would be financed out of general corporate funds. It is indicated that to the extent the total cash requirements of Applicant, including the cost of the proposed facilities, exceeds cash on hand and cash generated from operations, additional external capital would be utilized.

Any person desiring to be heard or to make any protest with reference to said application should on or before November 19, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessay for Applicant to appear or be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-33948 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP80-18]

United Gas Pipe Line Co.; Application

October 29, 1979.

Take notice that on October 9, 1979, United Gas Pipe Line Company (Applicant), P.O. Box 1478, Houston, Texas 77001, filed in Docket No. CP80-18 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the transportation of natural gas for Mid Louisiana Gas Company (Mid Louisiana), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant proposes to transport up to 750 Mcf of natural gas per day for the account of Mid Louisiana pursuant to a gas transportation agreement between Applicant and Mid Louisiana dated September 21, 1979. It is stated that Mid Louisiana has acquired a right to purchase such gas supply from The Superior Oil Company, attributable to its interest in production from the St. Mary Parish Land Company's Well No. 1 in Wax Lake Field, St. Mary Parish, Louisiana. It is further stated that said gas would be received by Applicant at a mutually agreeable point of interconnection located on Applicant's existing 16-inch Belle Isle Field main pipeline, near Wax Lake Field. Applicant states it would redeliver equivalent quantities, less fuel and company-used gas, to Mid-Louisiana at (i) the existing point of interconnection between Applicant's and Mid Louisiana's pipelines located at the Scotland Compressor Station site Baton Rouge Parish, Louisiana, and/or (ii) any other mutually agreeable existing authorized point of interconnection.

Applicant asserts that, under the agreement, it would charge Mid Louisiana an amount per Mcf equal to Applicant's jurisdictional transportation rate in effect from time to time in Applicant's Southern Rate Zone, the current rate being 19.40 cents per Mcf. It is further asserted that the transportation agreement provides for a term of five years and from year to year thereafter.

Applicant states that the proposed transportation would enable Mid Louisiana to receive additional quantities of natural gas into its system without the additional construction of costly transmission facilities.

Any person desiring to be heard or to make any protest with reference to said application should on or before November 19, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-33949 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

Availability of Federal Power Commission Reports: Volume No. 54

October 30, 1979.

Notice is hereby given that Volume No. 54 (parts 1 and 2 of the *Federal Power Commission Reports* is on sale at the United States Government Printing Office Bookstore. Volume No. 54 contains Federal Power Commission (Federal Energy Regulatory Commission's predecessor) opinions, orders, and precedential procedural orders for the period July through December, 1975. Persons interested in purchasing this volume may remit $36.00

for GPO stock No. 061-002-00020-1 to the following address:

Superintendent of Documents, United States Government Printing Office, Washington, D.C. 20402.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-34017 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

Office of Hearings and Appeals

Objection to Interim Remedial Order for Immediate Compliance Filed With the Office of Hearings and Appeals

Notice is hereby given that on September 27, 1979 a Notice of Objection to the Interim Remedial Order for Immediate Compliance (IROIC) identified in the Appendix to this notice was filed with the Office of Hearings and Appeals of the Department of Energy.

Within 20 days after publication of this notice, any person who wishes to participate in the proceeding which the Department of Energy will conduct concerning the IROIC described in the Appendix to this notice must file a request to participate pursuant to 10 CFR 205.194 (44 FR 7926, February 7, 1979). Within 30 days of the publication of this notice, the Office of Hearings and Appeals will determine those persons who may participate on an active basis in this proceeding, and will prepare an official service list which it will mail to all persons who filed requests to participate. Persons may also be placed on the official service list as non-participants for good cause shown. All requests regarding this proceeding shall be filed with the Office of Hearings and Appeals, Department of Energy, Washington, D.C. 20461.

Issued in Washington, D.C. October 26, 1979.

Richard T. Tedrow,

Deputy Director Office of Hearings and Appeals.

Cubbon Lumber Company, Oil City, Pennsylvania, DRR-0079 Motor Gasoline

On September 27, 1979, Cubbon Lumber Company d/b/a Miller Auto Supply Company, 217 Elm Street, Oil City, Pennsylvania 16301 filed a Notice of Objection to an Interim Remedial Order for Immediate Compliance (IROIC) that the Department of Energy (DOE) Northeast District Office of Enforcement issued to the firm on June 1, 1979. The IROIC found that during a period ending April 17, 1979 the firm had committed pricing violations in connection with the sale of motor gasoline in Oil City, Pennsylvania. The IROIC directs the firm immediately to bring itself into compliance with DOE regulations by: (i) reducing prices to no more than its maximum lawful selling prices; (ii) posting such maximum lawful selling prices; (iii) maintaining required records; and (iv) ceasing to engage in discriminatory practices.

[FR Doc. 79-33929 Filed 11-1-79; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[FRL1350-6]

Section 110(f) Energy Emergencies; Open Meetings; Notice of Changed Meeting

AGENCY: Environmental Protection Agency.

ACTION: Notice of Changed Meeting.

SUMMARY: The Section 110(f) Energy Emergencies open meeting with environmental and other interest groups scheduled for November 5, 1979 (44 FR 57200) has been changed. The meeting has been rescheduled for November 16, 1979. It will begin at 10:00 a.m. in Room 2126, EPA headquarters, 401 M. Street, S. W., Washington, D. C. 20460.

FOR FURTHER INFORMATION CONTACT: Office of Policy Analysis (ANR-444), U.S. Environmental Protection Agency, 401 M. Street, S. W., Washington, D. C. 20460, (202) 426-2482.

Dated: October 29, 1979.

David G. Hawkins,

Assistant Administrator for Air, Noise and Radiation.

[FR Doc. 79-33975 Filed 11-1-79; 8:45 am]

BILLING CODE 6560-01-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA-609-DR]

California; Major Disaster and Related Determinations

AGENCY: Federal Emergency Management Agency.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for the State of California (FEMA-69-DR), dated October 19, 1979, and related determinations.

DATED: October 19, 1979.

FOR FURTHER INFORMATION CONTACT: Sewall H. E. Johnson, Disaster Response and Recovery, Federal Emergency Management Agency, Washington, D.C. 20472 (202) 634-7825.

NOTICE: Pursuant to the authority vested in the Director of the Federal Emergency Management Agency by the President under Executive Order 12148 effective July 15, 1979, and delegated to me by the Director under Federal Emergency Management Agency Delegation of Authority, and by virtue of the Act of May 22, 1974, entitled "Disaster Relief Act of 1974" (88 Stat. 143); notice is hereby given that, in a letter of October 19, 1979, the President declared a major disaster as follows:

I have determined that the damage in certain areas of the State of California resulting from an earthquake occurring on October 15, 1979, is of sufficient severity and magnitude to warrant a major disaster declaration under Public Law 93-288. I therefore declare that such a major disaster exists in the State of California.

The time period prescribed for the implementation of Section 313(a), Priority to Certain Applications for Public Facility and Public Housing Assistance, shall be for a period not to exceed six months after the date of this declaration.

Notice is hereby given that pursuant to the authority vested in the Director of Federal Emergency Management Agency under Executive Order 12148, and delegated to me by the Director under Federal Emergency Management Agency Delegation of Authority, I hereby appoint Francis S. Manda of the Federal Emergency Management Agency to act as the Federal Coordinating Officer for this declared major disaster.

I do hereby determine the following area of the State of California to have been affected adversely by this declared major disaster.

The following for Individual Assistance and Public Assistance:

Imperial County

(Catalog of Federal Domestic Assistance No. 14.701, Disaster Assistance.)

William H. Wilcox,

Acting Director, Disaster Response and Recovery, Federal Emergency Management Agency.

[FR Doc. 79-33965 Filed 11-1-79; 8:45 am]

BILLING CODE 6718-02-M

GENERAL ACCOUNTING OFFICE

Regulatory Reports Review; Notice of Receipt of Report Proposals

The following requests for clearance of reports intended for use in collecting information from the public were received by the Regulatory Reports Review Staff, GAO, on October 30, 1979.

See 44 U.S.C. 3512(c) and (d). The purpose of publishing this notice in the Federal Register is to inform the public of such receipt.

The notice includes the title of each request received; the name of the agency sponsoring the proposed collection of information; the agency form number, if applicable, and the frequency with which the information is proposed to be collected.

Written comments on the proposed FCC requests are invited from all interested persons, organizations, public interest groups, and affected businesses. Because of the limited amount of time GAO has to review the proposed requests, comments (in triplicate) must be received on or before November 20, 1979, and should be addressed to Mr. John M. Lovelady, Assistant Director, Regulatory Reports Review, United States General Accounting Office, Room 5106, 441 G Street, NW, Washington, DC 20548.

Further information may be obtained from Patsy J. Stuart of the Regulatory Reports Review Staff, 202-275-3532.

Federal Communications Commission

The FCC requests an extension without change clearance of Form L, Annual Report of Licensee in Domestic Public Land Mobile Radio Service. Form L is required by Section 1.785 of the Commission's Rules and Regulations and is filed annually by licensees in the domestic public land mobile radio service who do not report on Form M, Annual Report. The FCC estimates respondent burden to average 30 hours per response and that approximately 3,000 reports are filed annually.

The FCC requests an extension without change clearance of Form M, Annual Report. Form M is required by Sections 43.21 and 1.785 of the Commission's Rules and Regulations and is filed annually by telephone carriers with annual operating revenues in excess of $1,000,000 and telephone companies not operating telephone exchanges but operating to overseas points or in the Maritime Services and having operating revenues in excess of $50,000. The FCC estimates there are approximately 68 reports filed annually and that respondent burden averages one hour per million dollars of plant investment.

Norman F. Heyl,

Regulatory Reports Review Officer.

[FR Doc. 79-34007 Filed 11-1-79; 8:45 am]

BILLING CODE 1610-01-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[Docket No. 78N-0319; DESI 9149]

Thioridazine Hydrochloride; Drugs for Human Use; Drug Efficacy Study Implementation; Followup Notice and Opportunity for Hearing

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice announces the conditions for marketing thioridazine hydrochloride for the indications for which it is now regarded as effective and offers an opportunity for a hearing concerning indications reclassified to lacking substantial evidence of effectiveness. The drug is used as a tranquilizer.

DATES: Hearing requests due on or before December 3, 1979; supplements to approved new drug applications due on or before January 2, 1980.

ADDRESSES: Communications forwarded in response to this notice should be identified with the reference number DESI 9149, directed to the attention of the appropriate office named below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

Supplements to full new drug applications (identify with NDA number): Division of Neuropharmacological Drug Products (HFD-120), Rm. 10B-34, Bureau of Drugs.

Original abbreviated new drug applications and supplements thereto (identify as such): Divisoin of Generic Drug Monographs (HFD-530), Bureau of Drugs.

Requests for hearing (identify with Docket number appearing in the heading of this notice): Hearing Clerk (HFA-305), Rm. 4-65.

Requests for opinion of the applicability of this notice to a specific product: Division of Drug Labeling Compliance (HFD-310), Bureau of Drugs.

Other communications regarding this notice: Drug Efficacy Study Implementation Project Manager (HFD-501), Bureau of Drugs.

FOR FURTHER INFORMATION CONTACT: Herbert Gerstenzang, Bureau of Drugs (HFD-32), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION: In a notice (DESI 9149; Docket No. FDC-D-334 (now Docket No. 78N-0319)) published in the Federal Register of April 3, 1971 (36 FR 6447), and amended on November 2, 1971 (36 FR 20997), the Food and Drug Administration (FDA) announced its conclusion that the drug products described below are (1) effective for the management of manifestations of psychotic disorders, (2) probably effective for the relief of symptoms of neurotic depressive reaction and for the control of moderate to severe agitation, hyperactivity, or aggressiveness in disturbed children; (3) possibly effective for their other labeled indications of alcohol withdrawal syndrome, intractable pain, and senility.

NDA 11-808; Mellaril Tablets and Concetrate, both containing thioridazine hydrochloride; Sandoz Pharmaceuticals, Division of Sandoz, Inc., East Hanover, NJ 07936.

Sandoz submitted clinical studies to demonstrate the effectiveness of the drug for the following indications.

Relief of Symptoms of Neurotic Depressive Reaction and Senility

For these indications 19 double-blind studies (11 of which were for the sensility claim), 4 placebo-controlled studies and 4 studies comparing the drug to diazepam, were submitted. These studies were evaluated and determined to provide substantial evidence of effectiveness for the following modified indication: "For the short-term treatment of moderate to marked depression with variable degrees of anxiety in adult patients and for the treatment of multiple symptoms such as agitation, anxiety, depressed mood, tension, sleep disturbances, and fears in geriatric patients."

For Control of Moderate to Severe Agitation, Hyperactivity, or Aggressiveness in Disturbed Children

The studies submitted for this indication were reviewed by the Pediatric Advisory Subcommittee of the FDA Psycholpharmacological Agents Advisory Committee and determined not to provide substantial evidence of effectiveness. However, in reviewing all available literature the subcommittee found sufficient well-controlled studies that provided substantial evidence of effectiveness for the indication, if certain language modifications were made. The indication reads as follows: "For the treatment of severe behavioral problems in children marked by combativeness and/or explosive hyperexcitable behavior (out of proportion to immediate provocations), and in the short-term treatment of hyperactive children who show excessive motor activity with accompanying conduct disorders consisting of some or all of the following

symptoms: impulsivity, difficulty sustaining attention, aggressivity, mood liability, and poor frustration tolerance."

Alcohol Withdrawal Syndrome

For this indication six studies were submitted. The agency evaluated them and in July 1973 issued an "incomplete" letter to Sandoz. On January 16, 1976, Sandoz submitted 10 studies (reanalysis of 4 of the previously submitted studies plus 6 new studies). Two of the original studies were not resubmitted (Godfrey and the first Lowenstam) as the daily dose of Mellaril in those studies was less than 50 milligrams a day, which is below the claimed effective range of 50–200 milligrams a day.

The 10 studies submitted were double-blind, parallel, random assignment studies, of 4 weeks' duration. Patients were of either sex, age 21 to 65, and in the late withdrawal phase of alcoholism or restabilization stage. To be included in the studies, patients must have exhibited manifestations of both anxiety and depression and must have had a Hamilton score of at least 3 on both the depression and the psychic anxiety items at the end of a washout period, which was 2 weeks for major tranquilizers and MAO inhibitors and 3 days for minor tranquilizers. Target symptoms of alcohol withdrawal included anxiety, agitation, tension, apprehension, mixed anxiety-depression, and sleep disturbances. Daily dosage range of the Mellaril given was 50–200 milligrams.

Three of the studies (the third Lowenstam, Albahary, and the second Harrison) compared Mellail to Librium and a placebo; five studies (Sugerman, Pena-Ramos, Alonso, Viamontes, and the first Harrison) compared Mellaril to Librium; and two studies (the second Lowenstam, and Dudley) compared Mellaril to placebo. The results of the studies are as follows:

a. *Mellaril Compared to Librium and Placebo.* The third Lowenstam study showed statistically significant improvements in patients taking Mellaril compared to those taking Librium or placebo. This study is considered adequate and well-controlled, but does not provide substantial evidence of effectiveness as there is no other study that corroborates its findings. The other studies submitted do not confirm the results of this study. The exact dosage used in this study was not stated and only the most frequent or average dose was stated, both of which were greater than 150 milligrams. Therefore the study could not be used to provide substantial evidence of effectiveness for the entire dosage range of 50–200 milligrams/day.

The Albahary and second Harrison studies are not considered adequate and well-controlled. In the Albahary study there were a large number of protocol violations, improper screening of the patients, and inadequate dosages used. 21 CFR 314.111(a)(5)(ii)(*a*)(*3*). The average dose of Mellaril was barely above 50 milligrams/day, which is the lower limit of effectiveness claimed for the drug by the firm. Of the 90 patients in the study, 30 either dropped out or were excluded from the study. In addition the study failed to demonstrate superiority of Mellaril over placebo, since only 27 percent of the Hamilton scale items showed a statistically significant difference favoring Mellaril. The study also yielded no significant difference of Mellaril over Librium. In the second Harrison study the dosage requirements specified in the protocol were not properly adhered to, and thus the validity of the results is questionable. 21 CFR 314.111(a)(5)(ii)(*a*)(*3*). Neither Mellaril or Librium showed significant superiority over placebo and therefore the study does not provide substantial evidence of effectiveness.

b. *Mellaril Compared to Librium.* Studies by Sugarman, Viamontes, the first Harrison, Pena-Ramos, and Alonso are not considered adequate and well-controlled in that the drug was only compared to Librium and no placebo was used. 21 CFR 314.111(a)(5)(ii)(*a*)(*4*)(*ii*). Librium is not known to be effective for treatment of the restabilization phase of alcohol withdrawal and thus is not an appropriate positive control to be used in determining the effectiveness of Mellaril. The Pena-Ramos study was only able to show Mellaril superior to Librium on one parameter, symptoms of depression, out of 23 parameters tested for on the Hamilton scale. In the Alonso study nearly half the patients were excluded from the statistical analysis of the study, the vast majority for noncompliance. There were other protocol violations, such as taking other medications, and eight of the patients in the study were inappropriate patients for the study. 21 CFR 314.111(a)(5)(ii)(*a*)(*2*)(*i*). The Sugarman, Viamontes, and Harrison studies did not demonstrate evidence of effectiveness. Therefore, as none of these studies showed Mellaril to be superior to Librium they cannot be used to provide evidence that Mellaril is effective.

c. *Mellaril Compared to Placebo.* The Dudley study and second Lowenstam study showed some support for the drug but did not provide substantial evidence of effectiveness. In the Dudley study five of the 23 Hamilton Depression Scale parameters tested showed significant differences favoring Mellaril, and in the second Lowenstam study only four of the parameters favored Mellaril, as compared to the placebo. In both studies there were no significant differences.

d. *Pooling of Submitted Studies.* The results of the above studies were pooled, excluding the second Harrison study and patients from the other studies who had low Hamilton scores. The assumption that these studies can be pooled and conclusions reached demonstrating the effectiveness of the drug for the dosage range of 50–200 milligrams/day is an invalid assumption as each of the studies has a different dosage range. The results of the pooling procedure were also disproportionately influenced by the positive results of the third Lowenstam study. There is a lack of randomization in the pooled study as the assignment of patients to the different dosage groups was not an assignment made prior to treatment but rather depended on the success of the treatment itself. It is also questionable that a dose-response determination can be made by means of factorial analysis based on data from studies that were not designed for such a purpose.

In summary, only the third Lowenstam study showed statistically significant differences favoring Mellaril, but no other study corroborated its findings. Therefore, the drug is reclassified to lacking substantial evidence of effectiveness for the indication "alcohol withdrawal syndrome." To provide substantial evidence of effectiveness for Mellaril for this indication at a dosage range of 100–200 milligrams/day, at least one confirmatory adequate and well-controlled study, at the suggested dosage range, is needed.

Intractable Pain

No data were submitted for this indication, and it is reclassifed to lacking substantial evidence of effectiveness.

Accordingly, the April 3, 1971 notice is amended to read as follows as it pertains to thioridazine hydrochloride drug products. Other products included in the April 3, 1971 notice are not affected by this notice.

Such drugs are regarded as new drugs (21 U.S.C. 321(p)). Supplemental new drug applications are required to revise the labeling in and to update previously approved applications providing for such drugs. An approved new drug application is a requirement for marketing such drug products.

In addition to the products specifically named above, this notice applies to any drug product that is not the subject of an

approved new drug application and is identical to a product named above. It may also be applicable, under 21 CFR 310.6, to a similar or related drug product that is not the subject of an approved new drug application. It is the responsibility of every drug manufacturer or distributor to review this notice to determine whether it covers any drug product that the person manufactures or distributes. Such person may request an opinion of the applicability of this notice to a specific drug product by writing to the Division of Drug Labeling Compliance (address given above).

A. *Effectiveness classification.* The Food and Drug Administration has reviewed all available evidence and concludes that the drug is effective for the indications listed in the labeling conditions below. The drug lacks substantial evidence of effectiveness for its other labeled indications.

B. *Conditions for approval and marketing.* The Food and Drug Administration is prepared to approve abbreviated new drug applications and supplements to previously approved new drug applications under conditions described herein.

1. *Form of drug.* The drug is in tablet or concentrate form suitable for oral adminsitration.

2. *Labeling conditions.* a. The label bears the statement "Caution: Federal law prohibits dispensing without prescription."

b. The drug is labeled to comply with all requirements of the act and regulations, and labeling bears adequate information for safe and effective use of the drug. The Indications are as follows:

For the management of manifestations of psychotic disorders.

For the short-term treatment of moderate to marked depression with variable degrees of anxiety in adult patients and for the treatment of multiple symptoms such as agitation, anxiety, depressed mood, tension, sleep disturbances, and fears in geriatric patients.

For the treatment of severe behavioral problems in children marked by combativeness and/or explosive hyperexcitable behavior (out of proportion to immediate provocations), and in the short-term treatment of hyperactive children who show excessive motor activity with accompanying conduct disorders consisting of some or all of the following symptoms: implusivity, difficulty sustaining attention, aggressivity, mood liablility, and poor frustration tolerance.

3. *Marketing Status.* a. Marketing of such drug products that are now the subject of an approved or effective new drug application may be continued provided that, on or before January 2, 1979, the holder of the application has submitted (i) a supplement for revised labeling as needed to be in accord with the labeling conditions described in this notice, and complete container labeling if current container labeling has not been submitted, and (ii) a supplement to provide updating information with respect to items 6 (components), 7 (composition), and 8 (methods, facilities, and controls) of new drug application form FD-356H (21 CFR 314.1(c)).

b. Approval of an abbreviated new drug application (21 CFR 314.1(f) containing full information with respect to items 6 (components), 7 (composition), and 8 (methods, facilities, and controls) of new drug application form FD-356H (21 CFR 314.1(c)), must be obtained prior to marketing such products. Bioavailability regulations (21 CFR 320.21) published in the Federal Register of January 7, 1977, require any person submitting an abbreviated new drug application after July 7, 1977, to include either evidence demonstrating the in vivo bioavailability of the drug or information to permit waiver of the requirement, unless such evidence is already waived under section 320.22(c). Marketing prior to approval of a new drug application will subject such products, and those persons who caused the products to be marketed, to regulatory action.

C. *Notice of opportunity for hearing.* On the basis of all the data and information available to him, the Director of the Bureau of Drugs is unware of an adequate and well-controlled clinical investigation, conducted by experts qualified by scientific training and experience, meeting the requirements of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and 21 CFR 314.111(a)(5), demonstrating the effectiveness of the drug for the indications lacking substantial evidence of effectiveness referred to in paragraph A of this notice.

Notice is given to the holder of the new drug application, and to all other interested persons, that the Director of the Bureau of Drugs proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)), withdrawing approval of the new drug application and all amendments and supplements thereto providing for the indications lacking substantial evidence of effectiveness referred to in paragraph A of this notice on the ground that new information before him with respect to the drug products, evaluated together with the evidence available to him at the time of approval of the application, shows there is a lack of substantial evidence that the drug products will have all the effects they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in the labeling. An order withdrawing approval will not issue with respect to any application supplemented, in accord with this notice, to delete the claims lacking substantial evidence of effectiveness.

In addition to the ground for the proposed withdrawal of approval stated above, this notice of opportunity for hearing encompasses all issues relating to the legal status of the drug products subject to it (including identical, related, or similar drug products as defined in 21 CFR 310.6), e.g., any contention that any such product is not a new drug because it is generally recognized as safe and effective within the meaning of section 201(p) of the act or because it is exempt from part or all of the new drug provisions of the act pursuant to the exemption for products marketed prior to June 25, 1938, contained in section 201(p) of the act, or pursuant to section 107(c) of the Drug Amendments of 1962, or for any other reason.

In accordance with the provisions of section 505 of the act (21 U.S.C. 355) and the regulations promulgated thereunder (21 CFR Parts 310, 314), the applicant and all other persons who manufacture or distribute a drug product that is identical, related, or similar to a drug product named above (21 CFR 310.6), are hereby given an opportunity for a hearing to show why approval of the new drug application providing for the claims involved should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of a drug product named above and all identical, related, or similar drug products.

An applicant or any person subject to this notice pursuant to 21 CFR 310.6 who decides to seek a hearing shall file (1) on or before December 3, 1979, a written notice of appearance and request for hearing, and (2) on or before January 2, 1980 the data, information, and analyses relied on to justify a hearing, as specified in 21 CFR 314.200. Any other interested person may also submit comments on this proposal to withdraw approval. The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for hearing, a submission of data, information, and analyses to justify a hearing, other comments, and a grant or denial of hearing, are contained in 21 CFR 314.200.

The failure of an applicant or any other person subject to this notice pursuant to 21 CFR 310.6 to file timely

written appearance and request for hearing as required by 21 CFR 314.200 constitutes an election by such person not to make use of the opportunity for a hearing concerning the action proposed with respect to such drug product and a waiver of any contentions concerning the legal status of such drug product. Any such drug product labeled for the indications lacking substantial evidence of effectiveness referred to in paragraph A of this notice may not thereafter lawfully be marketed, and the Food and Drug Administration will initiate appropriate regulatory action to remove such drug products from the market. Any new drug product marketed without an approved NDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must set forth specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. If it conclusively appears from the face of the data, information, and factual analyses in the request for the hearing that there is no genuine and substantial issue of fact that precludes the withdrawal of approval of the application, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who requests the hearing, making findings and conclusions, denying a hearing.

All submissions pursuant to this notice of opportunity for hearing shall be filed in quintuplicate. Such submissions, except for data and information prohibited from public disclosure pursuant to 21 U.S.C. 331(j) or 18 U.S.C. 1905, may be seen in the office of the Hearing Clerk between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050–1053, as amended (21 U.S.C. 352, 355)) and under the authority delegated to the Director of the Bureau of Drugs (21 CFR 5.82).

Dated: October 15, 1979.

J. Richard Crout,

Director, Bureau of Drugs.

[FR Doc. 79-33605 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

Consumer Participation; Open Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming consumer exchange meeting to be chaired by William C. Hill, District Director, San Francisco District Office, San Francisco, CA.

DATE: The meeting will be held at 1 p.m., Tuesday, November 27, 1979.

ADDRESS: The meeting will be held at the Federal Office Building Rm. 546, 50 United Nations Plaza, San Francisco, CA 94102.

FOR FURTHER INFORMATION CONTACT: Stephanie R. Gray, Consumer Affairs Officer, Food and Drug Administration, Department of Health, Education, and Welfare, 50 United Nations Plaza, San Francisco, CA 94102, 415–556–2062.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to encourage dialogue between consumers and FDA officials, to identify and set priorities for current and future health concerns, to enhance relationships between local consumers and FDA's San Francisco District Office, and to contribute to the agency's policymaking decisions on vital issues.

Dated: October 26, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33921 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

Consumer Participation; Open Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This document announces a forthcoming consumer exchange meeting to be chaired by James A. Adamson, District Director, Kansas City District Office, Kansas City, MO.

DATE: The meeting will be held at 9:30 a.m., Monday, November 19, 1979.

ADDRESS: The meeting will be held at the Federal Building, Rm. 807, 15th & Dodge St., Omaha, NE 68102.

FOR FURTHER INFORMATION CONTACT: Tywanna G. Paul, Consumer Affairs Officer, Food and Drug Administration, Department of Health, Education, and Welfare, 1619 Howard St., Omaha, NE 68102, 402–221–4675.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to encourage dialogue between consumers and FDA officials, to identify and set priorities for current and future health concerns, to enhance relationships between local consumers and the FDA Kansas City District Office, and to contribute to the agency's policymaking decisions on vital issues.

Dated: October 26, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33922 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

Consumer Participation; Open Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming consumer exchange meeting to be chaired by Loren Y. Johnson, District Director, Philadelphia District Office, Philadelphia, PA.

DATE: The meeting will be held from 9:30 a.m. to 12 noon, Thursday, November 15, 1979.

ADDRESS: The meeting will be held at the Federal Bldg., Rm. 2214, 1000 Liberty Ave., Pittsburgh, PA.

FOR FURTHER INFORMATION CONTACT: Louise A. Nestico, Consumer Affairs Technician, Food and Drug Administration, Department of Health, Education, and Welfare, 7 Parkway Center, Rm. 645, Pittsburgh, PA 15220, 412–644–2858.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to encourage dialogue between consumers and FDA officials, to identify and set priorities for current and future health concerns, to enhance relationships between local consumers and FDA's Philadelphia District Office, and to contribute to the agency's policymaking decisions on vital issues.

Dated: October 26, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33923 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

Farnam Cos., Inc.; Trichlorfon Oral; Withdrawal of Approval of NADA

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The agency withdraws approval of a new animal drug application sponsored by The Farnam Companies, Inc., providing for use of trichlorfon as an oral anthelmintic in horses. The sponsor requested the withdrawal.

EFFECTIVE DATE: November 12, 1979.

FOR FURTHER INFORMATION CONTACT: Louis L. Nangeroni, Bureau of Veterinary Medicine (HFV-216), Food and Drug Administration, Department of Health, Education, and Welfare, 5600

Fishers Lane, Rockville, MD 20857, 301-443-4093.

SUPPLEMENTARY INFORMATION: The Farnam Companies, Inc., 2230 E. Magnolia, Phoenix, AZ 85036, is the sponsor of NADA 43-166, which provides for safe and effective use of trichlorfon as an oral anthelmintic for treating bot, ascarid, and pinworm infections of horses. The application was originally approved April 20, 1971 (36 FR 7422). By letter of January 19, 1979, the sponsor requested withdrawal of approval of the NADA because the product is no longer marketed.

In a separate document published elsewhere in this issue of the Federal Register, § 520.2520a *Trichlorfon oral* (21 CFR 520.2520a) is amended in paragraph (b) to delete that portion which reflects approval of this NADA.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(e), 82 Stat. 345-347 (21 U.S.C. 360(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.84), and in accordance with § 514.115 *Withdrawal of approval of applications* (21 CFR 514.115), notice is given that approval of NADA 43-166 and all supplements for The Farnam Companies, Inc., trichlorfon oral is hereby withdrawn, effective November 12, 1979.

Dated: October 26, 1979.

Lester M. Crawford,

Director, Bureau of Veterinary Medicine.

[FR Doc. 79-33924 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

[Docket No. 79N-0352]

Food Chemicals Codex, Third Edition; Opportunity for Public Comment

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This document announces an opportunity for public review and comment on the material in the "Food Chemicals Codex," an agency-recognized compilation of specifications for substances used as food ingredients, prepared under contract for the Food and Drug Administration by the National Academy of Sciences/National Research Council.

DATE: Comments by January 31, 1979.

ADDRESS: Written comments and information 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 Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, D.C. 20204, 202-472-4750.

SUPPLEMENTARY INFORMATION: The Food and Drug Administration (FDA) provides contract funds to the National Academy of Sciences/National Research Council to support preparation of the "Food Chemicals Codex," a compilation of specifications for substances used as food ingredients.

The first edition of the "Food Chemicals Codex" (April 1968) was given FDA recognition by means of a letter from the Commissioner of Food and Drugs. The letter stated in part:

> The FDA will regard the specifications in "Food Chemicals Codex" as defining an appropriate food grade within the meaning of section 121.101(b)(3) (now § 182.1(b)(3)) and section 121.1000(a)(2) (now § 172.5(a)(2)) of the food additives regulations, subject to the following qualifications: this endorsement is not construed to exempt any food chemical appearing in the "Food Chemicals Codex" from compliance with requirements of Acts of Congress or with regulations and rulings issued by the Food and Drug Administration under authority of such Acts.

Later, the "Food Chemicals Codex" was officially recognized by FDA when the definitions and procedural and interpretive regulations under § 170.30 (21 CFR 170.30), relating to eligibility of substances for classification as generally recognized as safe (GRAS), were revised and published in the Federal Register of June 25, 1971 (36 FR 12093).

In 1978, the agency placed a notice in the Federal Register of April 18, 1978 (43 FR 16413), inviting comments and suggestions by all interested parties on the specifications for certain substances scheduled for revision at that time.

The agency now gives notice of review of the entire content of the "Food Chemicals Codex," 2d Ed., and the three supplements issued thereto, in preparation for publication of the "Food Chemicals Codex," 3d Ed. (FCC III) in mid-1980.

The agency invites comments and suggestions by all interested parties on any substances for which monographs on specifications exist in the "Food Chemicals Codex," 2d Ed., and its three supplements. Any comments, recommendations, and requests pertaining to revisions of assay or impurity limits, or other specification parameters, or to revision of analytical test procedures and preparation of solution and other reagents, shall be accompanied by adequate substantiating data or other information in support of such comments, recommendations, or requests.

Several general revisions that will affect all monographs to be published in FCC III include the following: (a) the large section within each monograph previously entitled "Specifications" will be entitled "Requirements" in FCC III; (b) all tests for "Identification," which previously fell outside the "Specifications" section, will be made part of the "Requirements" section in FCC III; (c) all monographs in FCC III shall contain adequate "Identification" tests to aid in identifying a particular substance and in differentiating one substance from another; (d) all monographs in FCC III shall contain, where possible, a suitable "Assay" (or the equivalent of an assay), compliance with which will demonstrate that the substance in question a contains quantifiable amount of material or component as may be specified; and (e) the policy on "Added Substances," as previously defined on page 8 of the "Food Chemicals Codex," 2d Ed. (and as modified on page 1 of the first supplement to the 2d Ed.), has been changed for FCC III; the effect of this change is to prohibit the use of such "Added Substances" unless they are specifically provided for in an individual monograph in FCC III.

In addition to the monographs contained in the "Food Chemicals Codex," 2d Ed., and its three supplements, new monographs for a number of substances are planned for incorporation in FCC III, including an as yet undetermined number of new monographs for flavoring agents and spice oleoresins. Other new ingredients and color additives for which food-grade specifications and applicable test procedures have not been proposed as yet, and for which such information is hereby invited from interested parties, include:

Annatto extract
β-Apo-8'-carotenal
Arabinogalactan
Beets, dehydrated
Butane
Canthaxanthin
Carbon dioxide
Casein
Cetyl alcohol, synthetic
Char smoke flavor
Collagen
Copper sulfate
Decyl alcohol, synthetic
Dextrin
Dextrose
Dimethyl dialkyl ammonium chloride
Folic acid (Folacin)
Fructose
Gelatin
Grape skin extract
Helium
Hexane
Hexyl alcohol, synthetic

Ion-exchange resins (as defined in 21 CFR 173.25)
Iso-butane
Lactose
Lauryl alcohol, synthetic
Lecithin, bleached with benzoyl peroxide
Lecithin, bleached with hydrogen peroxide
Myristyl alcohol, synthetic
Nitrogen
Nitrous oxide
Octyl alcohol, synthetic
Peptones
Polypropylene glycol
Polyvinylpolypyrrolidone
Propane
Propylene glycol mono- and diesters of fatty acids
Sodium caseinate
Stearyl alcohol, synthetic
Sulfur dioxide
Talc
Thiopropionic acid
Vitamin B
Zinc gulconate
Zinc oxide

New monographs that are candidates for inclusion in FCC III are not limited to those cited above. Other substances being used in foods in compliance with applicable regulations under the Federal Food, Drug, and Cosmetic Act, for which suitable food-grade specifications can be prepared, will also be considered upon request by interested parties.

Six copies of written comments regarding this notice are to be submitted to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday. Copies of all comments will be made available to the National Academy of Sciences/National Research Council.

Dated: October 29, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33919 Filed 10-30-79; 11:12 am]

BILLING CODE 4110-03-M

Office of the Secretary

Advisory Panel on Financing Elementary and Secondary Education; Meeting

AGENCY: Advisory Panel on Financing Elementary and Secondary Education.

ACTION: Notice of Meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of a forthcoming meeting of the Advisory Panel on Financing Elementary and Secondary Education. It also describes the functions of the Panel. Notice of this meeting is required under the Federal Advisory Committee Act (5 U.S.C. Appendix 1, section 10(a)(2)). This document is intended to notify the general public of its opportunity to attend.

DATE: November 19, 1979, 9:00 a.m. to 5:00 p.m.

ADDRESS: 200 Independence Avenue, S.W., Washington, D.C., Rooms 337-A, 723-A, and 727-A.

FOR FURTHER INFORMATION CONTACT: Dr. George B. Lane, Acting Executive Director, Advisory Panel on Financing Elementary and Secondary Education, Room 313-H, 200 Independence Avenue, S.W., Washington, D.C. 20202 (202-245-8220).

SUPPLEMENTARY INFORMATION: The Advisory Panel on Financing Elementary and Secondary Education is established under Section 1203, Title XII of the Education Amendments of 1978 (P.L. 95-561). The Panel is directed to provide the Secretary and the Congress with periodic advice and counsel concerning public policies on raising and distributing revenues to support elementary and secondary education. The views and recommendations of the Advisory Panel shall provide periodic advice to the Secretary concerning the conduct of studies authorized by Section 1203 and make interim reports to the President and the Congress in 1980, 1981, and 1982 on the results of the studies conducted. The Advisory Panel shall also provide comments on the Secretary's annual reports and such additional recommendations for legislation or other appropriate action to the Congress no later than sixty days after submission of such reports.

The meeting of the Advisory Panel will be open to the public.

The proposed agenda includes:

(1) Meeting of the three subcommittees for Budget, Calendar, and Draft Report

(2) General review of organizational business

Records shall be kept of all Advisory Panel proceedings and shall be available for public inspection at the Office of the Assistant Secretary for Education, 200 Independence Avenue, S.W., Room 313-H, Washington, D.C. 20202.

Signed at Washington, D.C., on October 30, 1979.

George B. Lane,

Acting Executive Director, Advisory Panel on Financing Elementary and Secondary Education.

[FR Doc. 79-33918 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-89-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Neighborhoods, Voluntary Associations and Consumer Protection

[Docket No. N-79-958]

Neighborhood Self-Help Development Program

AGENCY: Department of Housing and Urban Development/NVACP.

ACTION: Notice of Public Meetings.

SUMMARY: The Department of Housing and Urban Development's Office of Neighborhoods, Voluntary Associations and Consumer Protection announces eitht (8) public meetings to provide information on the interim regulations governing the Neighborhood Self-Help Development program. Among other things, the meetings will assist the public in commenting on the interim regulations which were published in the Federal Register on October 22, 1979. The deadline for submitting written comments is January 7, 1980. Instructions for submitting written comments are set forth in the interim regulations (see Federal Register/ Vol.44 No. 205/Monday, October 22, 1979/ p. 60934).

LOGISTICS FOR THE MEETINGS:

Date and time	Location	Local contact
1. Nov. 12, 1979	Faneuil Hall, Faneuil Hall Square, Government Center, Boston, MA.	Phil Salamoni (617) 223-4066.
2. Nov. 12, 1979	Bean Towers, 135 23rd Street, Denver, CO.	Andy Villarosa (303) 327-2857.
3. Nov. 13, 1979	Blue Gargoyle, 5655 University Ave., Disciples of Christ, University Church, Chicago, IL.	Tony Medinah (312) 353-5680.
4. Nov. 14, 1979	Earl Cabelle Federal Building, 1100 Commerce, Room 7A23, Dallas, TX.	Clarence Babers (214) 749-1401.

Date and time	Location	Local contact
5. Nov. 15, 1979	Treasure Island Theatre, 9th Street & Ave. I, San Francisco, CA.	Sue Hogge (415) 556-4752.
6. Nov. 15, 1979	Georgia Institute of Technology, Electrical Engineering Auditorium, Between North Avenue and 10th Street, Atlanta, GA.	Clyde Barron (404) 221-4576.
7. Nov. 19, 1979	State Office Building, Art Gallery, 163 West 126 Street, New York, NY.	Sonia Rivera (212) 264-8068 or Irma Miranda (212) 264-8068.
8. Nov. 19, 1979	Federal Office Building Auditorium, 915 Second Avenue, Seattle, WA.	Lois Brown (206) 399-5363.

All Public Meetings will start at 12:30 pm and end at 6:00 pm.

FOR FURTHER INFORMATION CONTACT: Joseph McNeely, Office of Neighborhoods, Voluntary Associations and Consumer Protection, Department of Housing and Urban Development, 451 7th Street, S.W. Room 4232, Washington, D.C. 20410, (202) 755-8227.

SUPPLEMENTARY INFORMATION: The Neighborhood Self-Help Development Act was passed by Congress on October 15, 1978 as Title VII of the Housing and Community Development Amendments of 1978. The Congress recently passed the first appropriation for the program. The purpose of the Neighborhood Self-Help Development program is to provide grants and other forms of assistance to neighborhood organizations to prepare and implement specific housing, economic and community development projects in low and moderate income neighborhoods. The program also intends to increase the capacity of neighborhood organizations to utilize and coordinate public and private resources to assist in the revitalization of their neighborhoods. More detailed information on the program is provided in the interim regulations. HUD's Office of Neighborhoods, Voluntary Associations and Consumer Protection is responsible for the development and administration of the Neighborhood Self-Help Development program.

PUBLIC MEETINGS: The eight (8) public meetings represent one component of the public participation plan for the program. Additional methods for enhancing participation include:

Consultation with other Federal Agencies, with public interest groups, national neighborhood network organizations, and civil rights groups.

The eight (8) public meetings will be open to all interested parties, and will be coordinated on a local level by a HUD representative identified in the above schedule of meetings. Representatives from the Central Office of the Department of Housing and Urban Development will also attend the eight (8) meetings.

Issued at Washington, D.C., October 24, 1979.

Richard C. D. Fleming,

General Deputy Assistant Secretary for Neighborhoods, Voluntary Associations and Consumer Protection.

[FR Doc. 79-34075 Filed 11-1-79; 8:45 am]

BILLING CODE 4210-01-M

INTERNATIONAL COMMUNICATION AGENCY

Advisory Committee on Music Charter Renewal

In accordance with the provisions of the Federal Advisory Committee Act (P.L. 92-463) the International Communication Agency announces that it has, with the concurrence of the General Services Administration, approved for a two year period a renewed charter for the Advisory Committee on Music. The new expiration date is October 15, 1981.

Copies of the charter have been filed with the Senate Foreign Relations Committee, the House International Relations Committee and the Library of Congress, as provided by law.

Jane S. Grymes,

Management Analysis Management Analysis/Regulations Staff, Associate Directorate for Management, International Communication Agency.

[FR Doc. 79-33957 Filed 11-1-79; 8:45 am]

BILLING CODE 8230-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[Colorado 24128AA]

Northwest Pipeline Corp.; R/W Applications for Pipeline

October 25, 1979.

Notice is hereby given that, pursuant to section 28 of the Mineral Leasing Act of 1920 (41 Stat. 449), as amended (30 USC 185), Northwest Pipeline Corporation, P.O. Box 1526, Salt Lake City, Utah 84110, has applied for a right-of-way additions 79430, 78826, 78827, for the Philadelphia Creek Gathering Systems of approxiamtely 2.152 miles of pipeline on the following Public Land:

Sixth Principal Meridian, Rio Blanco County, Colo.

T. 1 S., R. 101 W.
Sec. 32: SE¼SE¼;
Sec. 33: SW¼SW¼.
T. 2 S., R. 101 W.
Sec. 4: Lot 8, S½NW¼, E½SW¼; SW¼SE¼;
Sec. 5: Lots 5 and 6.

The above-named gathering systems will enable the applicant to collect natural gas and to convey it to its customers. The purpose for this notice are: (1) to inform the public that the Bureau of Land Mangement is proceeding with the preparation of environmental and other analytic reports, necessary for determing whether or not the application should be approved and if approved, under what terms and conditions; (2) to give all interested parties the opportunity to comment on the application; (3) to allow any party asserting a claim to the lands involved or having bona fide objections to the proposed natural gas gathering system to file its claim or objections in the Colorado State Office. Any party so filing must include evidence that a copy thereof has been served on *Northwest Pipeline Corporation.* Any comment, claim or objections must be filed with the Chief, Branch of Adjudication, Bureau of Land Management, Colorado State Office, Room 700, Colorado State Bank Building, 1600 Broadway, Denver, Colorado 80202, as promptly as possible after publication of this notice.

Andrew W. Heard, Jr.,

Leader, Craig Team, Branch of Adjudication.

[FR Doc. 79-33907 Filed 11-1-79; 8:45 am]

BILLING CODE 4310-84-M

[W-59189]

Sixth Principal Meridian, Wyoming; Notice of Application

October 23, 1979.

Notice is hereby given that pursuant to Sec. 28 of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 185), the Marathon Pipe Line Company of Casper, Wyoming filed an application to amend their existing right-of-way grant W-59189 to construct a rectifier and deep well bed and related facilities affecting the following described lands:

Sixth Principal Meridian, Wyoming

T. 47 N., R. 90 W.,
Sec. 8, W½SW¼.

The proposed rectifier and deep well bed and related facilities are to be located within a 20' right-of-way width as part of Marathon Pipe Line Company's maintenance program for an existing crude oil pipeline located in the W½SW¼ of Section 8, T. 47 N., R. 90 W., Washakie County, Wyoming.

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 do so promptly. Persons submitting comments should include their name and address and send them to the District Manager, Bureau of Land Management, 1700 Robertson Avenue, P.O. Box 119, Worland, Wyoming 82401.

Harold G. Stinchcomb,

Chief, Branch of Lands and Minerals Operations.

[FR Doc. 79-33908 Filed 11-1-79; 8:45 am]

BILLING CODE 4310-84-M

National Park Service

Gulf Islands National Seashore Advisory Commission; Meeting

Notice is hereby given in accordance with the Federal Advisory Committee Act that a meeting of the Gulf Islands National Seashore Advisory Commission will be held at 1 p.m. on December 6, 1979, at the Holiday Inn, Gulf Breeze, Florida, to be followed by a tour of Santa Rosa Island, Florida at 9:30 a.m. on December 7, 1979.

The purpose of the Gulf Islands National Seashore Advisory Commission is to consult and advise with the Secretary of the Interior or his designee on matters of planning and development of Gulf Islands National Seashore.

The members of the Advisory Commission are as follows:

Paul A. Daniel, Chairman (Florida)
Charles S. Liberis, Jr. (Florida)
Mrs. Erica Woolley (Florida)
Michael M. Mitchell (Florida)
Gordon D. Allen (Mississippi)
Lloyd J. Caillavet (Mississippi)
John Duncan Moran (Mississippi)
Michael Merritt (Florida)
William S. Rosasco III (Florida)
Mrs. J. H. Etheridge (Florida)
Frederick Donovan (Florida)
The Reverend A. A. Dickey (Mississippi)
Mrs. Joan Gilley (Mississippi)
Mrs. Ann P. LaRosa (Mississippi)

The matters to be discussed at this meeting will include: (1) An Operations Report, (2) Seashore Statement for Management, and (3) Review of Hurricane Frederic damage to Seashore resources.

The meeting will be open to the public. However, facilities and space for accommodating members of the public are limited and it is expected that not more than 25 persons will be able to attend. Any member of the public may file with the commission a written statement concerning the matters to be discussed. Members of the public may attend the tour of Santa Rosa Island, Florida if they provide their own transportation.

Persons wishing further information concerning this meeting or who wish to submit written statements may contact Franklin D. Pridemore, Superintendent, Gulf Islands National Seashore, P.O. Box 100, Gulf Breeze, Florida 32561, Telephone 904-932-6316. Minutes of the meeting will be available at Park Headquarters for public inspection approximately four weeks after the meeting.

Dated: October 22, 1979.

Joe Brown,

Regional Director, Southeast Region.

[FR Doc. 79-33904 Filed 11-1-79; 8:45 am]

BILLING CODE 4310-70-M

Geological Survey

Lessees of Federal Oil and Gas Leases in the Outer Continental Shelf (OCS), Gulf of Mexico Area; Relief From Compliance With Certain Requirements of OCS Order No. 13

October 25, 1979.

In response to an appeal by a lessee, the Acting Director of the Geological Survey, on January 18, 1979, issued a decision which provided relief from compliance with some of the requirements of the existing OCS Order No. 13.

In order to prevent unequal treatment, pending the final revision of OCS Order No. 13, all other OCS lessees in the Gulf of Mexico Area are hereby notified that they are excused from compliance with certain requirements of OCS Order No. 13.

The modified requirements are set forth below as items 1 through 5.

Effective January 18, 1979, lessees have the option of complying either with the existing Order or with the Order as modified by the decision. Lessees who elect to abide by the modifications are relieved from compliance with the Order to the extent that it is modified; however, such lessees are charged with the responsibility of operating in accordance with the modifications.

A proposed revised Gulf of Mexico Area OCS Order No. 13 is now being developed and will be published at a later date with a solicitation for comments. It is contemplated that the proposed revised Order will contain several revisions in addition to the modifications itemized below.

Item No. 1. The first three sentences in subparagraph 2A(3), *Sampler*, are revised as follows:

(3) *Sampler.* A proportional-to-flow sampling device, which shall be pulsed by the meter counter, with the sampling point installed in the flow stream immediately upstream or downstream of the meters or diverter valve. The sampler container shall be vaportight, with a mixing device to permit complete mixing of the sample, prior to removal from the container. The sampler probe shall extend into the center of the flow piping in a vertical run, in a region of turbulent flow at least three pipe diameters downstream of any pipe fitting.

Item No. 2. The second sentence of the subparagraph 2C, *Sales Meter Proving Equipment*, is revised as follows:

Representatives of the seller, buyer, transporter, and U.S. Geological Survey (USGS) shall have the right to witness the calibration and proving of liquid sales meters.

Item No. 3. Subparagraph 2C(3)(b), *Master Meter*, is revised as follows:

(b) *Master Meter.* In establishing the operating meter factor with a master meter, the master meter shall first be operating within manufacturer's specifications, and be calibrated with similar gravity crude and flow rate. A minimum of two consecutive runs with a prover tank or five out of six consecutive runs with a mechanical-displacement prover which repeat within a tolerance of *0.0002* shall be made for determination of the master meter factor. In establishing the operating meter factor with the master meter, a minimum of three consecutive runs shall be within a tolerance of *0.0005.* The volume of each of these runs shall be at least 10 percent of the hourly rated capacity of the operating meter but must be of sufficient amount for determination of an accurate operating meter factor. The master meter installation shall include:

(i) A back-pressure valve downstream of the operating and master meter.

(ii) A check valve to prohibit backflow. The lessee shall submit a copy of the official record of each master meter calibration to the USGS Gulf of Mexico Area Office within 7 days.

Item No. 4. The first four sentences of subparagraph 5B(5), *Malfunction*, are revised as follows:

(5) *Malfunction.* If at any time the measuring equipment is found to be out-of-service or not registering within the limits of accuracy prescribed by the manufacturer, it shall be immediately removed from service until repaired or adjusted to read accurately. If the error in the measuring equipment is found to be within 2 percent, previous readings of such equipment shall be considered correct in computing deliveries of gas thereunder. If the error in the measuring equipment is found to be more than 2 percent, at a recording corresponding to the average hourly rate of flow for the period since the last preceding calibration (test), the volume measured since the last calibration shall be corrected as follows:

(a) *Sales Meters.*

(i) If the time of the error is ascertainable, the volume adjustment shall be calculated from the time the error occurred.

(ii) If the time the error occurred is not ascertainable, the volume adjustment shall be applied to one-half of the time elapsed since the last date of calibration or 28 days, whichever is less.

(b) *Allocation Meters.*

(i) If the time of the error is ascertainable, the volume adjustment shall be calculated from the time the error occurred; however, no retroactive adjustment of volumes metered for allocation is required beyond a 23-day period.

(ii) If the time the error occurred is not ascertainable, the volume adjustment shall be applied to one-half of the time elapsed since the last date of calibration or 23 days, whichever is less.

Item No. 5. Paragraph 8, *Accidents*, is revised as follows:

Accidents. Any accident involving metering equipment which causes a fire, damage to equipment, serious injuries, or pollution shall be reported to the Oil and Gas Supervisor, Operations Support, within 24 hours. A complete, detailed report shall be submitted to this Supervisor within 10 days.

Copies of this notice to lesses are available from D.W. Solanas, Oil and Gas Supervisor, Operations Support, Gulf of Mexico Region, U.S. Geological Survey, P.O. Box 7944, Metairie, La. 70011.

Hillary A. Oden,

Acting Chief, Conservation Division.

[FR Doc. 79-33917 Filed 11-1-79; 8:45 am]

BILLING CODE 4310-31-M

Bureau of Reclamation

Contract Negotiations To Pay Costs of American Falls Replacement Dam Minidoka Project—Idaho-Wyoming; Availability of Proposed Contract for Public Review and Comment

The Department of the Interior, through the Bureau of Reclamation, has sent a proposed draft contract to the various irrigation water users that hold space in American Falls Reservoir, Minidoka Federal Reclamation Project, Idaho, and have previously contracted with the United States and the Constructing Agency (American Falls Reservoir District) to pay a proportionate share of the costs of replacing the American Falls Dam, pursuant to the Act of December 28, 1973 (87 Stat. 904). The proposed contract would amend those irrigation spaceholder contracts dated March 31, 1976, which provided for replacement of the dam and related facilities and for the financing of the costs associated therewith by the sale of tax-exempt bonds, as authorized by section 7 of the Act of December 23, 1975 (89 Stat. 970, 976). The irrigation spaceholder's proportionate share of the total cost of the American Falls Replacement Dam Project is estimated to be about $19.2 million. The remaining cost of the program, estimated to be about $21 million, will be paid by Idaho Power Company under a falling water contract for downstream power generation executed March 31, 1976, and a spaceholder contract of the same date, which assumed a proportionate share of the replacement costs attributable to reservoir space that was contracted for on June 15, 1923. Upon completion, the replacement dam and related facilities will be conveyed to the United States, and the dam and reservoir will be operated as an integral part of the Minidoka Federal Reclamation Project. The capacity of the American Falls Reservoir will remain unchanged as will the acre-foot storage space entitlement of each irrigation spaceholder.

The proposed contract amendment will provide for payment by the United States of each obligated irrigation spaceholder's proportionate share of the final cost of construction of the American Falls Replacement Dam Program and will establish the terms and conditions under which the payment will be made. After acceptance by the spaceholders and approval by the Secretary of the Interior, the amendment will be executed pursuant to section 7 of the Reclamation Safety of Dams Act of 1978 (92 Stat. 2471), enacted November 2, 1978. That act authorizes and directs the Secretary of the Interior "to pay and discharge that portion of the costs associated with the replacement of the American Falls Dam which the irrigation spaceholder contracting entities are obligated to pay pursuant to implementation of the Act of December 28, 1973 (87 Stat. 904). . . ."

It is anticipated that contracts will later be offered to those irrigation water user entities that did not execute the spaceholder contract in 1976. These contracts will contain terms and conditions similar to the 1976 contracts and the proposed amendment.

The public may observe any negotiating sessions. Advance notice of such sessions, if any, will be furnished on request. Requests must be in writing and submitted one week prior to a scheduled session. Requests must identify the contract in which the party is interested. They should be addressed to the Regional Director, attention code 440, Bureau of Reclamation, 550 W. Fort Street—Box 043, Boise, Idaho 83724.

For further information on scheduled negotiating sessions and copies of the proposed contract amendment, please contact Richard Fuller, Repayment and Statistics Branch, Division of Water, Power, and Lands, Bureau of Reclamation, at the above address; telephone (208) 384-9503.

Comments on the proposed contract amendment will be accepted for 30 days from the date of this publication. All correspondence concerning the proposed amendment is available to the general public pursuant to the Freedom of Information Act (80 Stat. 383), as amended.

This notice is supplemental to the notice published on January 4, 1979, on the same subject.

Dated: October 26, 1979.

Clifford L. Barrett,

Assistant Commissioner of Reclamation.

[FR Doc. 79-33830 Filed 11-1-79; 8:45 am]

BILLING CODE 4310-09-M

DEPARTMENT OF JUSTICE

Proposed Consent Decree in Action To Enjoin Discharge of Water Pollutants

In accordance with Departmental Policy, 28 CFR § 50.7, 38 FR 1902, notice is hereby given that a proposed consent degree in *United States of America* v. *Bacardi Corporation*, Civil Action No. 79-2324, has been lodged with the United States District Court for District of Puerto Rico. The proposed decree would require Bacardi Corporation to construct, by December 1, 1983, and to operate treatment facilities in order to achieve compliance with a new NPDES permit to be issued to it.

The Department of Justice will receive for thirty (30) days from the date of publication of this notice, written comments relating to the proposed judgment. Comments should be addressed to the Assistant Attorney General, Land and Natural Resources Division, Department of Justice, Washington, D.C. 20530, and refer to *United States* v. *Bacardi Corporation*, D.J. Ref. 90-5-1-1-1261.

The proposed consent decree may be examined at the office of the United States Attorney, U.S. Post Office and Courthouse Building, Receipto Sur, Old San Juan, Puerto Rico, 00904; at the Region II office of the Environmental Protection Agency, Enforcement Division, 26 Federal Plaza, New York, New York 10007; and at the Pollution Control Section, Land and Natural Resources Division, Department of Justice, Room 2625, Ninth and Pennsylvania Avenue, N.W., Washington, D.C. 20530. A copy of the proposed consent decree may be obtained in person or by mail from the

Pollution Control Section, Land and Natural Resources Division, Department of Justice.

James W. Moorman,

Assistant Attorney General, Land and Natural Resources Division.

[FR Doc. 79-33952 Filed 11-1-79; 8:45 am]

BILLING CODE 4410-01-M

Antitrust Division

Hearing on Proposed Modification and Ultimate Termination of Final Judgment; United States v. Swift & Co., et al.

The following notice is published pursuant to the Order of the United States District Court for the Northern District of Illinois. It sets a hearing for January 17, 1980 and invites public comment on a proposal to modify and ultimately terminate an antitrust judgment against major meat packing companies.

Dated: October 26, 1979.

Gregory B. Hovendon,

Assistant Chief, Judgment Enforcement Section, Antitrust Division, Department of Justice.

In the U.S. District Court for the Northern District of Illinois, Eastern Division

United States of America, Plaintiff, v. *Swift & Company; Armour and Company; Wilson & Co., Inc.;* and *Cudahy Company; et al.,* Defendants.

Civil Action No. 58 C 613.

Notice of Hearing Concerning Proposed Modification of Packers Consent Decree (Entered February 27, 1920 and Previously Modified December 20, 1971 and January 17, 1975)

Pursuant to order of the Honorable Julius J. Hoffman, Senior Judge, United States District Court for the Northern District of Illinois, Eastern Division, a hearing shall be held at 10:00 a.m. on January 17, 1980, before the Honorable Judge Hoffman in Room 1719 of the United States Courthouse, 219 S. Dearborn Street, Chicago, Illinois, 60604, for the purpose of considering the Joint Motion of plaintiff, United States of America, and defendants, Swift & Company and Armour and Company, for entry of an order entitled "Modified And Suplemental Final Judgment—III" in the aforesaid proceeding. The effect of the aforesaid Modified And Supplemental Final Judgment—III would be to permit the defendants, subject to the antitrust laws, to do the following:

1. Transport those non-meat food products and product lines listed and referred to in Article Third, Fourth and Eighth of the decree (referred to herein as Specified Product Lines), and use or permit others to use the distribution systems and facilities of the defendants in any manner for the purchase, sale, handling, transporting, distributing, or otherwise dealing in any Specified Product Line.

2. Enter by de novo entry through internal expansion into all types of meat and other grocery retailing (including the operation of meat markets, general retail grocery stores, dining rooms, restaurants, fast-food facilities, and all other retail activity).

3. Enter meat and grocery retailing by acquiring all or any part of the stock or assets of a company already engaged in retailing; provided that no such acquisition would be permitted (1) if the company whose stock were to be acquired made, or the assets which were to be acquired accounted for, more than $100 million of total sales in retailing of all Specified Product Lines in the United States in the immediately preceding fiscal year of the company, or (2) if the company whose stock were to be acquired or the assets which were to be acquired was one of the four leading sellers in total dollar sales of grocery and meat products through combination food stores in any Standard Metropolitan Statistical Area with a population of one million persons or more in the immediately preceding calendar year, if the four leading sellers in such area accounted for 50% or more of the sales of grocery and meat products through combination stores in that year.

4. Enter the manufacture or distribution of any Specified Product Line by acquiring all or any part of the stock or assets of a company already engaged in such manufacture or distribution; provided that no such acquisition would be permitted (1) if the company whose stock were to be acquired made, or the assets to be acquired accounted for, more than $100 million of total sales in manufacturing and distributing of all Specified Product Lines in the United States in the immediately preceding fiscal year of the company, or (2) if the company whose stock were to be acquired or the assets which were to be acquired was one of the four leading manufacturers or distributors in dollars in the United States of any product or group of products set forth in the proposed order (essentially groups of grocery products), if the four leading sellers of any such product or group of products accounted for 50% or more of such sales.

5. Acquire and subsequently hold no more than 10% of the outstanding voting securities of, or other interest in, any company (1) manufacturing, jobbing, selling, distributing or otherwise dealing in any Specified Product Line, (2) owning, operating or conducting any retail meat market, or (3) owning a public cold storage warehouse. Any securities or other interest acquired pursuant to this authority must be held solely for the purpose of investment by the acquiring defendant.

In addition, the proposed order provides that the Final Judgment, as amended, shall terminate and expire five years after the date of entry of the Modified And Supplemental Final Judgment—III, subject to the provision that the plaintiff may apply to the Court for continuation of all or any part of the Final Judgment, as amended, such application to be made not later than 180 days prior to the scheduled termination date of the Decree.

Additional information and copies of the proposed Modified And Supplemental Final Judgment—III may be obtained by contacting one of the undersigned attorneys for the United States:

Greogory B. Hovendon, Assistant Chief, Judgment Enforcement Section, Antitrust Division, United States Department of Justice, Washington, D.C. 20530, Phone: (202) 633-2495.

John Wilson, Judgment Enforcement Section, Antitrust Division, United States Department of Justice, Washington, D.C. 20530, Phone: (202) 633-2480.

John E. Sarbaugh, Chief, Midwest Office, United States Department of Justice, 219 South Dearborn Street, Chicago, Illinois 60604, Phone: (312) 353-7538.

Dated: October 25, 1979.

H. Stuart Cunningham,

Clerk of Court.

[FR Doc. 79-33953 Filed 11-1-79; 8:45 am]

BILLING CODE 4410-01-M

Proposed Consent Judgment, United States v. Acme Meat Company, et al. and Competitive Impact Statement Therein

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16 (b) through (h), that a proposed consent judgment and a competitive impact statement as set out below have been filed with the United States District Court for the Central District of California in Civil Action No. 78-1436-RMT (TX), *United States* v. *Acme Meat Company, et al.*

The complaint in this case alleges that twelve corporate defendants, engaged in the meat packing business, conspired to fix sales prices of carcass beef to Safeway supermarkets and other retail grocery chains in the Los Angeles Metropolitan area.

The proposed Judgment prohibits each defendant from agreeing to fix, determine, maintain, or stabilize prices with any other person or company and from communicating current and future price information concerning carcass beef to any other meat packing company or its agents. The proposed Judgment, which is ten years in duration, requires the corporate defendants to distribute copies of the Judgment to their directors, officers, and employees responsible for the pricing of carcass beef and to submit an annual statement to these persons that any knowing violation of the Judgment will result in termination of employment.

Public comment is invited within the statutory 60 day time period. Such comments and responses thereto will be published in the Federal Register and filed with the Court. Comments should be directed to Crossan R. Andersen, Assistant Chief, Los Angeles Field Office, Department of Justice, Room 3101 Federal Building, 300 North Los Angeles Street, Los Angeles, California 90012.

Dated: October 22, 1979.

Joseph H. Widmar,

Director of Operations.

Julian S. Greenspun, Irma Gonzales Dirst, Crossan R. Andersen, Antitrust Division, Department of Justice, 3101 Federal Building, 300 North Los Angeles Street, Los Angeles, California 90012, telephone: (213) 688-2515; Attorneys for the Plaintiff.

United States District Court, Central District of California

United States of America, Plaintiff, v. *Acme Meat Company; Bristol Foods, Incorporated,* d.b.a. *Gold Pak Meat Company; Delta Meat Packing Company; Federal Meat Company; Gem Packing Company; Globe Packing Company; Great Western Packing Company; Meat Packers, Incorporated; O.K. Meat Packing Company; Quality Meat Packing Company; Serv-U Meat Packing Company; Shamrock Meats, Incorporated; Union Packing Company;* and *Ward Foods, Incorporated,* Defendants.

Civil No. 78-1436-RMT (TX), Stipulation Re: Consent Judgment. Filed: October 22, 1979.

IT IS HEREBY STIPULATED by and between the undersigned parties, by their respective attorneys, that:

(1) A Final Judgment in the form attached may be filed and entered by the Court, upon the motion of any party or upon the Court's own motion, at any time after compliance with the requirements of the Antitrust Procedures and Penalties Act (15 U.S.C. § 16), and without further notice to any party or other proceedigs, provided that Plaintiff has not withdrawn its consent, which it may do at any time before the entry of the proposed Final Judgment by serving notice on the defendant and by filing that notice with the Court.

(2) In the event Plaintiff withdraws its consent or if the proposed Final Judgment is not entered pursuant to this stipulation, this stipulation shall be of no effect whatever, and the making of the stipulation shall be without prejudice to Plaintiff and the defendants in this or any other proceeding.

Dated: This 22nd day of October, 1979.

For Plaintiff:

John H. Shenefield,

Assistant Attorney General.

Joseph H. Widmar,

Director of Operations.

Crossan R. Andersen,

Assistant Chief, Antitrust Division Los Angeles Field Office.

Julian S. Greenspun,

Attorney.

Julian S. Greenspun, Irma Gonzalez Dirst, Crossan R. Andersen, Antitrust Division, Department of Justice, 3101 Federal Building, 300 North Los Angeles Street, Los Angeles, California 90012, telephone: (213) 688-2515; Attorneys of the Plaintiff.

United States District Court, Central District of California

United States of America, Plaintiff, v. *Acme Meat Company; Bristol Foods, Incorporated,* d.b.a. *Gold Pak Meat Company; Delta Meat Packing Company; Federal Meat Company; Gem Packing Company; Globe Packing Company; Great Western Packing Company; Meat Packers, Incorporated; O.K. Meat Packing Company; Quality Meat Packing Company; Serv-U Meat Packing Company; Shamrock Meats, Incorporated; Union Packing Company;* and *Ward Foods, Incorporated,* Defendants.

Civil No. 78-1436-RMT (TX), Stipulation Re: Final Judgment. Filed: October 22, 1979.

Plaintiff, United States of America, having filed its Complaint on April 13, 1978, and the plaintiff and the defendants, by their respective attorneys, having consented to the entry of this Final Judgment, without trial or adjudication of any issue of fact or law herein, without admission by any party with respect to any such issue, and without this Final Judgment constituting evidence with respect to any such issue;

Now, Therefore, before any testimony or evidence has been taken herein, and without trial or adjudication of any issue of fact or law herein, and upon the consent of the parties hereto,

It is hereby ordered, adjudged and decreed as follows:

I

This Court has jurisdiction of the subject matter hereof and of the parties hereto. The Complaint states a claim against the defendants upon which relief may be granted under Section 1 of the Sherman Act, 15 U.S.C. § 1.

II

As used in this Final Judgment:

(A) "Person" means any individual, partnership, firm, corporation, association, or other business or legal entity;

(B) "Meat packer" means a business entity which slaughters cattle (or has cattle slaughtered for it by a third party) and dresses and sells such slaughtered cattle as beef products, such as dressed beef, primal cuts, fabricated meat or finished meat products;

(C) "Carcass beef" means slaughtered beef which has been dressed and not processed into primal or subprimal cuts or otherwise further products;

(D) "Los Angeles area" means the geographic area comprising the Counties of Los Angeles, Orange, Riverside, San Bernardino, Ventura and Santa Barbara, California;

(E) "Defendant corporation" means each defendant named in the complaint in this case and listed in the caption in this Final Judgment, except the defendant Meat Packers, Incorporated, which no longer exists.

III

The provisions of this Final Judgment are applicable to the defendant corporations and to each of their officers, directors, agents, employees, subsidiaries, successors and assigns, and to all other persons in active concert or participation with any of them who shall have received actual notice of this Final Judgment by personal service or otherwise.

IV

Each defendant corporation is enjoined and restrained from entering into, adhering to, maintaining or furthering any contract, agreement, understanding, plan or program with any other person directly or indirectly, to:

(A) Fix, determine, maintain or stabilize prices, or other terms or conditions for the sale of carcass beef to any third person in violation of the Sherman Act; and

(B) Communicate or exchange information with any other meat packing company, employee or officer thereof, concerning the present or future prices, including terms and conditions of sale, that any meat packing company is charging or may charge for beef carcass(es) in the Los Angeles area as defined in Paragraph II(D) above. "Present prices" is herein defined as prices being charged on the date of the communication or exchange and any open bid or offer as of said date.

V

Each defendant corporation is enjoined and restrained from:

(A) Directly or indirectly communicating or exchanging information with any other meat packing company, employee or officer thereof, concerning the present or future prices, including terms and conditions of sale, that any meat packing company is charging or may charge for beef carcass(es) in the Los Angeles area as defined in Paragraph II(D) above. "Present prices" is herein defined as prices being charged on the date of the communication or exchange and any open bid or offer as of said date.

(B) Directly or indirectly communicating or exchanging any information with other meat packing company, employee or officer thereof, for the purpose of fixing, increasing, decreasing, maintaining or stabilizing the price of sale of carcass beef to purchasers thereof within the Los Angeles area as defined in Paragraph II(D) above.

(C) Joining, participating in or belonging to any trade association, organization, or other group with knowledge that any of the activities thereof are inconsistent with any terms of this Final Judgment.

VI

Each defendant corporation is ordered and directed:

(A) Within sixty (60) days after the date of entry of this Final Judgment to furnish a copy thereof to each of its directors, officers, plant managers and sales managers who have pricing responsibility in connection with the sale of carcass beef in the Los Angeles area; and shall advise and inform each such person that violation of this Final Judgment could result in a conviction for contempt of court and imprisonment and/or fine; and

(B) Within sixty (60) days after the date of entry of this Final Judgment to file an affidavit of compliance with the Clerk of the Court, and serve upon the plaintiff reciting the fact and manner of compliance with provision (A) of this Section.

VIII

(A) Each defendant corporation shall advise each of the persons described in

Section VI(A) of this Final Judgment, and each of their successors, of its and their obligations under this Final Judgment, and for a period of ten (10) years from the entry of this Final Judgment, shall maintain a program to insure compliance with this Final Judgment. Defendant corporation's compliance program shall include at a minimum the following with respect to each of the persons described in Section VI(B), and each of their successors:

(1) The distribution to them of this Final Judgment;

(2) The annual submission to them of a statement that corporate policy absolutely prohibits any violation of the antitrust laws or of this Final Judgment, and a knowing disregard of this policy will result in termination;

(3) The imposition of a requirement that each of them sign and submit to his employer a certificate in substantially the following form:

"The undersigned hereby (1) acknowledges receipt of a copy of the 1979 Meat Packing Final Judgment and a written directive setting forth the company policy regarding compliance with the antitrust laws and with such Final Judgment, (2) represents that the undersigned has read and understands such Final Judgment and directive, (3) acknowledges that the undersigned has been advised and understands that non-compliance with such policy and Final Judgment will result in dismissal, and (4) acknowledges that the undersigned has been advised and understands that non-compliance with the Final Judgment may also result in conviction for contempt of court and imprisonment and/or fine";

(4) The holding of one or more meetings with them to review the terms of this Final Judgment and the obligations it imposes, with such meetings to be arranged and conducted so that each of them attends at least one such meeting per year.

(B) For a period of ten (10) years from the entry of this Final Judgment, each defendant corporation shall file with the Court and with the plaintiff, on the anniversary date of this Final Judgment, a sworn statement, by a responsible official designated by the defendant corporation to perform such duties, and the person in charge of sales, setting forth all steps it has taken during the preceding year to discharge its obligations under this Section VII. This statement shall be accompanied by copies of all written directives issued by the defendant corporation during the prior year with respect to compliance with the antitrust laws and with this Final Judgment.

(C) The plaintiff may demand and obtain a more detailed statement of a defendant corporation's compliance with this Final Judgment if plaintiff determines that such defendant corporation's annual compliance statement incompletely states the steps it has taken to discharge its duties under this Section VII.

VIII

Nothing in this Final Judgment shall prohibit any defendant corporation:

(A) From entering into or carrying out a bona fide purchase or sale transaction involving such defendant and any other person engaged in the production and/or sale of carcass beef, when such person is either purchasing carcass beef on his own behalf or acting as a purchasing agent or group buying representative on behalf of any third person; or

(B) Communicating information to another person engaged in the production and/or sale of carcass beef in the course of, and related to, negotiating for, entering into, or carrying out a transaction as described in Section VIII(A).

IX

(A) For the purpose of determining or securing compliance with this Final Judgment, any duly authorized representative of the Department of Justice shall, on written request of the Attorney General or the Assistant Attorney General in charge of the Antitrust Division, and on reasonable notice to any defendant corporation made to its principal office, be permitted, subject to any legally recognized privilege:

(1) Access during the office hours of such defendant corporation to inspect and copy all books, ledgers, accounts, correspondence, memoranda, and other records, and documents in the possession or under the control of such defendant corporation, who may have counsel present, relating to any matters contained in the Final Judgment; and

(2) Subject to reasonable convenience of such defendant corporation and without restraint or interference from it, to interview any officers, directors, agents, partners or employees of such defendant corporation, any of whom may have counsel present, regarding any such matters.

(B) Each defendant corporation, upon the written request of the Attorney General or the Assistant Attorney General in charge of the Antitrust Division shall submit such reports in writing with respect to any of the matters contained in this Final Judgment, as may from time to time be requested, subject to any legally recognized privilege.

No information obtained by the means provided in this Section IX shall be divulged by any representative of the Department of Justice to any person other than a duly authorized representative of the Executive Branch of the United States, except in the course of legal proceedings to which the United States is a party, or for the purpose of securing compliance with this Final Judgment, or as otherwise required by law.

If at any time information or documents are furnished by a defendant corporation to plaintiff, such defendant corporation represents and identifies in writing the material in any such information or documents which is of a type described in Rule 26(c)(7) of the Federal Rules of Civil Procedure, and said defendant corporation marks each pertinent page of such material "Subject to claim of protection under Rule 26(c)(7) of the Federal Rules of Civil Procedure," then 10 days notice shall be given by plaintiff to such defendant corporation prior to divulging such material in any legal proceeding (other than a Grand Jury proceeding) to which the defendant corporation is not a party.

X

Jurisdiction is retained for the purpose of enabling any of the parties to this Final Judgment to apply to this Court at any time for such further orders and directions as may be necessary or appropriate for the construction or carrying out of this Final Judgment or for the modification of any of the provisions herein and for the enforcement of compliance herewith and the punishment of the violation of any of the provisions contained herein. The duration of this decree shall be ten (10) years from the date of entry of the Final Judgment.

XI

Entry of this Final Judgment is in the public interest.

Dated: this _____ day of _____, 1979.

United States District Judge.

Julian S. Greenspun, Irma Gonzalez Dirst, Crossan R. Andersen, Antitrust Division, Department of Justice, 3101 Federal Building, 300 North Los Angeles Street, Los Angeles, California 90012, telephone: (213) 688-2515; Attorneys for the Plaintiff.

U.S. District Court, Central District of California

United States of America, Plaintiff, v. *Acme Meat Company; Bristol Foods, Incorporated*, d.b.a. *Gold Pak Meat Company; Delta Meat Packing Company; Federal Meat Company; Gem Packing Company; Globe Packing Company; Great Western Packing Company; Meat Packers, Incorporated; O.K. Meat Packing Company; Quality Meat Packing Company; Serv-U Meat Packing Company; Shamrock Meats, Incorporated; Union Packing Company;* and *Ward Foods, Incorporated*, Defendants.

Civil No. 78-1436-RMT (TX), Competitive Impact Statement. Filed: October 22, 1979.

Pursuant to Section 2(b) of the Antitrust Procedures and Penalties Act, 15 U.S.C. § 16(b), the United States of America hereby files this Competitive Impact Statement relating to the proposed Final Judgment submitted for entry in this civil antitrust proceeding.

I

Nature and Purpose of the Proceeding

On August 13, 1978, the United States filed the complaint in this case, under Sections 1 and 4 of the Sherman Act, 15 U.S.C. §§ 1 and 4. The complaint alleges that from at least 1965 to at least 1974, the defendants and other conspirators engaged in a combination and conspiracy to fix, raise and stabilize the selling price of carcass beef in the metropolitan Los Angeles market area, in violation of Section 1 of the Sherman Act.

The complaint requested the Court to find that the defendants engaged in the unlawful conspiracy alleged and to enjoin its continuation and the exchange of carcass beef price information among the defendant meat packers.

The corporate defendants in this civil action as well as several of their officers

were also indicted on April 3, 1978 for the same activity which is the basis for the complaint in this case. All of the corporate and eight individual defendants plead nolo contendere to a criminal violation of Section 1 of the Sherman Act before the Honorable United States District Judge Malcom Lucas. Ruben Krasn, Senior Executive of Globe Packing Company, proceeded to jury trial on the indictment and was convicted.

Entry of the proposed Final Judgment will terminate this civil action as to all defendants. The Court will retain jurisdiction over the matter for any further proceedings which might be required to interpret, modify, or enforce the Judgment, or to punish violations of any of the provisions of the Judgment.

II

Description of Practices Involved in the Violation

The defendants are corporations engaged in the meat packing business in Southern California. They purchase cattle from feed lots located in five western states, then slaughter and dress the cattle into several products. The carcass beef sold by the defendants is beef which had been dressed but not processed further into sub-cuts, such as primal cuts, sub-primal cuts, and finished meat products.

The defendant meat packers' primary carcass beef customers are chain and independent retail grocery stores, food wholesalers, and government installations. In 1976, the defendants had total sales of $827 million, including approximately $277 million in sales of carcass beef.

The price fixing activities alleged in the complaint included weekly meetings between officers of the defendant meat packers at which a uniform sale price of carcass beef for the forthcoming week was discussed and agreed upon. The meetings were held on Wednesday mornings at the meat packers' trade association office. There the defendants' representatives discussed and arrived at prices which they would bid that afternoon to Safeway stores for Safeway's weekly purchases of carcass beef. The fixed price quoted to Safeway would often become the price also quoted by the defendants to other grocery chains and purchasers of carcass beef. In addition to the Wednesday meetings, the defendant packers occasionally fixed prices in telephone conversations with each other.

The complaint alleges that this conspiracy had the following effects: (a) price competition in the sale of carcass beef in the Los Angeles area has been restrained; (b) the defendants' customers have been deprived of the opportunity to purchase carcass beef in an open and competitive market; (c) prices for carcass beef sold to customers of the defendants in the Los Angeles area have been artificially increased and stabilized, and; (d) interstate commerce and trade in the purchase and sale of beef has been adversely restrained.

III

Procedural History of Case

The civil complaint in this case was filed on August 13, 1978. Negotiations towards a consent decree were commenced subsequent to the termination of litigation in the criminal case, in September of 1978. Meat Packers, Inc., the defendant trade association, has been officially dissolved and it is expected that it will be dismissed as a defendant, without prejudice.

IV

Explanation of the Proposed Consent Judgment

The United States and the defendants have agreed that a Final Judgment in the form negotiated by the parties may be entered by the Court at any time after compliance with the Antitrust Procedures and Penalties Act, provided that the Plaintiff has not withdrawn its consent. The stipulation provides that there has been no admission by any party with respect to any issue of fact or law. Under the provisions of Section 2(e) of the Antitrust Procedures and Penalties Act, entry of the Judgment is conditional upon a determination by the Court that it is in the public interest.

A. Prohibited Conduct

The proposed Judgment prohibits the defendants from entering into, or claiming rights under, any agreement to fix, determine, maintain, or stabilize prices or other terms or conditions of sale of carcass beef to any third person in violation of the Sherman Act. The defendants are further prohibited from communicating with another meat packing company concerning the prices or terms and conditions of sale of carcass beef which any meat packing company is charging that day, including unaccepted bids or offers as of that date, or may charge in the future to any past, present, or prospective purchaser in the Los Angeles Metropolitan area. Bond fide purchases and sales of carcass beef between a defendant and another meat packing company would be excluded from this restriction.

B. Scope of the Proposed Judgment

The Final Judgment applies not only to the defendant companies but also to their directors, officers, agents, and those employees who have pricing responsibility for the sale of carcass beef, as well as to any successors or assigns of the defendant. It also applies to anyone participating with the defendant in conduct prohibited by the Judgment who receives actual notice of the Judgment.

The duration of the Judgment is 10 years. It is applicable to sales of carcass beef anywhere within the Southern California counties of San Bernardino, Riverside, Los Angeles, Ventura and Santa Barbara. In addition, the defendant is obligated for a period of ten years to maintain a program to insure compliance with the Judgment. The defendant must distribute to their directors, officers and those employees involved in the pricing of carcass beef, a copy of the Judgment and these persons must acknowledge in writing the receipt of the Judgment. The defendants are also required to submit an annual statement to these persons that corporate policy absolutely prohibits any violation of the antitrust laws or of the Judgment and that the knowing disregard of this policy will result in termination of employment.

C. Effect of the Proposed Judgment on Competition

The terms of the Judgment are designed to insure that the corporate defendant will act completely independently in determining the prices, terms and conditions at which it sells or offers to sell beef carcasses.

The Department of Justice believes that the proposed Final Judgment adequately provides for the prevention of a continuance or reoccurrence of the violations of the antitrust laws charged in the complaint. The Government, upon reasonable notice, is also given access to the records and employees of the defendant to monitor its compliance with the provisions of the Judgment. In the Department of Justice's view, disposition of the lawsuit without further litigation is appropriate in that the proposed Judgment adequately provides the relief which the Government sought in its complaint.

V

Alternatives to the Proposed Consent Judgment

During the course of negotiating the proposed Judgment, the Department initially sought to obtain an additional injunctive provision prohibiting the defendants from agreeing to, or acting to, directly or indirectly communicate about past, as well as present or future, prices for carcass beef. Such a prohibition would have precluded meat packers from access to information about past closed transactions and would have expanded the scope of Paragraphs IV(B) and V(A). The defendants, however, argued that such information may be necessary for the meat packers adequately to gauge their future financial conduct vis-a-vis sales of beef products and their purchase price of cattle. Also, precluding access to such information may impede the ability of the defendant firms to buy and sell beef in a pro-competitive manner by denying them knowledge of the state of the market for beef. After some consideration, the Department concluded that permitting limited communications about past transaction prices in this market should not facilitate pricefixing, and that such relief as to past price information was not an indispensable element of settlement in this particular case. In any event, the Judgment prohibits *any* communications undertaken for the purpose of stabilizing prices. Thus, the proposed Judgment adequately provides the relief that the Government sought in its complaint without unduly interferring with the competitive operation of the carcass beef market.

Another alternative to the proposed Judgment is litigation of the case. In view of the fact that the proposed Judgment adequately provides the relief which the Government sought in its complaint, the Department of Justice therefore believes that such litigation is unnecessary against the defendants.

VI

Remedies Available to Private Litigants

Section 4 of the Clayton Act (15 U.S.C. § 15), provides that any person who has been

injured as a result of conduct prohibited by the antitrust laws may bring suit to recover three times the damages suffered, as well as costs and reasonable attorney fees. Entry of the proposed Final Judgment in this proceeding will neither impair nor assist the bringing of any such private antitrust actions, nor will it have any effect on pending actions. Under the provisions of Section 5(a) of the Clayton Act (15 U.S.C. § 16(a)), this Final Judgment has no prima facie effect in any lawsuits which might be brought against these defendants.

VII

Procedures Available for Modification of the Proposed Judgment

As provided by the Antitrust Procedures and Penalties Act, any person believing that the proposed Judgment should be modified may submit written comments to Crossan R. Anderson, Antitrust Division, United States Department of Justice, 300 North Los Angeles Street, Room 3101, Los Angeles, California, 90012, within the sixty day period provided by the Act. These comments and the Department's responses to them will be filed with the Court and published in the Federal Register. All comments will be given due consideration by the Department of Justice, which remains free to withdraw its consent to the proposed Judgment at any time prior to its entry if it should determine that some modification of it is necessary.

VIII

Other Materials

No other materials and documents of the type described in Section 2(b) of the Antitrust Procedures and Penalties Act (15 U.S.C. § 16(b)) were considered in formulating this proposed Judgment.

Dated: October 22, 1979.

Respectfully submitted,

Julian S. Greenspun,

Department of Justice.

[FR Doc. 79-33954 Filed 11-1-79; 8:45 am]

BILLING CODE 4410-01-M

DEPARTMENT OF LABOR

Bureau of Labor Statistics

Labor Research Advisory Council Committees; Meetings and Agenda

The regular fall meetings of committees of the Labor Research Advisory Council will be held on December 4, 5, and 6 in Room 4454, General Accounting Office Building, 441 G Street NW., Washington, D.C.

The Labor Research Advisory Council and its committees advise the Bureau of Labor Statistics with respect to technical matters associated with the Bureau's programs. Membership consists of union research directors and staff members.

The schedule and agenda of the meetings are as follows:

Tuesday, December 4

10:00 a.m.—Committee on Foreign Labor and Trade

1. International hourly compensation comparisons
2. International comparison of real gross domestic product per employed person based on United Nations International Comparison Project

Tuesday, December 4

1:30 p.m.—Committee on Productivity, Technology and Economic Growth

1. Status report on programs in Office of Productivity and Technology
2. Economic Growth
   (a) Fiscal 1979 publications
   (b) Revisions in the BLS economic growth model
   (c) Schedule for next set of projections

Wednesday, December 5

9:30 a.m.—Committee on Prices and Living Conditions

1. Family budgets
2. Recent interest in the housing component of the Consumer Price Index
3. Outlet sample updating for the Consumer Price Index
4. The Continuing Consumer Expenditure Survey
5. Developments in the revision of the Producer Price Index

Wednesday, December 5

1:30 p.m.—Committee on Wages and Industrial Relations

1. Review of work in progress
2. Report on the work of the Subcommittee on Long Range Planning
3. The Employment Cost Index

Thursday, December 6

9:30 a.m.—Committee on Employment Structure and Analysis

1. Status of Current Population Survey Quarterly Earnings Data activity
2. Response to Report of National Commission on Employment and Unemployment Statistics
   (a) Redesign of the Current Population Survey
   (b) Establishment survey review
   (c) Treatment of the Census undercount
3. Preliminary results of pilot studies of job vacancies
4. Preparation of the CETA wage adjustment area index

The meetings are open. It is suggested that persons planning to attend as observers contact Joseph P. Goldberg, Executive Secretary, Labor Research Advisory Council on (Area Code 202) 523-1247.

Signed at Washington, D.C. this 24th day of October 1979.

Janet L. Norwood,

Commissioner of Labor Statistics.

[FR Doc. 79-34020 Filed 11-1-79; 8:45 am]

BILLING CODE 4510-24-M

Occupational Safety and Health Administration

Nevada State Standards; 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—OSHA) 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 4, 1974 notice was published in the Federal Register (39 FR 1003) of the approval of the Nevada plan and the adoption of Subpart W to Part 1952 containing the decision.

The Nevada plan provides for the adoption of Federal standards as State standards by reference. The Nevada State plan submitted on December 12, 1972 and designated as Subpart W sets forth the State's schedule for the adoption of Federal standards. By letter dated June 28, 1979 from Alan R. Traenkner to Ray Owen and incorporated as part of the plan, the State submitted State standards identical to all revisions of 29 CFR Part 1910, 29 CFR Part 1926 and 29 CFR Part 1928 from July 28, 1975 through March 1, 1979. These standards, which are contained in Department of Occupational Safety & Health, Nevada Industrial Commission Occupational Safety and Health Standards, Safety and Health Standards for Construction, and Occupational Safety and Health Standards for Agriculture, were promulgated by resolution adopted by Department of Occupational Safety and Health of the Nevada Industrial Commission pursuant to Nevada Occupational Safety and Health Act.

2. Decision. Having reviewed the State submission 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—OSHA 450 Golden Gate Avenue, Room 9470, San

Francisco, California 94102; Director, Department of Occupational Safety and Health, 1923 N. Carson Street—Room 202, Carson City, Nevada 89701; and the Office of the Directorate of Federal Compliance and State Programs, Room N3101, 200 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 food cause which may be consistent with applicable laws. The Assistant Secretary finds that good cause exists for not publishing the supplement to the Nevada State plan as a proposed change and making the Regional Administrator—OSHA's approval effective upon publication for the following reasons:

1. The standards are identical to the Federal standards which were promulgated in accordance with Federal law including meeting requirements for public participation.

2. The standards were adopted in accordance with the procedural requirements of State law and further participation would be unnecessary.

This decision is effective November 2, 1979.

[(Sec. 18, Pub. L. 91-596, 84 Stat. 1608 (29 U.S.C. 667)].

Signed at San Francisco, California this 20th day of July 1979.

Gabriel J. Gillotti,

Regional Administrator—OSHA

[FR Doc. 79-34019 Filed 11-1-79; 8:45 am]

BILLING CODE 4510-26-M

Office of the Secretary

Air Baby, Inc., et al.; 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 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 November 13, 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 November 13, 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 NW., Washington, D.C. 20210.

Signed at Washington, D.C. this 30th day of October 1979.

Harold A. Bratt,

Acting Director, Office of Trade Adjustment Assistance.

Appendix

Petitioner: Union/workers or former workers of—	Location	Date received	Date of petition	Petition No.	Articles produced
Air Baby, Inc. (company)	Northvale, N.J	10/22/79	10/15/79	TA-W-6,291	Gloves and mittens and slippers for men, women, and children.
Bethlehem Steel Corp., San Francisco Works (USWA).	San Francisco, Calif	10/22/79	10/2/79	TA-W-6,292	Carbon steel products.
Champion Building Products (International Woodworkers Union).	McCloud, Calif	10/23/79	10/16/79	TA-W-6,233	Dimension lumber.
Creations by Kenscott, Inc. (workers)	New York, N.Y	10/18/79	10/11/79	TA-W-6,234	Ladies' and men's leather garments.
Fashion Rite Corp. (workers)	Neptune, N.J	10/23/79	10/15/79	TA-W-6,235	Children's outerwear.
The H.W. Gossard Company (ILGWU)	Logansport, Ind	10/24/79	10/18/79	TA-W-6,236	Girdles.
Henry Fredricks & Co., Inc.	New York, N.Y	10/24/79	10/16/79	TA-W-6,237	Ladies' coats, raincoats, and sportswear.
International Shoe Company (ACTWU—Shoe Division).	Batesville, Ark	10/24/79	10/15/79	TA-W-6,238	Men's dress shoes.
Kimberly Clark Corp. (workers)	Mount Shasta, Calif	10/23/79	10/16/79	TA-W-6,299	Lumber.
Kimberly Clark Corp. (workers)	Anderson, Calif	10/23/79	10/16/79	TA-W-6,300	Lumber.
Mackel Corp. (UMWA)	Logan, Va	10/24/79	10/12/79	TA-W-6,301	Construction and maintenance of mining equipment.
Seth Thomas (workers)	Jersey City, N.J	10/24/79	10/18/79	TA-W-6,302	Decorative clock.
Skyland Virginia Corp. (workers)	Chilhowie, Va	10/24/79	10/19/79	TA-W-6,303	Children's jeans, shorts, skirts, tops, crawlers, and jumpers.
Stephens-Keller Machine Co. (USWA)	Chelyan, W. Va	10/23/79	10/9/79	TA-W-6,304	Build and construct numerous and varied internal parts for coal mine equipment-machinery.
Textile Printing and Finishing Co. (ACTWU)	Lebanon, Pa	10/23/79	10/16/79	TA-W-6,305	Contract printer of fabrics.
Weyenberg Shoe Manufacturing Company (Boot & Shoe Workers Union—UFCW).	Beaver Dam, Wis	10/24/79	10/15/79	TA-W-6,306	Men's shoes.
Weyenberg Shoe Manufacturing Company (Boot & Shoe Workers Union—UFCW).	Milwaukee, Wis	10/24/79	10/15/79	TA-W-6,307	Component shoe parts for men's shoes.

[FR Doc. 79-34026 Filed 11-1-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6110]

Alpha Metals, Jersey City, N.J.; Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on September 27, 1979 in response to a worker petition received on September 24, 1979 which was filed by the International Brotherhood of Teamsters Local 945 on behalf of workers and former workers producing solder, flux, and goldplating at Alpha Metals, Jersey City, New Jersey.

The business agent for Teamsters Local 945 requested withdrawal of the petition regarding Alpha Metals. On the basis of this request, continuing the investigation would serve on purpose. Consequently, the investigation has been terminated.

Signed Washington, D.C. this 25th day of October 1979.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 79-34025 Filed 11-1-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-5972]

Auerbach & Co., d.b.a. La Jolla Sportswear Co., Los Angeles, Calif.; Certification Regarding Eligibility to Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Act must be met.

The investigation was initiated on September 6, 1979 in responde to a worker petition received on September 4, 1979 which was filed on behalf of workers and former works producing men's clothing; separate slacks, shirts, jackets and suits at Auerbach and Company, DBA La Jolla Sportswear Company, Los Angeles, California. The investigation revealed that the plant produces primarily men's slacks. It is concluded that all of the requirements have been met.

U.S. imports of men's and boys' dress and sport trousers and shorts increased absolutely and relative to domestic production in 1978 compared to 1977.

In a survey conducted by the Department of Commerce, customers accounting for a significant proportion of the sales decline at Auerbach and Company indicated that they had decreased purchases of men's slacks from Auerbach and had increased purchases of imported men's slacks in 1978 compared to 1977 and in 1977 compared to 1976. The Department of Commerce on June 8, 1979 certified Auerbach and Company as eligible to apply for firm adjustment assistance.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with men's slacks produced at Auerbach and Company, DBA La Jolla Sportswear Company, Los Angeles, California contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

All workers of Auerbach and Company, DBA La Jolla Sportswear Company, Los Angeles, California who became totally or partially separated from Employment on or after August 29, 1978 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 26th day October 1979.

Harry J. Gilman,

Supervisory International Economist, Office of Foreign Economic Research.

[FR Doc. 79-34027 Filed 11-1-79; 8:45 am]

BILLING CODE 4510-28-M

Avtex Fibers, Inc., et al.; 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 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 of 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 November 13, 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 November 13, 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, NW., Washington, D.C. 20210.

Signed at Washington, D.C. this 25th day of October 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
Avtex Fibers, Inc. (Workers)	Radford, Va	10/23/79	10/17/79	TA-W-6,267	Textured polyester.
Baros Coat & Suit Corp. (workers)	Brooklyn, N.Y	10/18/79	10/15/79	TA-W-6,268	Contractor of ladies' coats, suits, car coats, jackets, and quilted coats.
Bobby's Casuals (ILGWU)	Bridgeport, Conn	10/23/79	10/17/79	TA-W-6,269	Women's dresses.
Marcie Foundations (ILGWU)	Aibonito, P.R	10/3/79	9/26/79	TA-W-6,270	Brassiers and panties.
Seaside Blouse Manufacturing Corporation (ILGWU).	Bridgeport, Conn	10/23/79	10/17/79	TA-W-6,271	Women's blouses.
Torrington Company Excelsior Plant (UAW)	Torrington, Conn	9/25/79	9/18/79	TA-W-6,272	Sewing machine needles.

[FR Doc. 79-34028 Filed 11-1-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6050]

Cherokee Mining Co., Logan, W. Va.; Investigation Regarding Certification of Eligibility To Apply for Worker Adjustment Assistance; Correction

In FR Doc. 79-30233 appearing on page 56059-60 in the Federal Register of September 28, 1979, the date of petition in the Appendix under petitioner Cherokee Mining Company, Logan, West Virginia should be corrected to read "September 10, 1979."

Signed at Washington, D.C. this 26th day of October 1979.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 79-34029 Filed 11-1-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6054]

Copewell Paper Products, Inc., Brooklyn, N.Y.; Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the Act must be met.

The investigation was inititated on September 19, 1979 in response to a worker petition received on September 10, 1979 which was filed on behalf of workers and former workers selling scrap paper at Copewell Paper Products, Inc., Brooklyn, New York. The investigation revealed that Copewell Paper Products, Inc. is engaged in providing the service of distributing paper products and packing supplies.

Thus, workers of Copewell Paper Products, Inc. do not produce an article within the meaning of section 223(3) of the Act. Therefore, they may be certified only if their separation was caused importantly by a reduced demand for their services from a parent firm, a firm otherwise related to Copewell Paper Products, Inc. by ownership, or a firm related by control. In any case, the reduction in demand for services must originate at a production facility whose workers independently meet the statutory criteria for certification and that reduction must directly relate to the product impacted by imports.

Copewell Paper Products, Inc. and its customers have no controlling interest in one another. The subject firm is not corporately affiliated with any other company.

All workers engaged in distributing paper products and packing supplies at Copewell Paper Products, Inc. are employed by that firm. All personnel actions and payroll transactions are controlled by Copewell Paper Products, Inc. All employee benefits are provided and maintained by Copewell Paper Products, Inc. Workers are not, at any time, under employment or supervision by customers of Copewell Paper Products, Inc. Thus, Copewell Paper Products, Inc., and not any of its customers, must be considered to be the "workers' firm".

Conclusion

After careful review, I determine that all workers of Copewell Paper Products, Inc., Brooklyn, New York 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 26th day of October 1979.

Harry J. Gilman,

Supervisory International Economist, Office of Foreign Economic Research.

[FR Doc. 79-34030 Filed 11-1-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6122]

Detroit Steel Products, Detroit, Mich.; Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Act must be met.

The investigation was initiated on October 1, 1979 in response to a worker petition received on September 26, 1979 which was filed on behalf of workers and former workers producing multi-leaf springs at the Detroit, Michigan plant of Detroit Steel Products. It is concluded that all of the requirements have been met.

U.S. imports of leaf springs increased absolutely and relative to domestic production from 1977 to 1978 and increased absolutely during the first quarter of 1979 compared to the same period of 1978.

A Department survey with the major customer of the Detroit plant revealed that this customer decreased purchases of multi-leaf springs from Detroit Steel and increased purchases from foreign sources during the period January-September 1979 compared to the same period of 1978. Decreased purchases by this customer during 1979 account for virtually all of the sales decline at the Detroit plant during 1979.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with multi-leaf springs produced at the Detroit, Michigan plant of Detroit Steel Products contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

All workers of the Detroit, Michigan plant of Detroit Steel Products who became totally

or partially separated from employment on or after June 1, 1979 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 29th day of October 1979.

James F. Taylor,

Director, Office of Management, Administration and Planning.

[FR Doc. 79-34031 Filed 11-1-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-5903]

G & M Metal Fabricating Corp., Brooklyn, N.Y.; Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the Act must be met.

The investigation was initiated on August 27, 1979 in response to a worker petition received on August 21, 1979 which was filed by the Industrial Union of Marine & Shipbuilding Workers of America on behalf of workers and former workers of G & M Metal Fabricating Corporation, Brooklyn, New York, engaged in ventilation sheet metal work. In the following determination, without regard to whether any of the criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Results of a U.S. Department of Labor survey indicated that G & M Metal Fabricating Corporation did not lose any sales to its sole customer because of increased competitive imports. This customer did not purchase imports of ventilation ducts or smokestacks during the period under investigation.

Conclusion

After careful review, I determine that all workers of G & M Metal Fabricating Corporation, Brooklyn, New York, 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 26th day of October 1979.

Harry J. Gilman,

Supervisory International Economist, Office of Foreign Economic Research.

[FR Doc. 79-34032 Filed 11-1-79; 8:45 am]

BILLING CODE 4510-23-M

[TA-W-5907]

H. W. Ramberg, Inc., Brooklyn, N.Y.; Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the Act must be met.

The investigation was initiated on August 27, 1979, in response to a worker petition received on August 21, 1979, which was filed by the Industrial Union of Marine & Shipbuilding Workers of America on behalf of workers and former workers of H. W. Ramberg, Brooklyn, New York, engaged in machine work. The investigation revealed that the legal title of the firm is H. W. Ramberg, Incorporated and that the subject firm produces clamshell buckets to supplement the machine work operations. The intent of the petitioners was to cover only those aspects of H. W. Ramberg, Incorporated's operations associated with machine work performed for ship repairers. Thus, the scope of this investigation is limited to these machine work operations.

H. W. Ramberg, Incorporated is engaged in providing the service of machine work.

Thus, workers of H. W. Ramberg, Incorporated do not produce an article within the meaning of section 222(3) of the Act. Therefore, they may be certified only if their separation was caused importantly by a reduced demand for their services from a parent firm, a firm otherwise related to H. W. Ramberg, Incorporated by ownership, or a firm related by control. In any case, the reduction in demand for services must originate at a production facility whose workers independently meet the statutory criteria for certification and that reduction must directly relate to the product impacted by imports.

H. W. Ramberg, Incorporated and its customers have no controlling interest in one another. The subject firm is not corporately affiliated with any other company. No firm with which the subject firm shares common ownership produces an article.

All workers engaged in machine work at H. W. Ramberg, Incorporated are employed by that firm. All personnel actions and payroll transactions are controlled by H. W. Ramberg, Incorporated. All employee benefits are provided and maintained by H. W. Ramberg, Incorporated. Workers are not, at any time, under employment or supervision by customers of H. W. Ramberg, Incorporated. Thus, H. W. Ramberg, Incorporated, and not any of its customers, must be considered to be the "workers' firm".

Conclusion

After careful review, I determine that workers engaged in machine work at H. W. Ramberg, Incorporated, Brooklyn, New York 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 26th day of October 1979.

Harry J. Gilman,

Supervisory International Economist, Office of Foreign Economic Research.

[FR Doc. 79-34033 Filed 11-1-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6056]

Holiday Fashions, Hoboken, N.J.; Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Act must be met.

The investigation was initiated on September 19, 1979 in response to a worker petition received on September 14, 1979 which was filed on behalf of workers and former workers producing women's coats at Holiday Fashions, Hoboken, New Jersey. It is concluded that all of the requirements have been met.

Imports of women's, misses' and children's coats and jackets increased in 1978 compared to 1977.

A Department survey of the manufacturer for whom Holiday Fashions performed contract work

indicated that the manufacturer decreased its business with Holiday Fashions in 1978 compared to 1977 and increased its purchases of imported coats during this period.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with women's coats produced at Holiday Fashions, Hoboken, New Jersey contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

All workers of Holiday Fashions, Hoboken, New Jersey who became totally or partially separated from employment on or after August 28, 1978 and before April 20, 1979 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974. All workers who were separated on or after April 20, 1979 are denied eligibility to apply for adjustment assistance.

Singed at Washington, D.C. this 29th day of October 1979.

James F. Taylor,

Director, Office of Management, Administration and Planning.

[FR Doc. 79-34034 Filed 11-1-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-5562]

L.B. Evans' Son Co., Wakefield, Mass.; Revised Determination on Reconsideration

On October 10, 1979, (44 FR 59681), the Department of Labor granted administrative reconsideration of the Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance which it had made on August 24, 1979, (44 FR 49809) pursuant to section 223 of the Trade Act of 1974 for all workers at the Wakefield, Massachusetts, plant of the L.B. Evans' Son Company.

In its reconsideration, the Department reviewed its file on the L.B. Evans' Son Company. The review and additional customer inquiries conducted by the Department revealed that the Department's use of a broad category of slippers may have masked increased imports of men's slippers. The Department's use of an ITC survey which focused on the kinds of men's slippers produced at the L.B. Evans' Son Company revealed increased imports. The review of the customer survey revealed that it did not show the true picture of import competition because of the seasonality of men's slipper sales.

Men's slipper production which accounted for nearly 90 percent of L.B. Evans' Son production in 1979 decreased in the first nine months of 1979 compared to the same period in 1978. Employment decreased in the first nine months of 1979 compared to the same period in 1978.

U.S. imports of men's slippers increased from 2,249,000 pairs in 1977 to 3,000,000 pairs in 1978. The ratio of imports to domestic production was over 100 percent in both 1977 and 1978.

The Department's further survey of L.B. Evans' Son's customers indicated that several customers decreased their purchases of men's slippers from the subject firm and increased their imports of men's slippers in 1978 and 1979.

Conclusion

Based on additional evidence, a review of the entire record and in accordance with the provisions of the Act, I make the following revised determination:

All workers at the Wakefield, Massachusetts, plant of the L.B. Evans' Son Company who became totally or partially separated from employment on or after May 14, 1979, are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 29th day of October 1979.

James F. Taylor,

Director, Office of Management, Administration and Planning.

[FR Doc. 79-34035 Filed 11-1-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-5918 and TA-W-5939]

Linden Products Co., Linden, Tenn.; and Lexington Metal Products Co., Lexington, Tenn.; Negative Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents the results of the investigations regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met.

An investigation was initiated on August 27, 1979 in response to a worker petition received on August 23, 1979 which was filed on behalf of workers and former workers producing auto parts at Linden Products Company, Linden, Tennessee (TA-W-5918). The investigation revealed that Linden Products Company produces original equipment automotive body hardware stamping assemblies.

An investigation was initiated on August 30, 1979 in response to a worker petition received on August 27, 1979 which was filed on behalf of workers and former workers producing auto parts, Chrysler locks, AMC regulators and Chrysler seat recliners at Lexington Metal Products Company, Lexington, Tennessee (TA-W-5939). The investigation revealed that Lexington Metal Products Company produces original automotive equipment body hardware stamping assemblies. In the following determinations, without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Industry sources indicate that U.S. imports of automotive body stamping assemblies are negligible.

Petitioners allege that increased imports of automobiles have caused decreases in production and employment at Linden Products Company, Linden, Tennessee and at Lexington Metal Products Company, Lexington, Tennessee. Although imported automobiles incorporate body hardware stamping assemblies of the same origin, imports of the whole product are not "like or directly competitive" with their component parts.

Imports of automotive body stamping assemblies must be considered in determining import injury to workers producing automotive body hardware stamping assemblies at Linden Products Company, Linden, Tennessee and at Lexington Metal Products Company, Lexington, Tennessee.

Conclusion

After careful review, I determine that all workers of Linden Products Company, Linden, Tennessee and all workers of Lexington Metal Products Company, Lexington, Tennessee 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 26th day of October 1979.

Harry J. Gilman,

Supervisory International Economist, Office of Foreign Economic Research.

[FR Doc. 79-34036 Filed 11-1-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6247]

Mohawk Rubber Co., Memphis, Tenn.; Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Act must be met.

The investigation was initiated on October 23, 1979 in response to a worker petition received on October 18, 1979 which was filed on behalf of workers and former workers warehousing and distributing passenger car tires and truck tires at the Memphis, Tennessee plant of the Mohawk Rubber Company. It is concluded that all of the requirements have been met.

U.S. imports of both passenger car tires and truck tires increased absolutely and relative to domestic production in the first half of 1979 compared with the first half of 1978.

The Memphis, Tennessee plant of the Mohawk Rubber Company serves primarily as the warehousing/distribution facility for the tire output from the company's West Helena, Arkansas production facility. In previous determinations (TA-W-4447 and 4483, issued January 26, 1979), all workers at both the West Helena, Arkansas and Akron, Ohio plants of the Mohawk Rubber Company were certified as eligible to apply for adjustment assistance. The Akron, Ohio plant was shutdown permanently in November of 1978 and the West Helena, Arkansas plant closed down operations in June of 1979. Layoffs at the Memphis, Tennessee warehouse began in May of 1979 and resulted directly from the shutdown of the West Helena, Arkansas plant.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with passenger car tires and truck tires warehoused at the Memphis, Tennessee plant of the Mohawk Rubber Company contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

All workers at the Memphis, Tennessee plant of the Mohawk Rubber Company who became totally or partially separated from employment on or after May 21, 1979 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 29th day of October 1979.

James F. Taylor,

Director, Office of Management, Administration and Planning.

[FR Doc. 79-34037 Filed 11-1-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-5940]

Philtron Corp., Whitman, Mass.; Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met.

The investigation was initiated on August 30, 1979 in response to a worker petition received on August 27, 1979 which was filed on behalf of workers and former workers producing lighting fixtures and wood products at the Whitman, Massachusetts plant of the Philtron Corporation. In the following determination, without regard to whether any of the other criteria have been met for workers producing lighting fixtures, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

The Department conducted a survey of the lighting fixture customers of the Philtron Corporation. The survey did not reveal any lost sales on the part of the Philtron Corporation to foreign manufacturers of residential lighting fixtures.

For workers producing wood products all of the criteria have been met.

The wood products produced by the Philtron Corporation were used as components in the production of residential lighting fixtures. There is no separate import classification for wood components of lighting fixtures. Imports are included in the broader import category, "non-brass lighting fixture components". Imports of non-brass lighting fixture components increased in the first half of 1979 compared to the like 1978 period.

The Department conducted a survey of the customers of wood components of the Philtron Corporation. The survey revealed that the customers of wood components reduced purchases from the Philtron Corporation and increased purchases from foreign producers. The Philtron Corporation was dissolved on August 27, 1979.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with the wood products produced at the Philtron Corporation contributed importantly to the decline in sales or production and to the total or partial separation of workers engaged in employment related to the production of wood products at the firm. In accordance with the provisions of the Act, I make the following certification:

All workers of the Philtron Corporation in Whitman, Massachusetts engaged in employment related to the production of wood products who became totally or partially separated from employment on or after June 1, 1979 are eligibile to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 26th day of October 1979.

C. Michael Aho,

Director, Office of Foreign Economic Research.

[FR Doc. 79-34038 Filed 11-1-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-5955]

Richcraft Textile Corp., Easton, Pa.; Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents the results of an investigation regarding

certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the Act must be met.

The investigation was initiated on September 4, 1979 in response to a worker petition received on August 27, 1979 which was filed by the Amalgamated Clothing and Textile Workers' Union on behalf of workers and former workers producing textile fabrics at Richcraft Textile Corporation, Easton, Pennsylvania. The investigation revealed that the company also maintained an office in New York City. In the following determinations, without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Imports of finished fabric increased absolutely and relative to domestic production in 1978 compared with 1977 and decreased absolutely in the first half of 1979 compared with the like period in the previous year. Imported finished fabric represents a very small portion of the domestic market for that product. The ratio of imports to domestic production of finished fabric has not exceeded two percent in the period 1974–1978.

A Department survey revealed that customers of Richcraft Textile Corporation did not reduce their purchases of finished fabric from the firm in favor of foreign suppliers. Richcraft Textile's customers reported that they do not purchase any imported fabric.

Conclusion

After careful review, I determine that all workers of Richcraft Textile Corporation, Easton, Pennsylvania 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 26th day of October 1979.

Harry J. Gilman,

Supervisory International Economist, Office of Foreign Economic Research.

[FR Doc. 79-34039 Filed 11-1-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6156]

Robertson & Associates (Ala.), Inc., Fabius Mine, Fabius, Ala.; Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the Act must be met.

The investigation was initiated on October 4, 1979 in response to a worker petition received on October 1, 1979 which was filed on behalf of workers and former workers producing steam coal for Robertson & Associates, Inc., Fabius Mine, Fabius, Alabama. The investigation revealed that the company was Robertson & Associates (Alabama), Inc. In the following determination, without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

The bituminous coal mined at the Fabius Mine by Robertson & Associates was sold to a domestic company for use in electric power generation. U.S. imports of bituminous coal are negligible. The ratio of imports to domestic production did not exceed seven-tenths of one percent from 1974 through the first half of 1979.

Conclusion

After careful review, I determine that all workers of Robertson & Associates (Alabama), Inc., Fabius Mine, Fabius, Alabama 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 25th day of October 1979.

C. Michael Aho,

Director, Office of Foreign Economic Research.

[FR Doc. 79-34040 Filed 11-1-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-5932]

Wagner Industries, Inc., Reading, Mich.; Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents the results of an investigation regarding certification of eligiblity to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligiblity to apply for adjustment assistance, each of the group eligility requirements of Section 222 of the Act must be met.

The investigation was initiated on August 29, 1979 in response to a worker petition received on August 27, 1979 which was filed by the International Association of Machinists and Aerospace Workers on behalf of workers and former workers producing automotive wire harness assemblies at Wagner Industries, Inc., Reading, Michigan, part of the Wire Assembly Division of Essex Group, Inc. It is concluded that all of the requirements have been met.

U.S. imports of automotive wire harness assemblies increased in 1978 from 1977 and during January–June 1979 compared to January–June 1978.

In August 1978 production of wire harness assemblies for Mustangs began at a facility in Mexico which is operated by the Wire Assembly Division of Essex Group, Inc. Prior to August 1978 the Reading, Michigan plant was the only plant of the Division which manufactured wire harness assemblies for Mustangs.

A strike occurred at the Reading, Michigan plant from March 31, 1979 through May 16, 1979. After the strike production of automotive wire harness assemblies for Mustangs was transferred permanently from the Reading plant to the plant in Mexico. Declines in sales and employment occurred at the Reading facility from January 1979 to the time of the plant closing in September 1979.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with automotive wire harness assemblies produced at Wagner Industries, Inc., Reading, Michigan, part of the Wire Assembly Division of Essex Group, Inc. contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions

of the Act, I make the following certification:

All workers of Wagner Industries, Inc., Reading, Michigan who became totally or partially separated from employment on or after January 1, 1979 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 26th day of October 1979.

Harry J. Gilman,

Supervisory International Economist, Office of Foreign Economic Research.

[FR Doc. 79-34042 Filed 11-1-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6021]

Wellman Co., Medford, Mass.; Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Act must be met.

The investigation was initiated on September 12, 1979 in response to a worker petition received on September 10, 1979 which was filed on behalf of workers and former workers producing outsole cutting machines, forms, leaders and parts for machines, aluminum footwear lasts at Wellman Company, Medford, Massachusetts. The investigation revealed that the Wellman Company is a subsidiary of Uniroyal, Incorporated. It is concluded that all of the requirements have been met.

The majority of Wellmans Company's production of machines and lasts in 1977 and 1978 went to its parent firm, Uniroyal, Incorporated for use in the production of rubber/fabric footwear.

U.S. imports of rubber/fabric footwear increased absolutely and relative to domestic production in 1978 compared to 1977, and declined in the first six months of 1979 compared to the first six months of 1978. The ratio of imports to domestic production in the first six months of 1979 was higher than any previous year from 1974 through 1977.

Uniroyal company imports of rubber/fabric footwear increased absolutely in the first eight months of 1979 compared to the same period in 1978 and increased relative to domestic company production in 1978 compared to 1977. Total domestic production of rubber/fabric footwear at Uniroyal decreased from 1977 to 1978. Uniroyal estimates that domestic production of rubber/fabric footwear will decline for the full year 1979 compared to the full year 1978. Workers engaged in the production of rubber/fabric footwear at two plants of Uniroyal have been certified eligible to apply for trade adjustment assistance. Another rubber/fabric footwear plant is presently under investigation. As a result of the import impact on Uniroyal's domestic footwear production, the company's demand for production machinery has declined. Wellman Company's sales of machines and lasts to Uniroyal decreased in 1978 compared to 1977 and are estimated to decrease for the full year 1979 compared to 1978.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with rubber/fabric footwear produced at Uniroyal, Incorporated contributed importantly to the decline in sales or production and to the total or partial separation of workers producing outsole cutting machines, forms, leaders and parts for machines and aluminum footwear lasts at Wellman Company, Medford, Massachusetts, a subsidiary of Uniroyal, Incorporated. In accordance with the provisions of the Act, I make the following certification:

All workers of Wellman Company, Medford, Massachusetts who became totally or partially separated from employment on or after December 1, 1978 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 26th day of October 1979.

C. Michael Aho,

Director, Office of Foreign Economic Research.

[FR Doc. 79-34043 Filed 11-1-79; 8:45 am]

BILLING CODE 4510-28-M

Wage and Hour Division

Certificates Authorizing the Employment of Learners at Special Minimum Wages

Notice is hereby given that pursuant to section 14 of the Fair Labor Standards Act (52 Stat. 1062, as amended; U.S.C. 214), Reorganization Plan No. 6 of 1950 (3 CFR 1949-53 Comp., p. 1004), and Administrative Order No. 1-76 (41 FR 18949), the firms listed in this notice have been issued special certificates authorizing the employment of learners at hourly wage rates lower than the minimum wage rates otherwise applicable under section 6 of the Act. For each certificate, the effective and expiration dates, number or proportion of learners and the principal product manufactured by the establishment are as indicated. Conditions on occupations, wage rates, and learning periods which are provided in certificates issued under the supplemental industry regulations cited in the captions below are as established in those regulations; such conditions in certificates not issued under the supplemental industry regulations are as listed.

The following certificates were issued under the apparel industry learner regulations (29 CFR 522.1 to 522.9, as amended and 522.20 to 522.25, as amended). The following normal labor turnover certificates authorize 10 percent of the total number of factory production workers except as otherwise indicated.

Big River Mfg. Co., Kittanning, PA; 8-31-79 to 8-30-80. (Boys' shirts)

Bland Sportswear, Inc., Bland, VA; 7-24-79 to 7-23-80; 5 learners. (Men's and boys' shirts)

Caraway Mfg. Corp., Caraway, AR; 8-22-79 to 8-21-80; 10 learners. (Ladies' dresses)

Chatham Knitting Mills, Inc., Chatham, VA; 7-22-79 to 7-21-80; 6 learners. (Men's jackets)

Cordele Uniform Co., Cordele, GA; 9-8-79 to 9-7-80. (Men's pants)

Crane Mfg. Co., Crane, MO; 8-14-79 to 8-13-80. (Men's and women's jeans)

Elder Mfg. Co., Dexter, MO; 8-21-79 to 8-20-80. (Men's and boys' slacks)

Flushing Shirt Mfg. Co., Inc., Frostburg, MD; 9-24-79 to 9-23-80; 10 learners. (Men's shirts)

Giles Mfg. Corp., Narrows, VA; 9-5-79 to 9-4-80. (Children's shirts)

Soperton Mfg. Co., Soperton, GA; 9-10-79 to 9-9-80. (Men's shirts)

The following certificates were issued under the knitted wear industry regulations [29 CFR 522.1 to 522.9, as amended and 522.30 to 522.35, as amended.]

Louis Gallet, Inc., Uniontown, PA; 6-21-79 to 6-20-80; 5 learners for normal labor turnover purposes. (Boys' and men's sweaters)

Junior Form Lingerie, Inc., Boswell, PA; 6-23-79 to 6-22-80; 5 percent of the total number of factory production workers for normal labor turnover purposes. (Ladies pajamas)

The following learner certificates were issued in Puerto Rico to the companies hereinafter named. The effective and expiration dates, learner rates, occupations, learning periods and number of learners authorized to be employed are indicated.

General Cigar de Utuado, S.A., Utuado, PR; 7-2-79 to 7-1-80; 30 learners for normal labor turnover purposes in the occupation of cigar making machine operators for a learning period of 320 hours at the rate of

$2.64 an hour for the first 160 hours and $2.74 an hour for the remaining 160 hours. (Tobacco)

Glamourette Fashion Mills, Inc., Quebradillas, PR; 8-17-79 to 8-16-80; 58 learners for normal labor turnover purposes in the occupations of: (1) knitting, for a learning period of 480 hours at the rate of $2.50 an hour for the first 240 hours and $2.67 an hour for the remaining 240; (2) machine stitchers, for a learning period of 320 hours at the rate of $2.50 an hour for the first 160 hours and $2.67 an hour for the remaining 160 hours; (3) pressers, for a learning period of 320 hours at the rate of $2.50 an hour for the first 160 hours and $2.67 an hour for the remaining 160 hours; and (4) kettle handlers and dyers for a learning period of 240 hours at the rate of $2.50 an hour. (Sweaters and related products)

Each learner certificate has been issued upon the representations of the employer which, among other things were that employment of learners at special minimum rates is necessary in order to prevent curtailment of opportunities for employment, and that experienced workers for the learner occupations are not available.

The certificate may be annulled or withdrawn as indicated therein, in the manner provided in 29 CFR, Part 528. Any person aggrieved by the issuance of any of these certificates may seek a review or reconsideration thereof on or before November 19, 1979.

Signed at Washington, D.C. this 25th day of October 1979.

Arthur H. Korn,

Authorized Representative of the Administrator.

[FR Doc. 79-34021 Filed 11-1-79; 8:45 am]

BILLING CODE 4510-27-M

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards, Subcommittee on the Floating Nuclear Plant; Meeting

The ACRS Subcommittee on the Floating Nuclear Plant will hold a meeting on November 17, 1979, at the Los Angeles Marriott Hotel, 5855 West Century Boulevard, Los Angeles, CA 90045 to review the application of the Offshore Power Systems, et al, for a manufacturing license for the Floating Nuclear Plant. Notice of this meeting was published October 18, 1979 (44 FR 60178).

In accordance with the procedures outlined in the Federal Register on October 1, 1979 (44 FR 56408), oral or written statements may be presented by members of the public, recordings will be permitted only during those portions of the meeting when a transcript is being kept, and questions may be asked only by members of the Subcommittee, its consultants, and Staff. Persons desiring to make oral statements should notify the Designated Federal Employee as far in advance as practicable so that appropriate arrangements can be made to allow the necessary time during the meeting for such statements.

The agenda for subject meeting shall be as follows: *Saturday, November 17, 1979, 8:30 a.m. until the conclusion of business.*

The Subcommittee may meet in Executive Session, with any of its consultants who may be present, to explore and exchange their preliminary opinions regarding matters which should be considered during the meeting and to formulate a report and recommendations to the full Committee.

At the conclusion of the Executive Session, the Subcommittee will hear presentations by and hold discussions with representatives of the NRC Staff, Offshore Power Systems, et al, and their consultants, pertinent to this review. Specific topics to be discussed include the proposed design of the core ladle and implications of the Three Mile Island, Unit-2 Accident on the Floating Nuclear Plant design.

In addition, it may be necessary for the Subcommittee to hold one or more closed sessions for the purpose of exploring matters involving proprietary information. I have determined, in accordance with Subsection 10(d) of Public Law 92-463, that, should such sessions be required, it is necessary to close these sessions to protect proprietary information (5 U.S.C. 552b(c)(4)).

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefore can be obtained by a prepaid telephone call to the Designated Federal Employee for this meeting, Mr. Gary R. Quittschrieber, (telephone 202/634-3267) between 8:15 a.m. and 5:00 p.m., EST.

Background information concerning items to be considered at this meeting can be found in documents on file and available for public inspection at the NRC Public Document Room, 1717 H Street, N. W., Washington, DC 20555 and at the Jacksonville Public Library, 122 North Ocean St., Jacksonville, FL 32204, the Business and Science Division, New Orleans Public Library, 219 Loyola Ave., New Orleans, LA 70140, and the Stockton State College Library, Pomona, NJ 08240 and (regarding TMI-2 Accident Implications) at the Government Publications Section, State Library of Pennsylvania, Education Building, Commonwealth and Walnut Street, Harrisburg, PA 17126.

Dated: October 29, 1979.

John C. Hoyle,

Advisory Committee, Management Officer.

[FR Doc. 79-33623 Filed 11-1-79; 8:45 am]

BILLING CODE 7590-01-M

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. 10916; 811-2693]

Bowen Investment Co.; Application Pursuant to Section 8(f) of the Act for an Order Declaring That Company Has Ceased To Be an Investment Company

October 26, 1979.

Notice is hereby given that on September 18, 1979, Bowen Investment Company ("Bowen") (formerly called Automatic Service Company), 2175 Parklake Drive, N.E., Atlanta, Georgia 30345, filed an application for an order pursuant to Section 8(f) of the Investment Company Act of 1940 ("Act") declaring that it has ceased to be an investment company as defined in the Act. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein which are summarized below.

Bowen was incorporated under the laws of North Carolina and registered under the Act on October 31, 1976, as a diversified, closed-end management investment company.

Pursuant to approval by vote of shareholders on June 6, 1979, Bowen on June 8, 1979, transferred substantially all of its assets to Fidelity Municipal Bond Fund, Inc. ("Fidelity"), in exchange solely for the number of shares of Fidelity stock having an aggregate net asset value equal to the value of Bowen's net assets transferred to Fidelity. Immediately thereafter, Bowen commenced liquidation, distributing the Fidelity stock pro-rata to its shareholders of record entitled thereto by means of the establishment of open accounts on the stock records of Fidelity in the names of such stockholders representing the respective pro-rata number of shares of fidelity stock due such shareholders. At the time of the application, all but 136 of Bowen's shareholders had tendered their shares of Bowen stock and received their respective amounts of Fidelity stock in return. Pursuant to the laws of the State of North Carolina, Bowen will convert all unclaimed shares of Fidelity stock to cash and deposit same with the appropriate state officials to be held

until said remaining shareholders make a just claim therefor.

Bowen has retained $4829.00 to defray the costs of winding up its business and to pay certain accrued expenses. Bowen has ceased to conduct any business as an investment company, and has filed Articles of Dissolution pursuant to the laws of the State of North Carolina.

Automatic Services Company (formerly ASC Vending Company, Inc.) ("Automatic Service") will remain primarily liable on certain contingent liabilities presented by real-estate leases arising out of Bowen's business prior to becoming an investment company in 1976. Additionally, Fidelity has assumed Bowen's obligation pursuant to an indenture Bowen executed in connection with a 1968 debenture offering to make certain reports to the Trustee named in said indenture and to remain liable to convert said debentures into Fidelity stock. Stuart V. Bowen, Bowen's president, and Fidelity's investment adviser, Fidelity Management Research Company have each agreed to indemnify Fidelity against any loss arising out of the obligation to issue Fidelity stock under the indenture and any other of Bowen's contingent liabilities. Automatic Services will remain liable for all of the other obligations formerly undertaken by Bowen with respect to said debentures. All fixed obligations of Bowen have been discharged by Bowen out of funds reserved by it for that purpose prior to its liquidation.

Notice is further given that any interested person may, not later than November 19, 1979 at 5:30 p.m., submit to the Commission in writing a request for a hearing on the matter accompanied by a statement as to the nature of his interest, the reason for such request, and the issues, if any, of fact or law proposed to be controverted, or he may request that he be notified if the Commission shall order a hearing thereon. Any such communication should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request shall be served personally or by mail upon Bowen at the address stated above. Proof of such service (by affidavit, or in case of an attorney-at-law, by certificate) shall be filed contemporaneously with the request. As provided by Rule 0-5 of the Rules and Regulations promulgated under the Act, an order disposing of the application will be issued as of course following said date unless the Commission thereafter orders a hearing upon request or upon the Commission's own motion. Persons who request a hearing, or advice as to whether a hearing is ordered, will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 79-34055 Filed 11-1-79; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 21274; 70-6369]

New Orleans Public Service Inc.; Proposed Issuance and Sale of Short-Term Notes to Banks and Commercial Paper

October 26, 1979.

Notice is hereby given that New Orleans Public Service Inc. ("NOPSI"), 317 Baronne Street, New Orleans, La. 70160, a wholly-owned subsidiary of Middle South Utilities, Inc., a registered holding company, has filed a declaration and an amendment thereto with this Commission pursuant to the Public Utility Holding Company Act of 1935 ("Act"), designating Sections 6(a), 6(b), and 7 of the Act and Rule 50(a)(5) promulgated thereunder as applicable to the proposed transactions. All interested persons are referred to the declaration, which is summarized below, for a complete statement of the proposed transactions.

NOPSI proposes to issue and sell, from time to time during the period commencing on January 2, 1980, and continuing through June 30, 1981, unsecured short-term promissory notes (including commercial paper) to various commercial banks and/or a dealer in commercial paper in an aggregate principal amount outstanding at any one time of the lesser of $22,000,000 or 10 percent of the capitalization of the company at July 31, 1979. Applying this formula to NOPSI's capitalization at July 31, 1979, an aggregate principal amount of $22,500,000 of unsecured short-term promissory notes (including commercial paper) would be issuable.

The notes proposed to be issued and sold to commercial banks will be in the form of unsecured promissory notes payable not more than nine months from the date of issuance with right of renewal, will bear interest at the prime commercial bank rate in effect at the lending bank on the date of issuance or renewal or from time to time depending upon the requirements of the lending bank, and will, at the option of the company, be prepayable, in whole or in part, at any time without premium or penalty. While no formal commitments for future borrowings have been made with any bank, it is expected that the banks to whom such notes will be issued and sold and the maximum amount to be issued and outstanding at any one time to each such bank will be substantially as follows:

Whitney National Bank of New Orleans	$9,100,000
Hibernia National Bank in New Orleans	6,000,000
First National Bank of Commerce in New Orleans	3,500,000
National American Bank of New Orleans	2,400,000
The Chase Manhattan Bank (N.A.)	3,000,000
Total	22,000,000

It is stated that accounts are maintained with the above-mentioned banks, from which the borrowings are proposed to be made, and although balances in some of these accounts may be deemed to be compensating balances, these accounts are working accounts and fluctuations in their balances do not reflect or depend upon fluctuations in the amounts of bank loans outstanding. NOPSI does not have any commitments to maintain compensating balances with the above banks and no commitment fee is involved for any of the proposed borrowings.

NOPSI proposes to issue and sell commercial paper in denominations of not less than $100,000 directly to a dealer in commercial paper, at a discount which will not be in excess of the discount rate per annum prevailing at the date of issuance for commercial paper of comparable quality of that particular maturity. The proposed commercial paper will be in the form of unsecured promissory notes with varying maturities not to exceed 270 days, the actual maturities to be determined by market conditions, effective cost of money to the company, and the company's anticipated cash requirements at the time of issuance. The commercial paper will not be payable prior to maturity.

No commission or fee will be payable by NOPSI in connection with the issuance and sale of the commercial paper. The dealer, as principal, will reoffer and sell the commercial paper at the customary discount rate for commercial paper to customers on a non-public list of not more than 200 buyers of commercial paper. It is anticipated that the commercial paper will be held by the buyers to maturity; however, the dealer may, if desired by a buyer, repurchase the commercial paper for resale to others on the list of customers.

NOPSI has requested that it be granted authority to file on a quarterly basis its certificate under Rule 24 with respect to the proposed transactions.

The expenses to be incurred in connection with the proposed transactions are estimated not to exceed $17,000. It is stated that no State or federal commission, other than this Commission, has jurisdiction over the proposed transactions.

Notice is further given that any interested person may, not later than November 26, 1979, request in writing that a hearing be held on such matter, stating the nature of his interest, the reasons for such request, and the issues of fact or law raised by the filing which he desires to controvert; or he may request that he be notified if the Commission should order a hearing thereon. Any such request should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request should be served personally or by mail upon the declarant at the above-stated address, and proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. At any time after said date, the declaration, as amended or as it may be further amended, may be permitted to become effective as provided in Rule 23 of the General Rules and Regulations promulgated under the Act, or the Commission may grant exemption from such rules as provided in Rules 20(a) and 100 thereof or take such other action as it may deem appropriate. Persons who request a hearing or advice as to whether a hearing is ordered will receive any notices or orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Corporate Regulation, pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 79-34054 Filed 11-1-79; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 10917; 812-4547]

Nuveen Municipal Bond Fund, Inc.; Filing of Application Pursuant to Section 6(c) of the Act for an Order of Exemption From the Provisions of Section 22(d) and Rule 22d-1 Thereunder

October 26, 1979.

In the matter of Nuveen Municipal Bond Fund, Inc., 115 South LaSalle Street, Chicago, Illinois 60603 and John Nuveen & Co. Incorporated, Nuveen Tax-Exempt Bond Fund, Nuveen Tax-Exempt Bond Fund-Medium Term, Nuveen Tax-Exempt Bond Fund-Multi-State, Nuveen Income Fund, 209 South LaSalle Street Chicago, Illinois 60604.

Notice is hereby given that Nuveen Municipal Bond Fund, Inc, Nuveen Tax-Exempt Bond Fund, Nuveen Tax-Exempt Bond Fund-Medium Term, Nuveen Tax-Exempt Bond Fund-Multi-State, and Nuveen Income Fund (collectively the "Funds"), and John Nuveen & Co. Incorporated ("Nuveen") (hereinafter collectively referred to as "Applicants"), filed an application on October 3, 1979, for an order of the Commission pursuant to Section 6(c) of the Investment Company Act of 1940 (the "Act"), exempting Applicants from the provisions of Section 22(d) of the Act and Rule 22d-1 thereunder to the extent necessary to permit sales of the Funds' securities at net asset value to Nuveen Affiliated Employees, as defined below, who are participants in a non-tax qualified employee benefit plan. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein, which are summarized below.

Nuveen Municipal Bond Fund, Inc. is registered under the Act as a diversified, open-end management investment company and is organized as a corporation under Maryland law. Nuveen Municipal Bond Fund, Inc. is currently engaged in continuous public offerings of its shares through Nuveen, as principal underwriter, at public offering prices equal to net asset value plus a sales charge.

Nuveen Tax-Exempt Bond Fund, Series 1 and subsequent Series, Nuveen Tax-Exempt Bond Fund-Multi-State, Series 1 and subsequent Series, Nuveen Tax-Exempt Bond Fund-Medium Term, Series 1 and subsequent Series, and Nuveen Income Fund, Series 1 and subsequent Series, are each a series of unit investment trusts issuing redeemable securities created by Nuveen as sponsor, all of which are similar but each of which is separate and is designated by a different Series number. Each Series of such unit investment trusts was created under the laws of the State of New York pursuant to a Trust Indenture and Agreement between Nuveen and United States Trust Company of New York. Nuveen acts as principal underwriter of each Series of the unit investment trusts at public offering prices based on a pro rata share of the offering side prices of the bonds in the portfolio of a Series during the initial offering period and a pro rata share of the bid side prices of the bonds in the portfolio of a Series for secondary market purposes plus a sales charge.

Nuveen, a Delaware corporation, is the parent and sole stockholder of Nuveen Advisory Corporation, which serves as investment manager for Nuveen Municipal Bond Fund, Inc., and Nuveen Government Securities, Inc., a dealer in securities issued by the United States and/or agencies thereof ("hereinafter Nuveen and its current or future subsidiaries are referred to as the "Nuveen Companies"). As of August 31, 1979, the full time employees of the Nuveen Companies totalled approximately 294, including 3 employees of Nuveen Advisory Corp. and 12 employees of Nuveen Government Securities, Inc. (hereinafter employees of the Nuveen Companies are referred to as "Nuveen Affiliated Employees").

Applicants propose to permit those Nuveen Affiliated Employees participating in an employee benefit plan ("Plan") sponsored by the employers constituting the Nuveen Companies to purchase shares or Units of the Funds at net asset value. Applicants state that participating Nuveen Affiliated Employees will be able to invest in Nuveen Municipal Bond Fund, Inc. through the Plan (1) by payroll deduction in the amount of $25 or more for each investment, (2) through automatic periodic bank checking account withdrawal plans in the amount of $25 or more for each investment, and (3) by investment at any time in the amount of $50 or more sent directly from the participant to DST, Inc., the shareholder service agent, provided the participant has invested at least $500 in shares of Nuveen Municipal Bond Fund, Inc., regardless of whether such investment was made pursuant to the Plan. In addition, Plan participants would be permitted to purchase Units of any Series of any unit investment trust being offered in either the primary or secondary market at the current public offering price without the sales charge. However, Applicants state that any such purchases would be subject to the minimum account size requirements of the unit investment trust to be purchased, i.e. $5000 or 50 Units, whichever is less (except for purchases of Nuveen Income Fund where the minimum purchase is $1000 or 10 Units, whichever is less). Distribution on shares of the Nuveen Municipal Bond Fund, Inc. acquired under the Plan could be reinvested at net asset value in the shares of such Fund. Applicants also state that participants will agree not to resell Fund shares or Units acquired through their participation in the Plan except by repurchase or redemption by

or for the account of the Fund issuing such shares or Units.

Applicants assert that no individual or in-person group sales solicitations or presentations concerning the Plan will be made. According to the application, all Nuveen Affiliated Employees will receive, at least annually, notice from their employers concerning the Plan. This notice, which will be furnished at the expense of such employers, will describe the Funds and their investment objectives, indicate that investments in the Plan would be at net asset value and detail the payroll deduction and other ways in which investments could be made. This notice would also indicate that additional information concerning the Plan and the Funds could be obtained from Nuveen and would inform employees of the availability of prospectuses of the Funds from the employers.

Section 22(d) of the Act provides, in pertinent part, that no registered investment company shall sell any redeemable security issued by it to any person except at a current public offering price described in the prospectus, and if such class of security is being currently offered to the public by or through an underwriter, no principal underwriter of such security and no dealer shall sell any such security to any person except at a current public offering price described in the prospectus. Rule 22d-1 permits reductions in, or elimination, of the sales load charged upon the sale of shares under certain circumstances. Applicants submit that the sale of Fund shares to Nuveen Affiliated Employees at net asset value under the Plan may conflict with the provisions of Section 22(d) of the Act and Rule 22d-1 thereunder.

Applicants argue that while Rule 22d-1(i) permits sales without any sales charge to certain employees of affiliated persons of the Funds, this would not be available to employees of the Nuveen Companies who are employed in positions that do not directly provide investment advice to, or distribute shares of, the Funds. Applicants also claim that an argument may be made that purchases of Fund shares at net asset value by Nuveen Affiliated Employees under the plan are permitted by Rule 22d-1(f), which permits elimination of sales charges upon the sale pursuant to a uniform offer described in the prospectus and made to, *inter alia,* employee benefit plans not qualified under Section 401 of the Internal Revenue Code provided such non-qualified plans satisfy uniform criteria relating to the realization of economies of scale in sales effort and sales-related expense. Applicants submit that it is not clear, however, that net asset value sales to the Nuveen Affiliated Employees covered by the Plan would meet the "uniform offer" requirement of Rule 22d-1(f).

Section 6(c) of the Act provides, in pertinent part, that the Commission, by order upon application, may conditionally or unconditionally exempt any person, security or transaction, or any class or classes of persons, securities or transactions, from any provision of the Act or of any rule under the Act, if and to the extent such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Applicants submit that investment by Nuveen Affiliated Employees pursuant to the Plan in shares of the Funds at net asset value is supported by policy considerations, that such sales should result in demonstrable economies in sales effort and sales related expense as compared with other sales and would not be unjustly discriminatory, and that the grant of the exemption requested by the application is appropriate in the public interest and consistent with the protection of investors and the purposes of Section 22(d) of the Act. Applicants further submit that the affiliation of the Funds with the other Nuveen Companies is the basis for a unique relationship of the Nuveen Companies to the Funds, which can be expected to result in economies of sales effort and sales related expenses that justifies elimination of all sales charges on Funds shares and Units purchased by participants in the Plan without discrimination against other employee benefit plans or other purchasers of Funds shares or Units.

According to the application, features of the Plan which are expected to give rise to economies of scale in sales effort and sales related expense are: (1) there will not be any personal solicitation of participants by Nuveen, its representatives or other broker-dealers; (2) employees purchasing shares of Nuveen Municipal Bond Fund, Inc. through payroll deduction will have shares purchased for their accounts at each payroll date with payment for such shares being made by a single check; and (3) all eligible employees will receive at least annually, at the expense of their employers, notice of the availability of the Plan. Applicants believe that the proposed investments in Funds shares or Units promote employee incentive, goodwill, and loyalty.

Notice is further given that any interested person may, not later than November 20, 1979, at 5:30 P.M., submit to the Commission in writing a request for a hearing on the application accompanied by a statement as to the nature of his interest, the reasons for such request, and the issues, if any, of fact or law proposed to be controverted, or he may request that he be notified if the Commission shall order a hearing thereon. Any such communication should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request shall be served personally or by mail upon the Applicants at the addresses stated above. Proof of such service (by affidavit or, in the case of an attorney-at-law, by certificate) shall be filed contemporaneously with the request. As provided by Rule 0-5 of the Rules and Regulations promulgated under the Act, an order disposing of the application herein will be issued as of course following said date unless the Commission thereafter orders a hearing upon request or upon the Commission's own motion. Persons, who request a hearing or advice as to whether a hearing is ordered, will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Investment Management, pursuant to delegated authority,

George A. Fitzsimmons,

Secretary.

[FR Doc. 79-34056 Filed 11-1-79; 8:43 am]

BILLING CODE 8010-01-M

[Rel. No. 21273; 70-6373]

Ohio Power Co.; Proposed Agreement Concerning the Financing of Pollution Control Facilities

October 26, 1979.

Notice is hereby given that Ohio Power Company ("Ohio Power"), 301 Cleveland Avenue, S.W., Canton, Ohio 44702, an electric utility subsidiary of American Electric Power Company, Inc., a registered holding company, has filed with this Commission an application-declaration pursuant to the Public Utility Holding Company Act of 1935 ("Act"), designating Sections 9(a), 10 and 12(d) of the Act and rule 44(b)(3) promulgated thereunder as applicable to the proposed transactions. All interested persons are referred to the application-declaration, which is summarized below, for a complete statement of the proposed transactions.

Ohio Power states that in order to comply with federal and Ohio environmental control requirements with respect to air quality it has under construction certain particulate emission control and related facilities at Unit No. 1 of the Cardinal Plant (which unit is owned and operated by Ohio Power), located in Jefferson County, Ohio, and at Unit No. 5 of its Muskingum River Plant, located in Washington County, Ohio (collectively referred to hereinafter as the "Facilities"). It is estimated that the Facilities will cost approximately $100,000,000 ($50,000,000 each for the Cardinal portion and the Muskingum River portion). By resolutions adopted on September 4, 1974, November 19, 1975, November 9, 1976, November 16, 1977, and November 14, 1978, the Ohio Air Quality Development Authority (the "Authority") determined that it would authorize and issue one or more series of its pollution control revenue bonds ("Revenue Bonds"), in maximum amounts of $50,000,000 with respect to the Cardinal portion and of $50,000,000 with respect to the Muskingum River portion, to finance the acquisition, construction and installation of the Facilities.

Ohio Power proposes to enter into an agreement of sale ("Agreement") with the Authority whereby the Authority will construct and install the Facilities, and will issue and sell Revenue Bonds in an initial principal amount of up to $60,000,000 ("Series A Bonds") and additional Revenue Bonds in principal amounts, presently estimated not to exceed $40,000,000, sufficient to cover the cost of construction of the Facilities (as defined in the Agreement). The proceeds from the sale of the Series A Bonds will be deposited by the Authority with BancOhio National Bank, as trustee (the "Trustee"), under an indenture (the "Indenture") to be entered into by the Authority and the Trustee, under which Indenture the Series A Bonds are to be issued and secured. Such proceeds will be applied to the payment of the costs of construction of the Facilities, including reimbursement for any such costs paid by Ohio Power. The Agreement will also provide for the sale of the Facilities to Ohio Power, the payment by Ohio Power of the purchase price in semiannual installments over a term of years, and the assignment and pledge to the Trustee of the Authority's interest in, and monies receivable by the Authority under, the Agreement.

The Agreement will also provide that each installment of the purchase price will be in such an amount (together with other monies held by the Trustee under the Indenture for that purpose) as will enable the Authority to pay, when due: (i) the interest on the Revenue Bonds (including any refunding bonds); (ii) the principal amount of the Revenue Bonds (including any refunding bonds) at their stated maturities; and (iii) amounts, including any accrued interest, payable in connection with any mandatory redemption of the Revenue Bonds (including any refunding bonds). The Agreement will also obligate Ohio Power to pay the fees and charges of the Trustees, as well as certain administrative expenses of the Authority. Ohio Power shall have the option to prepay the purchase price in whole (i) upon the occurrence of certain events by paying amounts sufficient to redeem all Revenue Bonds then outstanding, the fees and expenses of the Trustee, and all other amounts payable under the Indenture, or (ii) at any time by depositing monies in the Bond Fund (as defined in the Indenture) or delivering to the Trustee governmental obligations sufficient in either case to provide for the release of the Indenture in accordance with its terms. Upon prepayment of the entire purchase price of the Facilities, Ohio Power may terminate the Agreement. Ohio Power may also prepay the purchase price in part, such payments to be paid to the Trustee for deposit in the Bond Fund and credited against the purchase price and used for the redemption or purchase of outstanding Revenue Bonds in the manner and to the extent the outstanding Revenue Bonds are redeemable or subject to purchase as provided in the Indenture.

Ohio Power proposes to convey the Authority the Facilities at the Cardinal and Muskingum River Plants, to the extent they have already been constructed and are then in place at the plant sites, subject to its first mortgage lien, and Ohio Power will be entitled under the Agreement to be reimbursed from the proceeds of the sale of the Series A Bonds for its costs of construction. Such conveyed Facilities will thereupon become a part of the Facilities which Ohio Power will purchase from the Authority as provided in the Agreement. The amounts to be received by Ohio Power in reimbursement of its costs of construction will be applied by Ohio Power to the payment of its short-term indebtedness (which was $69, 143,000 at June 30, 1979) and for other corporate purposes.

It is contemplated that the Series A Bonds will be sold by the Authority pursuant to arrangements with a group of underwriters represented to Goldman, Sachs & Co. Although Ohio Power will not be a party to the underwriting arrangements, it will not enter into the Agreement unless the terms of the Series A Bonds and their sale by the Authority are satisfactory to it.

Ohio Power understands that the interest on the Series A Bonds will be exempt from federal income taxation. The Series A Bonds will be dated on or about the first day of the month in which they are issued, will bear interest semiannually and will mature at a date or dates not more than 30 years from the date of their issuance. It is expected that the Series A Bonds will not be redeemable at the option of the Authority within 10 years from their date of issuance except under certain circumstances. The Series A Bonds will be subject to mandatory redemption under the circumstances and terms specified in the Indenture.

The fees and expenses to be incurred in connection with the proposed transactions will be supplied by amendment. It is stated that the Public Utilities Commission of Ohio has jurisdiction over the proposed transactions and that no other state commission and no federal commission, other than this Commission, has jurisdiction thereover.

Notice is further given that any interested person may, not later than November 21, 1979, request in writing that a hearing be held on such matter, stating the nature of his interest, the reasons for such request, and the issues of fact or law raised by said application-declaration which he desires to controvert; or he may request that he be notified if the Commission should order a hearing thereon. Any such request should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request should be served personally or by mail upon the applicant-declarant at the above-stated address and proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. At any time after said date the application-declaration, as filed or as it may be amended, may be granted and permitted to become effective as provided in Rule 23 of the Genral rules and Regulations promulgated under the Act, or the Commission may grant exemption from such rules as provided in Rules 20(a) and 100 thereof or take such other action as it may deem appropriate. Persons who request a hearing or advice as to whether a hearing is ordered will receive any notices and orders issued in this matter, including the date of the

hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Corporate Regulation, pursuant to delegated authority.

George A. Fitzsimmons,

Secretary.

[FR Doc. 79-39053 Filed 11-1-79; 8:45 am]

BILLING CODE 8010-01-M

OFFICE OF THE SPECIAL REPRESENTATIVE FOR TRADE NEGOTIATIONS

Textile Policy Advisory Committee; Meeting

The Textile Policy Advisory Committee (the Advisory Committee) will meet on Friday, November 9, 1979 at 10:00 am, at the Office of the Special Representative for Trade Negotiations, 1800 G Street, NW., Washington, D.C. In accordance with section 135(f)(2) of the Trade Act of 1974 (Pub. L. 93-618), as amended by section 1103 of the Trade Agreements Act of 1979 (Pub. L. 96-39), and section 10 of the Federal Advisory Committee Act (Pub. L. 92-463), as amended by sectoin 5(c) of the Government in the Sunshine Act (Pub. L. 94-409), this meeting has been closed to the public.

Robert C. Cassidy, Jr.,

General Counsel.

[FR Doc. 79-34080 Filed 11-1-79; 8:45 am]

BILLING CODE 3190-01-M

DEPARTMENT OF STATE

[Public Notice 687]

Fishery Conservation and Management Act of 1976; Applications for Permits To Fish Off the Coasts of the United States

The Fishery Conservation and Management Act of 1976 (Pub. L. 94-265) as amended (the "Act") provides that no fishing shall be conducted by foreign fishing vessels in the Fishery Conservation Zone of the United States after February 28, 1977, except in accordance with a valid and applicable permit issued pursuant to Section 204 of the Act.

The Act also requires that a notice of receipt of all applications for such permits, a summary of the contents of such applications, and the names of the Regional Fishery Management Councils that receive copies of these applications, be published in the Federal Register.

Individual vessel applications for fishing 1979 have been received from Mexico and are summarized herein.

If additional information regarding any applications is desired, it may be obtained from: Permits and Regulations Divison (F37), National Marine Fisheries Service, Department of Commerce, Washington, D.C. 20235, (Telephone: (202)634-7265).

Dated: October 24, 1979.

James A. Storer,

Director, Office of Fisheries Affairs.

Fishery codes and designation of regional councils which review applications for individual fisheries are as follows:

Code and fishery	*Regional council*
ABS—Atlantic billfishes and sharks	New England. Mid-Atlantic. South Atlantic. Gulf of Mexico. Caribbean.
BSA—Bering Sea and Aleutian Islands trawl, longline and herring gillnet.	North Pacific.
CRB—Crab (Bering Sea)	North Pacific.
GOA—Gulf of Alaska	North Pacific.
NWA—Northwest Atlantic	New England. Mid-Atlantic.
SMT—Seamount groundfish (Pacific Ocean).	Western Pacific.
SNA—Snails (Bering Sea)	North Pacific.
WOC—Washington, Oregon, California trawl.	Pacific.

Activity codes specify categories of fishing operations applied for as follows:

Activity Code and Fishing Operations

1 Catching, processing, and other support.
2 Processing and other support only.
3 Other support only.

Nation/vessel name/vessel type	Application No.	Fishery	Activity
MEXICO			
Esguio, medium stern trawler.	MX-79-0015	NWA	1
Arriscado, medium stern trawler.	MX-79-0065	NWA	1
Avoir, medium stern trawler.	MX-79-0066	NWA	1

[FR Doc. 79-34023 Filed 11-1-79; 8:45 am]

BILLING CODE 4710-09-M

[Public Notice 688]

Fishery Conservation and Management Act of 1976; Applications for Permits To Fish Off the Coasts of the United States

The Fishery Conservation and Management Act of 1976 (Pub. L. 94-265) as amended (the "Act") provides that no fishing shall be conducted by foreign fishing vessels in the Fishery Conservation Zone of the United States after February 28, 1977, except in accordance with a valid and applicable permit issued pursuant to Sec. 204 of the Act.

The Act also requires that a notice of receipt of all applications for such permits, a summary of the contents of such applications, and the names of the Regional Fishery Management Councils that receive copies of these applications, be published in the Federal Register.

Applications have been received from Italy and Korea for fishing during 1979 and 1980 and are reproduced herewith. Individual vessel applications for fishing in 1979 and 1980 have been received from Italy and Japan and are summarized herein.

If additional information regarding any applications is desired, it may be obtained from: Permits and Regulations Divisions (F37), National Marine Fisheries Service, Department of Commerce, Washington, D.C. 20235, (Telephone: (202)634-7265).

Dated: October 29, 1979.

James A. Storer,

Director, Office of Fisheries Affairs.

Fishery codes and designation of regional councils which review applications for individual fisheries are as follows:

Code and fishery	*Regional council*
ABS—Atlantic billfishes and sharks	New England. Mid-Atlanta. South Atlantic. Gulf of Mexico. Caribbean.
BSA—Bering Sea and Aleutian Islands trawl, longline and herring gillnet.	North Pacific.
CRB—Crab (Bering Sea)	North Pacific.
GOA—Gulf of Alaska	North Pacific.
NWA—Northwest Atlantic	New England. Mid-Atlantic.
SMT—Seamount groundfish (Pacific Ocean).	Western Pacific.
SNA—Snails (Bering Sea)	North Pacific.
WOC—Washington, Oregon, California trawl.	Pacific.

Activity codes specify categories of fishing operations applied for as follows:

Activity Code and Fishing Operations

1 Catching, processing, and other support.
2 Processing and other support only.
3 Other support only.

Nation/vessel name/vessel type	Aplication No.	Fishery	Activity
ITALY			
Borea,[1] factory/mothership.	IT-79-0024	NWA	2
KOREA			
Book Neung,[2] factoryship	KS-80-0079	BSA, GOA	2
Soo Gong No. 51,[2] large stern trawler.	KS-80-0042	BSA, GOA	2

[1] This vessel is applying for authorization to conduct activities in support of U.S. fishing vessels. Specifically, the request is to purchase fish for processing and shipment to Italy form U.S. fishing vessels in the Northwest Atlantic during 1979 and 1980. A total of 2,000 metric tons including incidental species is requested.

[2] These vessels are applying for authorization to conduct activities in support of U.S. fishing vessels. Specifically, the request is to purchase fish from processing and shipment to Korea from U.S. fishing vessels in the Gulf of Alaska and Bering Sea and Aleutian Area during 1980. Pollock semi-fillets to be produced from larger pollock and smaller pollock whole processed in the round. Round pollock to be marketed by KMIDC, distributed in Korea. Semi-fillets to be processed in Korea for export to U.S. and perhaps other work markets as frozen pollock blocks. By-catch to be sold in Korea to extent of market. Surplus will be sold in work market, principally to Japan.

[FR Doc. 79-34024 Filed 11-1-79; 8:45 am]

BILLING CODE 4710-09-M

INTERSTATE COMMERCE COMMISSION

[Directed Service Order 1398; Authorization Order No. 5]

Kansas City Terminal Railway Co. Directed to Operate Over Chicago, Rock Island & Pacific Railroad Co., Debtor (William M. Gibbons, Trustee)

Decided: October 25, 1979.

On September 26, 1979, the Commission directed Kansas City Terminal Railway Company (KCT) to provide service as a directed rail carrier (DRC) under 49 U.S.C. 11125 over the lines of the Chicago, Rock Island & Pacific Railroad Company, Debtor (William M. Gibbons, Trustee) ("RI"). *See* Directed Service Order No. 1398 (decided and served September 26, 1979; published in the Federal Register on October 1, 1979 at 44 FR 56343).

RI owns a certain bridge (Bridge No. 2662; timber trestle) which is in need of repair. DSO No. 1398 required the DRC to obtain prior approval for rehabilitation of lines and related facilities which exceeds $5,000 per mile. *See* DSO 1398, at page 24 [44 FR 56348, 1st column]. Accordingly, the DRC submitted a detailed statement of repairs needed to Bridge 2662 at Abbott, AR, requiring repairs costing $10,398. *See* "DRC Report No. 4" (dated October 18, 1979).

The DRC sought Commission authorization to repair Bridge 2662 on the grounds that: (1) the bridge is essential to operation over the RI between Memphis, TN, and Tucumcari, NM; (2) rehabilitation of Bridge 2662 will permit resumption of through train service to "captive" shippers between Little Rock, AR, and Oklahoma City, OK; and (3) service on this line segment is essential to make substantial savings and efficiencies in certain car repair programs, as materials normally moving in non-revenue service must now move in revenue service under foreign line reroute arrangements. The estimated cost of moving RI company materials and heavy bad order cars over other railroads in revenue service to the required locations on the RI is estimated to be $188,890.

Bridge 2662 is located on the RI main line between Little Rock, AR, and Oklahoma City, OK, and is impassable. The DRC has been rerouting through-traffic which ordinarily moves over this line. Rerouting of RI traffic means that much of the freight revenue goes to other railroads. The DRC is now handling traffic normally routed over this line in trains which are detoured on foreign lines around this bridge. These detour movements will very quickly exceed the cost of repairing the bridge.

We find:

(1) This action will not significantly affect either the quality of the human environment or the conservation of energy resources. *See* 49 CFR Parts 1106, 1108 (1978).

It is ordered:

(1) The DRC is authorized to make repairs to RI Bridge 2662 located at Abbott, AR, in Scott County. The total cost authorized for repairs is:

Material	$6,798
Labor	3,600
Total	10,398

(2) The repairs authorized above shall be initiated within 30 days of the commencement of directed-service operations and completed within 15 days of commencement. *See* DSO No. 1398, page 24 [44 FR 56348, 1st column]; *accord* Supplemental Order No. 3 (served October 5, 1979).

(3) This decision shall be effective on its service date.

By the Commission, Railroad Service Board, Member Joel E. Burns, Robert S. Turkington, and John R. Michael.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 79-33963 Filed 11-1-79; 8:45 am]

BILLING CODE 7035-01-M

[Directed Service Order No. 1398; Authorization Order No. 4]

Kansas City Terminal Railway Co. Directed To Operate Over Chicago, Rock Island & Pacific Railroad Co., Debtor (William M. Gibbons, Trustee)

Decided: October 23, 1979.

On September 26, 1979, the Commission directed Kansas City Terminal Railway Company (KCT) to provide service as a directed rail carrier (DRC) under 49 U.S.C. § 11125 over the lines of the Chicago, Rock Island & Pacific Railroad Company, Debtor (William M. Gibbons, Trustee) ("RI"). *See* Directed Service Order No. 1398 (decided and served September 26, 1979; published in the Federal Register on October 1, 1979 at 44 FR 56343).

On October 12, 1979, the Railroad Service Board decided Authorization Order No. 1 (served October 15, 1979; 44 FR 60466, Oct. 19, 1979) which dealt with the lease-related difficulties discussed below. Upon further consideration, we believe that Authorization Order No. 1 should be vacated and superseded by this Authorization Order.

RI has acquired numerous freight cars, passenger cars, locomotives, and work equipment under lease arrangements from the owners of such equipment. Most, if not all, such arrangements require quarterly payments, in some cases in advance of the designated time periods and, in some cases, at the end of such time periods. These time periods do not coincide with the period of directed service as determined in Directed Service Order No. 1398. The failure to make timely payments on these lease agreements will result in the recall of the equipment by the owners and the impairment of directed service.

Even in the event that the DRC was able to negotiate new leases for the same equipment, the default of existing lease agreements would present a serious problem for the continuation of directed service operations. We understand that current leasing contracts carry much higher lease payment levels, and almost none are entered into for periods of less than five years.

It is essential to the continued provision of directed service that this equipment be available to the DRC. Moreover, the use of such equipment in directed service operations is required both by the public interest and by the necessities of interstate commerce. Accordingly, we are taking the following action to avoid what could be serious problems in the provision of directed service.

The Commission authorizes KCT, as the directed rail carrier, to make payments on freight car, passenger car, locomotive, and work equipment leases as they become due during the period of directed service, including payments on leases covering the use of equipment which extend beyond the duration of the Directed Service Order. Such payments shall be made directly to the lessors of the involved equipment. The cost of those payments made during the directed service period shall be treated as a reimbursable cost of directed service. This action is necessary to make vital equipment available to the directed service operations.

KCT is also authorized to make payments on freight car, passenger car, locomotive, and work equipment leases which fell due during the period between the service date and effective

date of Directed Service Order No. 1398. These payments shall be made by KCT directly to the lessors of the involved equipment upon the terms and conditions established by the Commission in Supplemental Order No. 2 (decided and served October 3, 1979; 44 FR 58581, Oct. 10, 1979).

We find:

1. This action will not significantly affect either the quality of the human environment or the conservation of energy resources. *See* 49 C.F.R. Parts 1106, 1108 (1978).

It is ordered:

1. KCT is authorized to make lease payments on RI freight cars, passenger cars, locomotives, and work equipment upon the terms and conditions set forth above.

2. The costs of such lease payments shall be treated as a reimbursable cost of directed service, to the extent indicated above.

3. Authorization Order No. 1 (served October 15, 1979; 44 FR 60466, Oct. 19, 1979) is vacated.

4. This decision shall be effective on its service date.

By the Commission, Railroad Service Board, Members Joel E. Burns, Robert S. Turkington, and John R. Michael.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 79-33962 Filed 11-1-79; 8:45 am]

BILLING CODE 7035-01-M

[37237]

Mississippi Intrastate Rail Freight Rates and Charges 1979—Sand, Gravel, Stone and Related Articles

Decided: October 22, 1979.

By joint petition filed July 23, 1979, petitioners, 6 common carriers by railroad [1] operating in intrastate commerce in Mississippi, request that this Commission institute an investigation of their Mississippi intrastate freight rates and charges, under 49 U.S.C. 11501 and 11502; section 13 of the former Interstate Commerce Act. They seek an order authorizing them to increase such rates and charges to the same levels as the present interstate rates and charges on sand, gravel, stone, and related articles. Petitioners have stated grounds sufficient to warrant instituting an investigation.

Protestants are 4 shippers and receivers of sand and gravel by rail in Mississippi,[2] and 3 shippers and receivers of lightweight aggregates by rail in Mississippi.[3]

Petitioners filed an application on February 6, 1979, with the Mississippi Public Service Commission to increase all intrastate rates on sand, gravel, stone and related articles to the present level of the intrastate rates and charges on those commodities. The Mississippi Commission did not finally act on the application within the 120-day period provided in 49 U.S.C. 11501.

Protestants move to dismiss the joint petition because the petitioners allegedly have waived their right to an investigation before this Commission under the above-mentioned 120-day provision. Petitioners filed a reply to the motion. This allegation is based on a general continuance obtained by protestants' attorney from the Mississippi Commission due to the attorney's illness and hospitalization. Petitioners agreed to this continuance until the attorney was able to resume his practice and the proceeding be resumed before the Mississippi Commission. Due to this agreement, protestants contend petitioners have now estopped themselves from seeking an investigation before this Commission under the 120-day provision. There is no merit to this contention. The provisions of the act may not be set aside by the agreement of the parties. See *Smith-Ingraham Grain Co.* v. *Chicago, R. I. & G. R. Co.* 177 I.C.C. 152, 153 (1931), and *Midstate Co.* v. *Penna. R. Co.*, 320 U.S. 356, 357, 367 (1943). The Mississippi Public Service Commission is, certainly, aware of the provisions of 49 U.S.C. 11501 and could have acted to prevent the delay. Furthermore, much time has elapsed since the petitions were filed and, to our knowledge, the State has not yet acted. Accordingly, petitioners are not estopped from filing the instant petition with this Commission seeking its exclusive jurisdiction in an investigation of the considered intrastate rates. The motion to dismiss is denied.

Protestants also submitted evidence on the substantive issues involved in this proceeding. After this proceeding has been set for oral hearing or modified procedure, protestants may request that this evidence be considered as their filing or they may submit new evidence based on respondent's submittals.

It is ordered:

The motion to dismiss the petition is denied.

The petition for investigation is granted. An investigation, under 49 U.S.C. 11501 and 11502, is instituted to determine whether the Mississippi intrastate rail freight rates in any respect cause any unjust discrimination against or any undue burden on interstate or foreign commerce, or cause undue or unreasonable advantage, preference, or prejudice as between persons or localities in intrastate commerce and persons or localities in interstate or foreign commerce, or are otherwise unlawful, by reason of the failure of such rates and charges to include the present interstate rate level. In the investigation we shall also determine if any rates or charges, or maximum or minimum charges, or both, should be prescribed to remove any unlawful advantage, preference, discrimination, undue burden, or other violation of law, found to exist.

All persons who wish to participate in the proceeding and to file and receive copies of pleadings shall make known the fact by notifying the Office of Proceedings, Room 5342, Interstate Commerce Commission, Washington, DC 20423, on or before 15 days from the Federal Register publication date. Although individual participation is not precluded, to conserve time and to avoid unnecessary expense, persons having common interests should endeavor to consolidate their presentations to the greatest extent possible. This Commission desires participation of only those who intend to take an active part in this proceeding.

As soon as practicable after the last day for indicating a desire to participate in this proceeding, this Commission will serve a list of names and addresses on all persons upon whom service of all pleadings must be made. Thereafter, this proceeding will be assigned for oral hearing or handling under modified procedure.

A copy of this order shall be served upon each of the petitioners and protestants herein. Mississippi shall be notified of the proceeding by sending copies of this order by certified mail to the Governor of Mississippi and the Mississippi Public Service Commission. Further notice of this proceeding shall be given to the public by depositing a copy of this order in the Office of the Secretary of the Interstate Commerce Commission at Washington, DC, and by filing a copy with the Director, Office of the Federal Register, for publication in the Federal Register.

This decision will not significantly affect either the quality of the human

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[1] Alabama Great Southern Railroad Company, Illinois Central Gulf Railroad Company, Louisville & Nashville Railroad Company, Missouri Pacific Railroad Company, St. Louis-San Francisco Railway Company, and Southern Railway Company.

[2] American Sand and Gravel Company, Concrete Products and Supply Company, Tatum Concrete Company, and Ashland-Warren, Inc.

[3] Jackson Ready-Mix Concrete, Alexander Materials Company, and Astro Brick & Block Company, Inc.

environment or conservation of energy resources.

By the Commission, Alan Fitzwater, Director, Office of Proceedings.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 79-33964 Filed 11-1-79; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB 7 (Sub-No. 86F)]

Stanley E. G. Hillman, Trustee of the Property of Chicago, Milwaukee, St. Paul & Pacific Railroad Co.—Abandonment—Portions of Pacific Coast Extension in Montana, Idaho, Washington, and Oregon

AGENCY: Interstate Commerce Commission, Office of Policy and Analysis, Energy and Environment Branch.

ACTION: Notice of due date for comments filed on the draft environmental impact statement prepared in the above-entitled proceeding.

SUMMARY: Because of scheduling problems the Energy and Environment Branch will serve its draft environmental impact statement in the above-entitled proceeding on October 31, 1979 instead of October 23, 1979 as previously planned. The Environmental Protection Agency has suggested that the period for filing comments on the draft statement extend 45 days from the date of service rather than 30 days as contemplated by the Branch. Accordingly, any comments on the DEIS filed on or before December 19, 1979 will be entertained. The Branch will respond to all comments received by December 3, 1979 and will respond to timely comments received after that date to the extent practicable. All comments will in any case be forwarded to the decisionmaker for appropriate consideration. A limited number of copies of the DEIS were made available on October 23, 1979 to parties attending the hearings in this proceeding in Chicago.

FOR FURTHER INFORMATION CONTACT: Paul S. Mushovic, Energy and Environment Branch, Interstate Commerce Commission, 12th and Constitution Avenue, Washington, DC 20423, Tel. (202) 275-7916.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 79-33961 Filed 11-1-79; 8:45 am]

BILLING CODE 7035-01-M

[Finance Docket 29132]

Western Railroad Properties, Inc.; Acquisition of One-Half Interest in Line of Railroad Owned in Part by Chicago & North Western Transportation Co., Exemption Under 49 U.S.C. 10505 From 49 U.S.C. 10901 and 11343

AGENCY: Interstate Commerce Commission.

ACTION: Notice of Proposed Exemption.

SUMMARY: Western Railroad Properties, Incorporated (WRPI) intends to take title to an undivided one-half interest in a line of railroad to be constructed jointly by its parent company, Chicago and North Western Transportation Company (North Western) and Burlington Northern, Inc. WRPI will take title to the one-half interest of North Western. A petition has been filed with the Interstate Commerce Commission on September 13, 1979, seeking exemption from 49 U.S.C. 10901 and 11343. These sections, from which exemption is sought, require the approval for the construction of or acquisition of control of a line of railroad. WRPI and North Western are seeking exemption from these sections under 49 U.S.C. 10505 on the basis that Commission review of the transaction is unnecessary.

DATES: Comments must be received on or before December 3, 1979.

ADDRESS: Send comments to: Interstate Commerce Commission, 12th Street & Constitution Ave., NW, Washington, D.C. 20423. All written submissions will be available for public inspection during regular business hours at the same address. All submissions should refer to F.D. 29132.

FOR FURTHER INFORMATION CONTACT: Michael Erenberg, (202) 275-7245.

SUPPLEMENTARY INFORMATION: WRPI and North Western have filed a petition for exemption under 49 U.S.C. 10505 on September 13, 1979, in order that their anticipated transaction may be exempted from the requirements of obtaining prior Commission approval under 49 U.S.C. 10901 and 11343.

Petitioners claim that the proposed transaction will not adversely affect other railroads or employees. It is alleged that since WRPI is a wholly-owned subsidiary of North Western, no useful public purpose would be served to develop, reproduce, and otherwise conform to the Commission's detailed application requirements under the statutory requirements in question. These assertions should be addressed in the comments.

The Transaction

WRPI is a wholly-owned subsidiary or North Western, and is authorized to do business in Nebraska and Wyoming. North Western is a common carrier by railroad operating in 11 States.

By report in Finance Docket No. 27579, *Burlington Northern, Inc.—Construction and Oper.* 348 I.C.C. 388 (1976), the Commission authorized North Western and Burlington Northern, Inc. (BN) jointly to construct, own and operate approximately 106.5 miles of a new line of railroad. On May 22, 1975, North Western and BN entered into an agreement defining the respective rights and obligations of each during construction and operation. The agreement permitted either carrier to create a wholly-owned subsidiary to own its undivided one-half interest in the joint line. The purpose of the instant application is to permit the subsidiary to take title to the interests of North Western in order to insulate the assets of the joint line from the reach of North Western's general mortgage.

WRPI and North Western state that the usual regulatory requirements contained in 49 U.S.C. 10901 and 11343 would serve no useful purpose.

The Statute

The construction and operation of a line of railroad requires the approval and authority of the Commission under 49 U.S.C. § 10901. The acquisition of control of a line of railroad by another railroad requires the approval and authority of the Commission under 49 U.S.C. 11343. WRPI and North Western have requested an exemption from 49 U.S.C. 10901 and 11343 so that they will not have to file applications under those sections.

The petitioners believe that this construction and acquisition is the type of transaction which Congress intended the Commission to exempt when it adopted 49 U.S.C. 10505. It maintains that the legislative history of the *Railroad Revitalization and Regulatory Reform Act* of 1976 reflects a Congressional purpose to exempt from regulation those transactions in which regulation would serve little or no useful public purpose. It acknowledges that the exemption will be limited to this transaction and that railroads would continue to be subject to Commission regulation.

Before granting an exemption, we are required to provide the opportunity for a proceeding. This request for comments on a requested exemption of the proposed transaction is that opportunity. All comments filed in response to this notice, along with petition for

exemption, will be used to determine whether or not the exemption under 49 U.S.C. 10505 should be granted.

This proceeding is instituted under the authority of 49 U.S.C. 10505 and pursuant to 5 U.S.C. 553, 559.

This proceeding is not a major Federal action significantly affecting energy consumption or the quality of the human environment.

Dated: October 16, 1979.

By the Commission, Chairman O'Neal, Vice Chairman Stafford, Commissioners Gresham, Clapp, Christian, Trantum, Gaskins, and Alexis.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 79-33930 Filed 11-1-79; 8:45 am]

BILLING CODE 7035-01-M

Sunshine Act Meetings

Federal Register
Vol. 44, No. 214
Friday, November 2, 1979

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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1

COUNCIL ON ENVIRONMENTAL QUALITY.

October 30, 1979.

TIME AND DATE: 11:30 a.m., Thursday, November 8, 1979.

PLACE: Conference room, 722 Jackson Place NW., Washington, D.C. 20006.

STATUS: Open meeting.

MATTERS TO BE CONSIDERED:

1. Old business.
2. Status report on the Soil and Water Resources Conservation Act (RCA)—study and reports underway by USDA.
3. Status report on the Toxic Substances Data Committee.
4. Briefing on status of agencies NEPA procedures.

CONTACT PERSON FOR MORE INFORMATION: John F. Shea III (202) 395-4616.

[S-2137 Filed 10-30-79; 4:16 pm]

BILLING CODE 3125-01-M

2

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION.

TIME AND DATE: 9:30 a.m. (eastern time), Tuesday, November 6, 1979.

PLACE: Commission conference room 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.

Open to the Public

1. Age Discrimination in Employment Act Regulations.
2. Proposed questionnaire requesting information on the impact of Federal employment-opportunity programs and activities, to be sent to employers.
3. Several proposed sole source contracts for services in support of litigation.
4. Sole source contract for Linolex word processing training for 33 District and Area offices.
5. Proposed 706 agency designation for Wisconsin State Personnel Commission.
6. Section 717 instructions for the development of Federal Affirmative Action Plans for fiscal year 1980.
7. Report on Commission Operations by the Executive Director.

Closed to the Public

Litigation authorization; General Counsel Recommendations.

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 October 31, 1979.

[S-2148-79 Filed 10-31-79; 3:52 pm]

BILLING CODE 6570-06-M

3

FEDERAL DEPOSIT INSURANCE CORPORATION.

Notice of Change in Subject Matter of Agency Meeting

Pursuant to the provisions of subsection (e)(2) of the "Government in the Sunshine Act" (5 U.S.C. 552b(e)(2)), notice is hereby given that at its closed meeting held at 4:00 p.m. on Monday, October 29, 1979, the Corporation's Board of Directors determined, on motion of Chairman Irvine H. Sprague, seconded by Director William M. Isaac (Appointive), concurred in by Director John G. Heimann (Comptroller of the Currency), that Corporation business required the addition to the agenda for consideration at the meeting, on less than seven days' notice to the public, of the following matters:

Application of Colonial Mutual Savings Bank, Philadelphia, Pennsylvania, a proposed new bank, for Federal deposit insurance coincident with its conversion from a savings and loan association into a mutual savings bank.

Application of The Western New York Savings Bank, Buffalo, New York, for consent to establish a branch at 807 Elmwood Avenue, Buffalo, New York.

Recommendation regarding the liquidation of assets acquired by the Corporation from Guaranty Bank & Trust Company, Chicago, Illinois, and Gateway National Bank of Chicago, Illinois (Case No. 44,113-L).

The Board further determined, by the same majority vote, that Corporation business required the withdrawal from the agenda for consideration at the meeting, on less than seven days' notice to the public, of a memorandum and resolution with regard to delinquent bank reports.

The Board further determined, by the same majority vote, that no earlier notice of these changes in the subject matter of the meeting was practicable; that the public interest did not require consideration of the matters added to the agenda in a meeting open to public observation; and that the matters added to the agenda could be considered in a closed meeting by authority of subsections (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

Dated: October 29, 1979.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[S-2140-79 Filed 10-30-79; 4:49 pm]

BILLING CODE 6714-01-M

4

FEDERAL DEPOSIT INSURANCE CORPORATION.

Notice of Change in Subject Matter of Agency Meeting

Pursuant to the provisions of subsection (e)(2) of the "Government in the Sunshine Act" (5 U.S.C. 552b(e)(2)), notice is hereby given that at its open meeting held at 3:30 p.m. on Monday, October 29, 1979, the Corporation's Board of Directors determined, on motion of Chairman Irvine H. Sprague, seconded by Director William M. Isaac (Appointive), concurred in by Director John G. Heimann (Comptroller of the Currency), that Corporation business required the addition to the agenda for consideration at the meeting, on less than seven days' notice to the public, of a personnel matter.

The Board further determined, by the same majority vote, that no earlier

notice of this change in the subject matter of the meeting was practicable.

Dated: October 29, 1979.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[S-2139-79 Filed 10-30-79; 4:39 pm]

BILLING CODE 6714-01-M

5

FEDERAL ENERGY REGULATORY COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 44 FR 62398.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 10 a.m., October 31, 1979.

CHANGE IN THE MEETING: The following itmes have been added:

Item Number, Docket Number, and Company

M-10(B). RM80- , Regulations On Natural Gas from New, Onshore Production Wells.

M-22. RM79-68, Final Rule Amending Regulations On New Natural Gas and Certain Natural Gas Produced from the Outer Continental Shelf.

M-23(A). RM79-73, Final Rule Amending Subpart H of Part 271 On Stripper Well Natural Gas and Amendments To Section 274.206 of the Interim Regulations.

M-23(B). RM79-73, Interim Regulation Under Section 108 of the NGPA Defining the Term "Produced."

M-24. RM79-57, Administrative Procedures for Adjustments of Natural Gas Curtailment Priority Regulations.

CP-4. TC80-26, Southern Natural Gas Company.

CP-5. RP76-52, Northern Natural Gas Company.

CAG-39. CP79-430, Natural Gas Pipeline Company of America.

Kenneth F. Plumb,

Secretary.

[S-2143-79 Filed 10-31-79; 12:31 pm]

BILLING CODE 6450-01-M

6

FEDERAL RESERVE SYSTEM.

TIME AND DATE: 10 a.m., Wednesday, November 7, 1979.

PLACE: 20th Street and Constitution Avenue NW., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Proposed construction, under competitive bidding, of a new building for the Baltimore Branch of the Federal Reserve Bank of Richmond.
2. Proposed acquisition of real property by a Federal Reserve Bank.
3. Federal Reserve Bank and Branch director appointments.
4. Any agenda items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board (202) 452-3204.

Dated: October 30, 1979.

Theodore E. Allison,

Secretary of the Board.

[S-2138-79 Filed 10-30-79; 4:16 pm]

BILLING CODE 6210-01-M

7

FEDERAL RESERVE SYSTEM.

TIME AND DATE: 10:45 a.m., Wednesday, October 31, 1979 (following a recess at the conclusion of an open meeting held earlier in the day).

PLACE: 20th Street and Constitution Avenue NW., Washington, D.C. 20551.

STATUS: Closed.

MATTER CONSIDERED: Personnel policies and procedures with respect to the Federal Reserve Bank examiners. (This matter was originally announced for a meeting on October 26, 1979).

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board (202) 452-3204.

Dated: October 31, 1979.

Theodore E. Allison,

Secretary of the Board.

[S-2147-79 Filed 10-31-79; 3:52 pm]

BILLING CODE 6210-01-M

8

NUCLEAR REGULATORY COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: To be published.

TIME AND DATE: Week of October 29 (changes).

PLACE: Commissioners' conference room, 1717 H Street NW., Washington, D.C.

STATUS: Open/closed.

MATTERS TO BE CONSIDERED:

Thursday, November 1—2 p.m.

1. Briefing by IE on TMI Lessons Learned (approximately 2 hours, public meeting), rescheduled from October 31.
2. Affirmation session (approximately 10 minutes, public meeting), (items are tentative): (a) Order in Shearon Harris and (b) Duke Power Co., Spent Fuel Transfer.

Friday, November 2—3 p.m.

1. Discussion of Proposed Testimony Concerning Report by Presidential Commission on TMI (closed—exemption 9).

Note.—The General Administrative Meeting and the Briefing on Reactor Licensing Schedules (postponed from November 1) will be rescheduled in the near future.

CONTACT PERSON FOR MORE INFORMATION: Walter Magee 202-634-1410.

Roger M. Tweed,

Office of the Secretary.

[S-2142-79 Filed 10-31-79; 12:12 pm]

BILLING CODE 7590-01-M

9

OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION.

TIME AND DATE: 10 a.m., November 15, 1979.

PLACE: Room 1101, 1825 K Street NW., Washington, D.C.

STATUS: Because of the subject matter, it is likely that this meeting will be closed.

MATTERS TO BE CONSIDERED: Discussion of specific cases in the Commission adjudicative process.

CONTACT PERSON FOR MORE INFORMATION: Ms. Patricia Bausell (202) 634-4015.

Date: October 29, 1979.

[S-2145-79 Filed 10-31-79; 2:29 pm]

BILLING CODE 7600-01-M

10

OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION.

TIME AND DATE: 10 a.m., November 29, 1979.

PLACE: Room 1101, 1825 K Street NW., Washington, D.C.

STATUS: Because of the subject matter, it is likely that this meeting will be closed.

MATTERS TO BE CONSIDERED: Discussion of specific cases in the Commission adjudicative process.

CONTACT PERSON FOR MORE INFORMATION: Ms. Patricia Bausell (202) 634-4015.

Date: October 29, 1979.

[S-2146-79 Filed 10-31-79; 2:29 pm]

BILLING CODE 7600-01-M

11

SECURITIES AND EXCHANGE COMMISSION.

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94-409, that the Securities and Exchange Commission will hold the following meetings during the week of November 5, 1979, in Room 825, 500 North Capitol Street, Washington, D.C.

An open meeting will be held on Tuesday, November 6, 1979, at 2:30 p.m. A closed meeting will be held on Wednesday, November 7, 1979, at 10:00 a.m.

The Commissioners, their legal assistants, the Secretary of the

Commission, and recording secretaries will attend the closed meeting. Certain staff members who are responsible for the calendared matters may be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, the items to be considered at the closed meeting may be considered pursuant to one or more of the exemptions set forth in 5 U.S.C. 552b(c)(4)(8)(9)(A) and (10) and 17 CFR 200.402 (a)(4)(8)(9)(i) and (10).

Chairman Williams and Commissioners Loomis and Karmel determined to hold the aforesaid meeting in closed session.

The subject matter of the open meeting scheduled for Tuesday, November 6, 1979, at 2:30 p.m., will be:

1. Consideration of whether to publish for comment proposed Rule 3a–1 under the Investment Company Act of 1940, which would deem not to be investment companies, for purposes of the Act, certain companies meeting the statutory requirements of Section 3(a)(3). For further information, please contact Mark J. Mackey at (202) 272–3045.

2. Consideration of whether to publish for comment proposed Rule 3a–2 under the Investment Company Act of 1940 to deem certain transient investment companies temporarily not to be investment companies for purposes of the Act for a period not to exceed one year. For further information, please contact Mark J. Mackey at (202) 272–3045.

3. Consideration of whether to publish for comment proposed Rule 3a–3 under the Investment Company Act of 1940, which would deem certain issuers that do not comply literally with a specified exclusion from the definition of investment company in Section 3(b)(3) of that Act nonetheless not to be investment companies for purposes of the Act. For further information, please contact Mark J. Mackey at (202) 272–3045.

4. Consideration of whether to publish for comment a proposed amendment to Rule 3a–2 under the Investment Company Act of 1940 to deem, under specified circumstances, a company's owning 10% or more of an issuer's outstanding voting securities to be beneficial ownership by one person. For further information, please contact Mark J. Mackey at (202) 272–3045.

5. Consideration of whether to rescind the moratorium on the capitalization of interest cost imposed under Accounting Series Release No. 163 in recognition of the establishment of an accounting standard on this issue by the Financial Accounting Standards Board. Consideration will also be given to amending the disclosure requirements for capitalized interest cost under Regulation S–X to conform with the disclosure requirements under the new standard. For further information, please contact Lawrence C. Best or John W. Albert at (202) 272–2130.

6. Consideration of whether to publish for comment proposed amendments of Regulation S–X (1) to reduce the required detailed disclosure of loans to nonofficer directors of bank holding companies and banks; and (2) to revise the reporting of large certificates of deposit and time deposits in domestic bank offices and in foreign offices. For further information, please contact Lawrence J. Bloch at (202) 272–2130.

7. Consideration of whether to publish for comment proposed amendments to Form S–8 and proposed related new rules under the Securities Act of 1933. The purpose of the form amendments and the new rules is to provide a means whereby all filings on Form S–8 (both pre-effective and post-effective, with certain limited exceptions) will become effective automatically, without affirmative action on the part of the Commission or its staff. For further information, please contact William H. Carter at (202) 272–2604.

8. Consideration of requests by VSI Corporation and Liquidonics Industries, Inc. that the Commission review the Division of Corporation Finance's denials of requests by the companies for extension of time within which to file their annual reports on form 10–K for the period ended June 30, 1979. For further information, please contact John Bernas at (202) 272–3205.

9. Consideration of whether to send a letter to the Office of the Comptroller of the Currency commenting on a proposal that national banks be permitted to participate in the marketing of single-premium annuity contracts. For further information, please contact Frederick Wade at (202) 272–2440.

The subject matter of the closed meeting scheduled for Wednesday, November 7, 1979, at 10:00 a.m., will be:

Settlement of injunctive action.
Order compelling testimony.
Litigation matters.
Freedom of Information Act appeals.
Freedom of Information Act and Privacy Act appeals.
Settlement of administrative proceedings of an enforcement nature.
Subpena enforcement action.
Institution of administrative proceeding of an enforcement nature.
Institution of injunctive action.
Regulatory matter regarding financial institutions.
Opinion.

At times changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: Paul Lowenstein at (202) 272–2092.

October 30, 1979.

[S–2141–79 Filed 10–31–79; 10:47 am]

BILLING CODE 8010–01–M

12

THE WHITE HOUSE CONFERENCE ON LIBRARY AND INFORMATION SERVICES.

TIME: Beginning at 8 a.m. and continuing into the evening hours.

DATE: 15–19 November 1979.

PLACE: Washington Hilton Hotel, 1919 Connecticut Avenue NW., Washington, D.C.

STATUS: Open.

MATTERS TO BE DISCUSSED: Recommendations and Resolutions concerning Library and Information Services.

CONTACT PERSON FOR MORE INFORMATION: Marilyn K. Gell, Director (202) 634–1530.

October 31, 1979.

Marilyn K. Gell,
Director.

[S–2144–79 Filed 10–31–79; 2:29 pm]

BILLING CODE 7527–01–M

Federal Register

Friday
November 2, 1979

Part II

Department of Health, Education, and Welfare

Food and Drug Administration

Oral Mucosal Injury Drug Products For Over-the-Counter Human Use; Establishment of a Monograph; Proposed Rulemaking

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Part 353

[Docket No. 78N-0196]

Oral Mucosal Injury Drug Products for Over-the-Counter Human Use, Establishment of a Monograph; Proposed Rulemaking

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish conditions under which over-the-counter (OTC) oral mucosal injury drug products (drugs which relieve oral soft tissue injury by cleansing or promoting the healing of oral wounds) are generally recognized as safe and effective and not misbranded. The proposed rule, based on the recommendations of the Advisory Review Panel on OTC Dentifrice and Dental Care Drug Products, is part of the ongoing review of OTC drug products conducted by the Food and Drug Administration (FDA).

DATES: Comments by January 24, 1980, and reply comments by February 25, 1980.

ADDRESS: Written 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 accordance with Part 330 (21 CFR Part 330), FDA received on April 28, 1978, a report of the Advisory Review Panel on OTC Dentifrice and Dental Care Drug Products. Under § 330.10(a)(6) (21 CFR 330.10 (a)(6)), the agency is issuing (1) a proposed regulation containing the monograph recommended by the Panel, which establishes conditions under which OTC oral mucosal injury drugs are generally recognized as safe and effective and not misbranded; (2) a statement of the conditions excluded from the monograph on the basis of a determination by the Panel that they would result in the drugs not being generally recognized as safe and effective or would result in misbranding; (3) a statement of the conditions excluded from the monograph on the basis of a determination by the Panel that the available data are insufficient to classify such conditions under either (1) or (2) above; and (4) the conclusions and recommendations of the Panel.

The unaltered conclusions and recommendations of the Panel are issued to stimulate discussion, evaluation, and comment on the full sweep of the Panel's deliberations. The report has been prepared independently of FDA, and the agency has not yet fully reviewed the report. The Panel's findings appear in this document as a formal proposal to obtain public comment before the agency reaches any decision on the Panel's recommendations. This document represents the best scientific judgment of the Panel members but does not necessarily reflect the agency's position on any particular matter contained in it.

After FDA has carefully reviewed all comments submitted in response to this proposal, the FDA will issue a tentative final regulation in the Federal Register to establish a monograph for OTC oral mucosal injury drug products.

In accordance with § 330.10(a)(2) (21 CFR 330.10(a)(2)), the Panel and FDA have held as confidential all information concerning OTC oral mucosal injury drug products submitted for consideration by the Advisory Review Panel on Dentifrice and Dental Care Drug Products.

All the submitted information will be put on public display at the office of the Hearing Clerk, Food and Drug Administration after November 26, 1979, except to the extent that the person submitting it demonstrates that it still falls within the confidentiality provisions of 18 U.S.C. 1905 or section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)). Requests for confidentiality should be submitted to William E. Gilbertson, Bureau of Drugs (HFD-510) (address above).

Based upon the conclusions and recommendations of the Panel, the agency proposes the following:

1. That the conditions included in the monograph, under which the drug products would be generally recognized as safe and effective and not misbranded (Category I), be effective 30 days after the date of publication of the final monograph in the Federal Register.

2. That the conditions excluded from the monograph because they would cause the drug to be not generally recognized as safe and effective or to be misbranded (Category II), be eliminated from OTC drug products effective 6 months after the date of publication of the final monograph in the Federal Register, regardless of whether further testing is undertaken to justify their future use.

The agency advises that the status of Category III conditions after publication of a final order is the subject of the recent decision in *Cutler* v. *Kennedy*, No. 77-0734 (D.D.C. July 16, 1979). In that case, the court held that "* * * the FDA may not lawfully maintain Category III in any form in which drugs with Category III conditions * * * are exempted from enforcement action." (*Cutler, supra.*, Slip Op. at 38). The agency is presently studying the effect of this decision on the OTC drug review procedures. Accordingly, although this document retains the concept of Category III in its original form, the agency's response to the court's decision may result in substantial changes in the regulatory treatment of Category III conditions.

In the Federal Register of January 5, 1972 (37 FR 85), the FDA announced a proposed review of the safety, effectiveness, and labeling of all OTC drugs by independent advisory review panels. In the Federal Register of May 11, 1972 (37 FR 9464), the agency published the final regulations providing for the OTC drug review under § 330.10 which were made effective immediately. Pursuant to these regulations, the agency issued in the Federal Register of January 30, 1973 (38 FR 2781) a request for data and information on all active ingredients utilized in dentifrice and dental care drug products except mouthwashes and oral antiseptics.

The agency appointed the following Panel to review the data and information submitted and to prepare a report pursuant to § 330.10(a)(1) on the safety, effectiveness, and labeling of those products:

Louis P. Gangarosa, D.D.S., Ph.D., Chairman
Joseph J. Aleo, D.D.S., Ph.D. (appointed September 1, 1973)
Howard H. Chauncey, D.M.D., Ph.D. (resigned April 30, 1976)
Valerie Hurst, Ph.D.
Joy B. Plein, Ph.D.
Delos E. Raymond, D.D.S.
Roger H. Scholle, D.D.S., M.S.
Lawrence E. VanKirk, Jr., D.D.S., M.P.H. (appointed June 29, 1976)
Benjamin O. Watkins, D.D.S. (resigned August 1, 1973)

The Panel was first convened on April 24, 1973 in an organizational meeting. Working meetings were held on May 24 and 25, June 21 and 22, August 15 and 16, October 10 and 11, November 29 and 30, 1973; January 17 and 18, February 27 and 28, April 3 and 4, May 9 and 10, June 19 and 20, July 24 and 25, September 19 and 20, October 16 and 17, December 4 and 5, 1974; January 15 and 16, February 26 and 27, April 2 and 3, May 7 and 8, June 24 and 25, August 12, 13, and 14, October 9 and 10, December 3 and 4, 1975;

January 23 and 24, February 24 and 25, March 31 and April 1, May 11 and 12, June 30 and July 1, July 28 and 29, August 25 and 26, October 5 and 6, December 1 and 2, 1976; January 12 and 13, March 9 and 10, April 20 and 21, June 1 and 2, July 13 and 14, August 24 and 25, October 19 and 20, November 30 and December 1, 1977; January 17 and 18, March 11 and 12, April 26, 27, and 28, May 30 and 31, and June 1, and July 11, 12, and 13, 1978.

The minutes of the Panel meetings are on public display in the office of the Hearing Clerk (HFA-305), Food and Drug Administration (address given above).

Five nonvoting liaison members served on the Panel. Judy Jackson, Esq., nominated by the Consumer Federation of America, served as the consumer liaison until April 1974. Mary Plaska, nominated by the American Public Health Association, succeeded Ms. Jackson in May 1974 and served until May 1976. Sandra Zimmerman, nominated by the Consumer Federation of America, succeeded Ms. Plaska in June 1976. Lester D. Apperson, Ph.D., nominated by the Cosmetic, Toiletry, and Fragrance Association, served as an industry liaison. Joseph L. Kanig, Ph.D., nominated by the Proprietary Association, also served as an industry liaison until January 1978.

The following employees of the Food and Drug Administration served: Clarence C. Gilkes, D.D.S. served as Executive Secretary. Michael D. Kennedy served as Panel Administrator until January 1978 followed by Thomas D. DeCillis, R.Ph. Melvin Lessing, M.S., R.Ph. served as Drug Information Analyst until June 1977. George Kerner, M.S. serves as Consumer Safety Officer. Cindy Barkdull served as special assistant from July 1977 to April 1978. Elmer M. Plein, Ph.D. and Gordon H. Schrotenboer, Ph.D. served as consultants to the Panel.

The following individuals were given an opportunity to appear before the Panel to express their views either at their own or at the Panel's request on all issues before the Panel:

John E. Alman, M.A.
Hazen J. Baron, D.D.S., Ph.D.
I. B. Bender, D.D.S.
Malcolm Boone, D.D.S.
R. K. Boutwell, Ph.D.
Herbet Brilliant, D.D.S.
Richard C. Brogle, Ph.D.
Finn Brudevold, D.D.S.
Lewis P. Cancro, Ph.D.
A. Chasens, D.D.S.
Neal W. Chilton, D.D.S.
Stephen A. Cooper, D.M.D., Ph.D.
D. Walter Cohen, D.D.S.
William E. Cooley, Ph.D.
Robert Ellison, D.D.S., M.S.
H. Fogels, D.D.S.
Sol Gershon, Ph.D.
William Gold, Ph.D.
Hans Graf, D.D.S.
F. Healey, Ph.D.
John Hefferren, Ph.D.
L. Kenneth Hiller, Ph.D.
George F. Hoffnagle, Sc.D.
Herschel S. Horowitz, D.D.S., M.P.H.
Marvin Kamisky, Ph.D.
Krishan Kapur, D.M.D., M.Sc.
Kenneth Kasses, Ph.D.
Homer Jamison, D.D.S., Ph.D.
Philip B. Lawson
Edgar Lazo-Wasem, Ph.D.
Donald A. M. MacKay, Ph.D.
John H. Manhold, D.M.D.
Craig R. Means, D.D.S., M.Sc.
Murray Rosenthal, M.S.
Albert L. Russell, D.D.S., M.Ph.
Bernard Schneider, D.D.S.
James H. Stanton
Willard J. Tarbet, D.D.S., Ph.D.
Patrick Toto, D.D.S.
Aaron Trubman, D.D.S.
Paul Vinton, D.D.S.
Carrol S. Weil, M.A.
Elizabeth K. Weisburger, Ph.D.
S. C. Yankell, D.D.S.
K. Yeh, Ph.D.
A. Albert Yurkstas, D.M.D.

No person who so requested was denied an opportunity to appear before the Panel.

The Panel was charged to review submitted data and information for OTC dentifrice and dental care drug products. Because all such agents are not used for the same purpose, it was not possible for the Panel to establish a single standard of requirements for effectiveness of each product. Therefore, in an attempt to simplify categorization of ingredients and labeling claims the Panel placed the dental care drug products into one of the following therapeutic classifications: (1) Agents for oral mucosal injury, (2) agents for the relief of oral discomfort, (3) anticaries agents, (4) dental plaque disclosing agents, and (5) denture aids.

On May 28, 1976, the Medical Device Amendments of 1976 became law. This legislation amends the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and provides new authority to assure the safety and effectiveness of medical devices. Several products previously regulated as drugs that were under review by the Panel came within the definition of a medical device under these amendments. The FDA reviewed the products previously regarded as drugs and concluded that the following products in the Federal Register of December 16, 1977 (42 FR 63472) fall within the definition of a medical device: Denture cushions, dental adhesives, dental reliners and repair kits, denture cleansers, and plaque-disclosing kits. The Panel wishes to point out that during its deliberations "kits" were not specifically addressed and that the Panel's terminology for dental devices differs from that published in the Federal Register. The Panel used the following terminology in evaluating these products: Denture adhesives, denture reliners, denture repair products, denture cleansers, and dental plaque-disclosing agents.

In a notice published in the Federal Register of May 2, 1978 (43 FR 18769), FDA announced that it had transferred the responsibility for regulating OTC dental care devices from the agency's Bureau of Drugs to its Bureau of Medical Devices and Diagnostic Products (BMDDP). In addition, the notice announced that the Advisory Review Panel on OTC Dentifrice and Dental Care Drug Products had summarized its findings and recommended that the agency transfer that portion of its report concerning products now regulated as medical devices, together with the data and information submitted in response to the January 30, 1973 notice, to BMDDP. A summary of the Panel's conclusions concerning the safety, effectiveness, and labeling of those products is included in the Panel's minutes for the March 11 and 12, 1978 meeting.

The Panel presents its conclusions and recommendations for oral mucosal injury drug products in this document. The Panel's conclusions and recommendations for the relief of oral discomfort drug products and anticaries drug products will be presented in future issues of the Federal Register.

The Panel has thoroughly reviewed the literature and data submissions, has listened to additional testimony from interested persons, and has considered all pertinent data and information submitted through April 26, 1978, in arriving at its conclusions and recommendations.

In accordance with the OTC drug review regulations (21 CFR 330.10), the Panel's findings with respect to OTC oral mucosal injury drug products are set out in three categories:

Category I. Conditions under which OTC oral mucosal injury drug products are generally recognized as safe and effective and are not misbranded.

Category II. Conditions under which OTC oral mucosal injury drug products are not generally recognized as safe and effective or are misbranded.

Category III. Conditions for which the available data are insufficient to permit final classification at this time.

I. Submission of Data and Information

Pursuant to the notice published in the Federal Register of January 30, 1973 (38

FR 2781) requesting the submission of data and information on OTC drugs containing dentifrice and dental care agents, the following firms made submissions relating to the indicated products that, the Panel has further determined, contain active ingredients or labeling which may be appropriately classified as oral mucosal injury drug products.

A. *Submissions by Firms*

Firms and *Marketed products*

A-Trol Laboratories, Topeka, KA 66604—I.D. Denture Medication.
Carter Products, Cranbury, NJ 08512—Aerodent (Green IV) Dentifrice, Hydrogen Peroxide.
Church & Dwight Co., Inc., Syracuse, NY 13201—Arm and Hammer Baking Soda.
Cooper Laboratories, Inc., Cedar Knolls, NJ 07927—Amosan.
International Pharmaceutical Corp., Warrington, PA 18976—Gly-Oxide Liquid.
McKesson Laboratories, Fairfield, CT 06430—Ora-Fix Medicated Denture Adhesive.
Merrell-National Laboratories, Cincinnati, OH 45215—Cepacol Mouthwash.
Rystan Co., Inc., White Plains, NY 10605—Chloresium Toothpaste, Chloresium Dental Ointment, Chloresium Solution.
Warner-Lambert Co., Morris Plains, NJ 07950—Listerine Antiseptic.
Carter-Wallace, Inc., Cranbury, NJ 08512—Dicalcium Phosphate, Hydrogen Peroxide, Sodium Fluoride.

B. *Labeled Ingredients Contained in Marketed Products Submitted to the Panel*

Alcohol
Allantoin
Benzocaine
Benzoic acid
Boric acid
Carbamide peroxide in anhydrous glycerol
Cetylpyridinium chloride
Eucalyptol
Hydrogen peroxide
Menthol
Methyl salicylate
Phosphate buffers
Sodium bicarbonate
Sodium bitartrate
Sodium perborate monohydrate
Sodium peroxyborate monohydrate (derived from sodium perborate) buffered with sodium bitartrate
Thymol
Thymol iodide
Water-soluble derivatives of chlorophyll "a"

C. *Classification of Ingredients*

1. *Active ingredients (for oral mucosal injury).*

Allantoin
Carbamide peroxide in anhydrous glyceron (carbamide peroxide in anhydrous glycerol)
Chlorophyllins water-soluble (water-soluble derivatives of chlorophyll "a")
Hydrogen peroxide in aqueous solution
Sodium perborate monohydrate (sodium peroxyborate monohydrate)

2. *Inactive ingredients.*

Glycerin
Phosphate buffers
Sodium bitartrate

3. *Ingredients to be discussed by the Panel in subsequent documents issued in the Federal Register either as OTC drugs for the relief of oral discomfort or as anticaries agents.*

Benzocaine (as an oral mucosal analgesic and as a toothache relief agent)
Menthol (as an oral mucosal analgesic)
Methyl salicylate (as an oral mucosal analgesic and as a toothache relief agent)
Sodium bicarbonate (as an anticaries agent).

4. *Ingredients deferred to the Advisory Review Panel on OTC Oral Cavity Drug Products for evaluation for oral antiseptic claims*

Alcohol
Benzoic acid
Boric acid
Cetylpyridinium chloride
Eucalyptol
Menthol
Sodium perborate monohydrate
Thymol
Thymol iodide

D. *Referenced OTC Volumes*

All "OTC Volumes" cited throughout this document include submissions made by interested persons pursuant to the call-for-data notice published in the Federal Register of January 30, 1973 (38 FR 2781). All of the submitted information included in these volumes, except for those deletions which are made in accordance with § 330.10(a)(2) (21 CFR 330.10(a)(2)), will be put on public display after November 26, 1979, in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

II. General Statements and Recommendations

A. *General Comments*

The OTC Dentifrice and Dental Care Agents Panel was charged with the review and the evaluation of safety and effectiveness data on dentifrice and dental care ingredients and combinations thereof, the adequacy of their labeling, and to advise the Commissioner on the promulgation of monographs establishing conditions under which these OTC drug products are generally recognized as safe and effective and not misbranded. The Panel also served as a forum for the exchange of views regarding the prescription or nonprescription status of these various active ingredients and combinations thereof. Panel members were expected to call upon their own expert knowledge and experience in carrying out each element of this charge.

This document contains both general statements and recommendations applicable to the entire class of products reviewed by the Panel as well as specific statements and recommendations applicable to oral mucosal injury drug products.

B. *Definitions*

The following definitions have been adopted by the Panel. These definitions reflect the Panel's intended meaning of terms as specifically used in this document in reference to oral mucosal injury drug products. Some of these definitions also apply to the other drug categories reviewed by the Panel. Some degree of variation with more widely accepted defintions of the same terms may exist.

1. *Buffering agent.* An agent or system which has the ability to resist a change in pH (hydrogen ion concentration), particularly in aqueous solution, upon the addition of an acid, alkali, or upon dilution with a solvent.

2. *Dental care agent.* Any drug or dosage form used to treat or prevent disease of the teeth or soft tissue in the oral cavity.

3. *Dental (dentin) hypersensitivity.* A term which implies that the teeth are much more reactive than normal to sensory stimuli such as heat, cold, sour, sweet, or touch. Hypersensitivity can occur when dentin is exposed to the oral environment as a result of abrasion, erosion, gingival recession, or a defect in the enamel or cementum.

4. *Dentifrice.* In this document a dentifrice is a substance used with a toothbrush to clean the accessible surfaces of the teeth. Dentifrices are ordinarily composed of water, detergent, humectant, binder, and flavoring agents and a finely powdered abrasive as the principal ingredient. In this document, dentifrice is considered to be an abrasive-containing dosage form for delivering therapeutic ingredients.

5. *Dosage.* A quantitative schedule that includes the amount of drug that is ingested or applied at one time (the dose) and the time intervals at which the dose is given; the schedule may include the duration of therapy.

6. *Dosage form.* The pharmaceutical preparation, e.g., solution, suspension, paste, tablet, ointment, in which the drug is administered.

7. *Dose.* The quantity of a drug that is ingested or applied at one time.

8. *Dose-response.* The relationship between the dose of a drug and the magnitude of the effect produced by that dose.

9. *Double-blind study.* A testing procedure in which neither the investigator nor the subject (patient) knows whether an experimental drug or its control has been given.

10. *Gingivitis.* Inflammation occurring in the marginal and/or papillary gingiva as a response to bacterial plaque.

11. *Hypersensitivity.* Literally means "more sensitive than normal." In general health care, the term is almost synonymous with allergy and implies that the person has been exposed to a drug, develops antibodies to it, and then reacts adversely to the drug upon subsequent exposure whereas the normal subject does not (see definition 3 above—Dental (dentin) hypersensitivity).

12. *Minor gum disorders (injury).* Inflammation related to mechanical irritation or minor injury of the gingival tissues. The Panel does not consider gingivitis caused by dental plaque to be a minor gum disorder amenable to self-diagnosis or treatment by OTC preparations.

13. *Mouthwash (oral rinse).* A resolution often containing breath-sweetening, astringent, demulcent, detergent, and/or germicidal agents which is used for freshening and cleansing the mouth, or for gargling. In some instances, such a vehicle may be used to deliver an active drug to the oral mucosa or teeth. The Panel prefers the terms oral rinse and dental rinse according to their respective areas of use (for the oral mucosa or the teeth) rather than mouthwash.

14. *Necrosis.* Refers to circumscribed localized areas of cell or tissue death caused by almost any type of seyere injury.

15. *Oral mucosal analgesic (topical anesthetic).* An ingredient used in dental care drug products for surface application in the oral cavity to provide temporary relief of oral discomfort by an analgesic or anesthetic effect.

16. *Oral mucosal injury.* Injury occurring to the soft tissue in the oral cavity.

17. *Oral mucosal injury agent.* An agent which relieves oral soft tissue injury, e.g., by cleansing or promoting the healing of oral wounds (minor oral irritations).

18. *Oral mucosal protectant.* An agent which is a pharmacologically inert substance which forms an adherent, continuous, flexible, or semirigid coating when applied to the oral mucous membranes. The coating protects the irritated area from further irritation due to the activity of oral structures.

19. *Oral wound cleanser.* A nonirritating preparation which assists (physically or chemicaly) in the removal of foreign material from small superficial oral wounds and does not delay wound healing.

20. *Oral wound healing agent.* A nonirritating agent which aids in the healing of small superficial oral wounds by means other than cleansing and irrigating, or by serving as a protectant.

21. *Pharmacotherapeutic.* The Panel classified ingredients into various pharmacotherapeutic groups according to the expected therapeutic effect at the intended site of action.

22. *Placebo.* An inactive substance or preparation used in controlled studies to determine the effectiveness of an agent presumed to be active. Generally, a placebo preparation will be identical to the test preparation except that the active or test agent will not be present.

23. *Professional labeling.* Drug directions for the use of a product intended for, and distributed only to, health care professionals.

24. *Prophylactic.* The term "prophylactic" indicates the prevention of disease. In this document, "prophylactic" is synonymous with "preventative."

25. *Sloughing.* A slough is a mass of dead tissue in, or cast out from, living tissue. Sloughing is the formation or separation of dead tissue from living tissue.

26. *Systemic effect.* An effect related to the entire body as contrasted to a local effect, which is an effect on one specific structure. In general, drugs which are absorbed into the blood stream can be assumed to exert systemic effects, although the desired and the observable sites of action may be fairly specific structures or organs.

C. The Dentist and OTC Drugs in Oral Health

The level of sophistication of dental science has accelerated at a remarkable rate in the past two decades. This era has seen the introduction of (1) an air turbine for high-speed tooth cutting, (2) improved methods of pain control, (3) new scientific findings in pulpal and periodontal biology, (4) advances in oral microbiology and plaque control, (5) modern restorative materials including tooth sealants, and (6) expanded research and utilization of paradental personnel. Modern dental practice now stresses total comprehensive dental care including the prevention of disease, multiple restoration at a single appointment, and preservation of natural teeth. Good examples of the new approach in dental care are the current emphasis on prevention of caries by fluorides and the promotion of mechanical plaque-control hygiene programs which are believed to prevent periodontal disease and caries.

In spite of these advances in dentistry, the need for dental care remains high and is thought to be increasing. Among factors responsible for the continuing need and increasing demand for dental care are (1) consumer education and sophistication, (2) availability of funds from increased personal income and from third-party payment plans, (3) requests by labor groups and low socioeconomic groups for more dental, as well as general, health care, and (4) the continuing use of refined diets.

Because of these factors, it is anticipated that the dental profession will be unable to keep up with consumer demand for oral health care. Therefore, an increasing demand for self-medication with OTC drugs will occur. Some OTC drugs may provide preventative care or temporary relief of symptoms of disease and injury.

The Panel is aware that there is a tremendous need for chemical agents to counteract gingivitis and control bacterial plaque. Control of plaque could reduce dental disease. However, it is difficult to achieve adequate control in the majority of the population. Children are not attentive to this need, while handicapped persons may be unable to carry out the plaque-control program which requires diligence and manual skills. Agents with antiplaque and antigingivitis properties should be developed through research by the pharmaceutical industry, by dental schools, and by governmental agencies. For such an agent to become an OTC drug quickly, it should be a drug presently in use in the U.S.A. for another purpose, either as an OTC or a prescription drug. However, it appears that such antiplaque and antigingivitis agents, if they are forthcoming, will be newly developed drugs requiring new drug application (NDA) approval. If after a period of testing they are proven safe and effective, and if they can be labeled for safe and effective nonprescription drug use, they may achieve OTC status.

The Panel wishes to emphasize that currently marketed mouthwashes containing antiseptics do not automatically fulfill the requirements of an agent which has an effect on plaque formation or which prevents gingivitis. The Panel is aware that dental plaque and gingivitis represent two of the leading dental health problems in the country today. For this reason the Panel initiated a discussion of, and search for, agents that could be generally recognized as safe and effective for the control, or prevention, of plaque and of gingivitis.

As a result of this discussion a number of ingredients and rationales for prevention or control of these conditions were submitted.

Present evidence suggests that good oral hygiene is important to the prevention or reduction of inflammatory periodontal disease (Ref. 1). This essentially means the removal of dental bacterial plaque and their products from teeth on a regular basis. The removal or reduction of these offending agents is best accomplished by mechanical means. The effectiveness of a patient's ability to remove offending agents mechanically depends upon the alignment of the teeth, the presence of cavities or calculus, and whether the supporting tissues are well adapted to the teeth.

To supplement mechanical removal of offending agents, a number of chemical agents claiming usefulness for prevention of plaque, calculus, or gingivitis are presently under investigation. The potential value and safety of these agents, which include quaternary ammonium compounds, enzymes, organic fluorides, and various antibiotics have not been conclusively ascertained. The specific antimicrobial compounds for which some success is claimed in clinical studies include several agents. Among them are cetylpyridinium chloride and combinations of cetylpyridinium chloride and domiphen bromide which achieved a 30 to 40 percent reduction in dental plaque (Refs. 2 and 3). Other potentially effective agents include thymol and eucalyptol (Ref. 4), alexidine (Ref. 5), peroxides (Ref. 6), chlorhexidine (Ref. 7), and an investigational compound CC10232 (Ref. 2). A major concern in the use of these agents is their tendency to disrupt the normal microbial ecologic balance of the host (Ref. 8).

After considering these ingredients and the theories and rationale proposed for the effectiveness of drugs used for prevention and control of plaque and gingivitis, the Panel has concluded that such approaches are at present so controversial that there can be no general recognition of the effectiveness of these agents for these indications at this time.

The Panel, therefore, recommends that all claims stating or implying prevention, control, or treatment of plaque or gingivits be placed in Category II and further recommends that antiplaque and antigingivitis agents be investigated and approved through the NDA process.

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(3) Beiswanger, B. B., O. P. Sturzenberger, and W. Bollmer, "Clinical Effect of an Antibacterial Mouthwash on Dental Plaque and Gingivitis," (Abstract), *Journal of Dental Research, Special Abstract Supplement (International Association for Dental Research)*, p. 146, 1974.

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(7) Schroeder, H. E., T. M. Marthaler, and H. R. Muhlemann, "Effects of Some Potential Inhibitors on Early Calculus Formation," *Helvetica Odontologica Acta*, 6:6–9, 1962.

(8) Draus, F. W., "The Microbiology of the Oral Cavity and its Systemic Significance," *Dental Clinics of North America*, 2:309, 1958.

D. Labeling for OTC Dental Products

Having reviewed all of the labels of OTC dental preparations submitted, the Panel recommends that labeling include the following:

1. *Labeling.* The Panel reviewed and concurs with the OTC drug regulation labeling (§ 201.61 (21 CFR 201.61)) which states:

(a) The principal display panel of an over-the-counter drug in package form shall bear as one of its principal features a statement of the identity of the commodity.

(b) Such statement of identity shall be in terms of the established name of the drug, if any there be, followed by an accurate statement of the general pharmacological category(ies) of the drug or the principal intended action(s) of the drug. In the case of an over-the-counter drug that is a mixture and that has no established name, this requirement shall be deemed to be satisfied by a prominent and conspicuous statement of the general pharmacological action(s) of the mixture or of its principal intended action(s) in terms that are meaningful to the layman. Such statements shall be placed in direct conjunction with the most prominent display of the proprietary name or designation and shall employ terms descriptive of general pharmacological category(ies) or principal intended action(s); for example, "antacid," "analgesic," "decongestant," "antihistaminic," etc. The indications for use shall be included in the directions for use of the drug, as required by section 502(f)(1) of the act and by the regulations in this part.

(c) The statement of identity shall be presented in bold face type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it designed to be displayed.

2. *Ingredients.* Dentifrice and dental care agents should contain only active ingredients plus such inactive ingredients as may be necessary for formulation. The label should state the quantity of each active ingredient in appropriate units to be specified later in each section of this document. The Panel encourages the use of metric units.

The Panel strongly recommends that all inactive ingredients be listed on the label in descending order of quantity, since the consumer may need to know, for a variety of reasons, the ingredients in the product. However the product should not imply or claim that its inactive ingredients have a therapeutic benefit.

The Panel recognizes that although full disclosure of flavoring and coloring ingredients is desirable, this may be impractical and confusing because of the large number of ingredients which may be involved. Thus, flavoring and coloring ingredients may be listed in accordance with present regulations for labeling such ingredients in food products.

3. *Indications.* The indications for use of a dentifrice or dental care agent should be simply and clearly stated.

Statements of indications for use should be specific and confined to the conditions for which the product is recommended. Indications should be confined to those that a significant portion of the target population can reasonably self-diagnose. No reference should be made, or implied, regarding the alleviation or relief of symptoms unrelated to the condition accepted as an indication for use of the product.

Thus, a prominent and conspicuous statement must be made of general pharmacotherapeutic action. In addition, the Panel recommends that the label contain a clear indication of the categories of dentifrice or dental care agent and provide the user with a reasonable expectation of the results to be anticipated from use of the product. For example, oral mucosal injury drug products shall be labeled as either an "oral wound cleanser" or an "oral wound healing agent."

4. *Directions for use.* The directions for use should be clear, direct, and provide the user with sufficient information to enable safe and effective use of the product.

The label should include a clear statement of the usually effective minimum and maximum dose (or concentration if more appropriate) per

time interval. If dosage varies with the consumer's age, the directions should be broken down by age groups. In appropriate instances, the usual directions may be followed by "except under the supervision of a dentist or physician." The Panel will recommend specific directions for use under each drug statement in later sections of this document.

E. Principles Applicable to Combination Products

1. *General combination policy.* In order to clarify the status of combination products in the marketplace, the Panel applied the OTC drug review regulation (§ 330.10(a)(4)) which states:

> (iv) An OTC drug may combine two or more safe and effective active ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s); when combining the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients; and when the combination, when used under adequate directions for use and warnings against unsafe use, provides rational concurrent therapy for a significant proportion of the target population.

A product may contain two Category I active ingredients that meet the regulatory requirements as well as the criteria adopted by the Panel, together with suitable inactive ingredients, provided that (a) the active ingredients are safe and effective and do not antagonize the therapeutic usefulness of each other, (b) the inactive ingredients are safe and do not interact with, or otherwise inhibit the effectiveness of the active ingredients, (c) there is a significant target population that has the concurrent symtoms and can thus benefit from use of the combination, (d) use of the combination does not decrease the safety due to adverse effects over use of the single ingredient, and (e) the combination contains adequate directions for use and is labeled with adequate warnings against unsafe use.

The Panel recognizes that some OTC dentifrice and dental care agent products contain combinations of ingredients. The Panel found that such combinations contain active ingredients both from the same and from different pharmacotherapeutic classes. The Panel is not convinced that combinations containing two or more oral mucosal injury agents from the same pharmacotherapeutic group would be more effective than the single ingredient alone. Moreover, combining full therapeutic concentrations of two or more ingredients for the relief of oral mucosal injury may incur unwarranted additional risk.

The alternative to combining two ingredients from the same pharmacotherapeutic class at each ingredient's effective dose is to combine subtherapeutic doses of the ingredients, on the theory that such a combination will reduce the risk of side effects or adverse reactions. The Panel prefers full concentrations of single ingredients, because it is not aware of any data to support the use of two ingredients in subtherapeutic doses. Combinations containing ingredients of the same pharmacotherapeutic group at less than the minimum effective concentration for any one of the ingredients are, therefore, classified in Category II.

The Panel recognizes that oral mucosal injury drug products have also been combined with active ingredients from other pharmacotherapeutic groups. The Panel has reviewed and classified combinations of oral mucosal injury active ingredients with active ingredients for the relief of oral discomfort, as discussed below.

The Panel is aware that oral mucosal injury active ingredients have also been combined with oral antiseptic, which are presently under review by the OTC advisory Review Panel on Oral Cavity Drug Products, and with denture adhesives, which are being reviewed by the Bureau of Medical Devices. These combination products were reviewed and classified by this Panel as to their rational for concurrent therapy.

The same general principles apply when an active ingredient from a different pharmacotherapeutic group reviewed by another OTC drug advisory Panel is combined with an active ingredient of a pharmacotherapeutic group reviewed by this Panel. The rationale for such combinations should be evaluated by FDA according to the combination policy set forth in the reports of both panels.

The Panel recognizes the extensive marketing history of many dental preparations. Members of the drug industry presented data to the Panel summarizing their marketing history and consumer complaint information. A number of marketed products are combinations which originated as dentists' private formulas or which has been adapted from formulas appearing in older editions of such compendia as the "Pharmaceutical Recipe Book" or the "National Formulary." The effectiveness of such products may never have been subjected to scientific assessment even though the products have been marketed for many years. Apparent consumer acceptance and testimonial data used by many manufacturers as the sole evidence of effectiveness and safety were not acceptable to the Panel. When claims of effectiveness were supported solely by outdated experimental methodology, this evidence for effectiveness was also considered unacceptable.

Regarding effectiveness, the Panel has applied the OTC drug review regulation (§ 330.10(a)(4)(ii)), which provides that the reports of significant human experience during marketing are appropriate as a source of corroboration for proof of effectiveness. In accordance with these regulations, the Panel took into account the marketing experience of manufacturers as stated in their submissions. Although the Panel found these data helpful, marketing experience did not overrule or substitute for the Panel's other sources of knowledge of safety, effectiveness, and rationale for such combinations. Marketing experience, alone, cannot be regarded as constituting adequate proof of effectiveness, nor should it be the only basis for assessing the rationality and validity of a combination drug product.

2. *Limitation of ingredients in combination products.* The Panel believes that the interests of the consumer are best served by exposing a user of OTC drugs to the fewest ingredients and the lowest dosage that will provide a satisfactory level of effectiveness. Single component OTC drugs are preferable because they afford a lower risk of undesirable side effects and permit more precise treatment of individual symptoms. The Panel recognizes that there may be a rationale for combining active ingredients in certain OTC drugs; however, such combinations must be based on a sound and logical scientific rationale.

The Panel recommends that not more than two dentifrice and dental care agent active ingredients be included in any combination product because the addition of more ingredients would increase the risk to the consumer without increasing the benefit.

3. *Labeling of active ingredients.* The labeling must indicate the name and quantity (concentration) of all active ingredients, and the principle intended action of each ingredient as well as the indication for use of the product. The Panel considers that the labeling for any product that contains an active ingredient for which no claim is made is misleading.

The Panel recommends that the labeling of a combination product containing active ingredients for treatment of two or more concurrent symptoms should emphasize that the consumer use the product only when all such symptoms are present. The

consumer should be adequately informed, through the labeling, of the total therapeutic capabilities of the product.

The Panel recommends that each claimed active ingredient in a combination product must make a statistically significant contribution to the claimed effect or effects of the product.

4. *Criteria for Category I combinations.* The Panel recommends the following general criteria for Category I combination drug products for the treatment of oral mucosal injury.

Two dentifrice and dental care agent Category I active ingredients from different pharmacotherapeutic groups may be combined to treat different symptoms concurrently if each Category I active ingredient is present within its established dosage range; the combination is rational; there is a significant target population that suffers from the concurrent symptoms; and the combination is as safe and as effective as each individual active ingredient used alone.

Labeling for the combination product must conform to recommended labeling for each active ingredient, and must specify any additional information such as drug interactions or adverse reactions that occur with the combination product, but not with the individual ingredients used alone. The labeling for a Category I combination product should stress that the product should be used only when both symptoms are present. The consumer needs to be properly informed about the therapeutic capabilities of the product. The product's labeling should not induce the consumer to take a combination drug when a single entity is appropriate and effective.

5. *Category I combination drug products for the treatment of oral mucosal injury.* The Panel recommends that the following combinations be classified as Category I for the treatment of oral mucosal injury.

a. *Combinations of an oral mucosal injury agent with an oral antiseptic.* (Note.—the advisability of adding an antiseptic for the stated purpose is under review by the OTC Advisory Review Panel on Oral Cavity Drug products.)

(i) *An oral wound cleanser and an oral antiseptic.* The Panel finds that this combination is rational and should provide additional protection from infection for an oral wound.

(ii) *An oral wound healing agent and an oral antiseptic.* The Panel finds that this combination is rational, and the antiseptic should help prevent infection, thus allowing healing to occur as rapidly as possible. At this time there are no Category I oral wound healing agents, but in the event data are generated to support the movement of an oral wound healing agent into Category I, this combination would be acceptable.

b. *Combinations of an oral mucosal injury agent with a denture adhesive.* (Note.—the advisability of adding a denture adhesive for the stated purpose is under review by the Bureau of Medical Devices.)

(i) *An oral wound healing agent and a denture adhesive.* The Panel finds that this combination is rational. There is a target population of persons who wear dentures and develop minor wounds or sores under the denture. This combination should contain a label instructing users that the combination should not be used unless both concurrent symptoms are present.

6. *Criteria for Category II combination products.* The Panel recommends the following criteria for Category II combination drug products for the treatment of oral mucosal injury.

a. A combination is Category II if a Category II active ingredient or Category II labeling is present in the combination product.

b. A combination product containing Category I active ingredients from the same or different pharmacotherapeutic groups is classified as Category II if it includes any ingredient in less than the minimum effective concentration established by the Panel.

c. If a combination contains an active ingredient or other condition that has not been reviewed by this or any other OTC drug advisory review panels, such ingredient or condition is Category II and the resulting combination then becomes Category II.

d. A combination product is classified as Category II if it includes more than two active ingredients from different pharmacotherapeutic groups.

e. A combination product is classified as Category II if it contains active ingredients from more than one pharmacotherapeutic group and there is not a significant target population that has a concurrent need for a drug from each of these groups.

f. A combination is Category II if there is no therapeutic rationale for the combination, even if the individual ingredients are Category I and the combination conforms in all other respects to the criteria for a Category I combination.

g. A combination of two Category I active ingredients from different pharmacotherapeutic groups is Category II if the ingredients cannot be combined because of chemical or physical formulation problems that would result in decreasing the safety or effectiveness of the individual ingredients.

7. *Category II combination drug products for the treatment of oral mucosal injury.* The Panel recommends that the following combinations be classified as Category II for the treatment of oral mucosal injury.

a. *Combinations of two oral mucosal injury agents*—(i) *Oral wound cleanser and an oral wound cleanser.* The Panel finds no rationale for such a combination. The Panel considered whether the combination of short-acting and a long-acting agent would be useful, but such a combination is not on the market. Based on current directions for use of oral wound cleansers (spit out after 1 minute), such a combination does not appear useful.

(ii) *Oral wound cleanser and an oral wound healing agent.* The Panel finds no rationale for such a combination. If an oral wound healing agent is administered in the same dosage form with an oral wound cleanser, the oral wound healing agent will be removed from its site of action when the oral wound cleanser is spit out before it has had an opportunity to exert its intended pharmacotherapeutic effect. In addition, when an oral wound healing agent is used, prolonged contact with the wound area is desired. These two pharmacotherapeutic agents are intended to be used sequentially and not at the same time.

(iii) *Oral wound healing agent and an oral wound healing agent.* The Panel finds no rationale for such a combination. The Panel did not review any data relating to such combinations. There may be a rationale for combining two such agents if each acts by a different mechanism of action but data must be generated to establish that each ingredient makes a contribution to the claimed effect.

b. *Combinations of an oral mucosal injury agent with an agent for the relief of oral discomfort*—(i) *Oral wound cleanser and an oral mucosal protectant.* The Panel finds no rationale for such a combination. An oral mucosal protectant forms a protective film over the area to which it is applied. The use of an oral wound cleanser in the same dosage form with an oral mucosal protectant would result in the cleanser removing the protectant from the affected area, thus making the protectant ineffective.

(ii) *Oral wound cleanser and a toothache relief agent.* The Panel finds no rationale for such a combination. If a toothache relief agent is administered in the same dosage form with an oral wound cleanser, the toothache relief agent will be removed from its site of

action when the oral wound cleanser is spit out and, thus, before it has had an opportunity to exert its intended pharmacotherapeutic effect. These two pharmacotherapeutic agents are intended to be used at different sites in the oral cavity.

(iii) *Oral wound cleanser and an oral mucosal analgesic.* The Panel finds no rationale for such a combination. If an oral mucosal analgesic is administered in the same dosage form with an oral wound cleanser, the oral mucosal analgesic will be removed from its site of action when the oral wound cleanser is spit out. These two pharmacotherapeutic agents are intended to be used sequentially and not at the same time.

(iv) *Oral wound cleanser and a counterirritant.* The Panel finds no rationale for such a combination. By definition, a counterirritant is irritating, and such an agent should not be used when cleansing a wound.

(v) *Oral wound cleanser and a tooth desensitizer.* The Panel finds no rationale for such a combination.

(vi) *Oral wound healing agent and a toothache relief agent.* An oral wound healing agent is intended for use on mucosal tissue, not on tooth pulp. A toothache relief agent is intended for use on irreversibly damaged pulp and should only be used when there is no possibility that the pulp injury is reversible. Hence, an oral wound healing agent would confer no benefit when applied to tissue that has no potential for healing.

(vii) *Oral wound healing agent and a counterirritant.* The Panel finds no rationale for such a combination. By definition, a counterirritant is irritating, and such an agent should not be used on a healing wound.

(viii) *Oral wound healing agent and a tooth desensitizer.* The Panel finds no rationale for such a combination.

(ix) *Peroxide-containing oral wound healing agent and a oral mucosal protectant.* The Panel finds no rationale for such a combination. If an oral mucosal protectant is administered in the same dosage form with a peroxide-containing oral wound healing agent, the bubbling action of the peroxide would remove the protectant from the site of action before it has had an opportunity to exert the intended pharmacotherapeutic effect.

(x) *Peroxide-containing oral wound healing agent and a oral mucosal analgesic.* The Panel finds no rationale for such a combination. If an oral mucosal analgesic is administered in the same dosage form with a peroxide-containing oral mucosal analgesic, the bubbling action of the peroxide would remove the analgesic from the site of action before it has had an opportunity to exert the intended pharmacotherapeutic effect.

c. *Combination of an oral mucosal injury agent with a denture adhesive.* (Note: the advisability of adding a denture adhesive for the stated purpose is under review by the Bureau of Medical Devices.)

(i) *An oral wound cleanser and a denture adhesive.* The Panel finds no rationale for such a combination. The bubbling action of the oral wound cleanser would be antagonistic to the adhesive and might dislodge it.

8. *Criteria for Category III combination products.* The Panel recommends the following criteria for Category III combination drug products for the treatment of oral mucosal injury.

a. If a Category III active ingredient or other condition is present in a combination product containing no Category II ingredient or labeling, the combination is classified as Category III.

9. *Category III combination drug products for the treatment or oral mucosal injury.* The Panel recommends that the following combinations be classified as Category III for the treatment of oral mucosal injury.

a. *Combinations of an oral mucosal injury agent with certain agents for the relief of oral discomfort*—(i) *nonperoxide-containing oral wound healing agent and a oral mucosal protectant.* These two types of agents may be combined providing testing is performed to establish that the oral mucosal protectant does not interfere with the action of the oral wound healing agent. The protectant will hold the oral wound healing agent in place at the site of the wound and will also protect the wound from further injury and irritation.

(ii) *Nonperoxide-containing oral wound healing agent and a oral mucosal analgesic.* The oral mucosal analgesic will provide relief of the symptoms of pain or discomfort while the oral wound healing agent promotes healing.

F. Statement on Category III Testing Procedures

1. *Comments on study design.* The Panel has agreed that the protocols recommended in this document for the studies required to bring a Category III active ingredient into Category I are in keeping with the present state of the art and do not preclude the use of any advances or improved technology in the future.

Experimental design should take into account the need to include a sufficient number of subjects or trials so as to provide meaningful conclusions which can be supported by appropriate statistical analysis. The selection of appropriate subjects or patients is of major importance when the effect of a drug in a specific condition for relief of a specific symptom is under study.

Some bias exists in all situations wherein the subject, the observer, or both make a judgment as to the nature or magnitude of a response. Biological factors also contribute to variation in response between individuals in a given study sample. Although bias and biological variation cannot be eliminated, their effect on the outcome of an experiment can be minimized by adopting a "double-blind, placebo-controlled" or other suitably blinded design. In such a design, one group of subjects receives a placebo or dummy preparation so that the placebo response, unmodified by the conditioning of the test, can be established. In a double-blind study, neither the subjects nor the observer can distinguish the identity of the preparations under test. This requires that the test and placebo preparations be indistinguishable in shape, color, odor, and taste. However, in the case of preparations containing active volatile agents or substances which affect sensory perception, it is impossible to make the placebo indistinguishable from active ingredients. When a placebo is used for comparison, the test medication should exert a quantitatively positive effect which is statistically significant when compared to the placebo. The level of statistical significance which is acceptable is described under each Category III protocol. (See part III, paragraph C, below—Data Required for Evaluation.)

It is often desirable to include as a positive control a standard drug which is known to exert a significant effect against the relevant symptoms being tested. When a standard drug is used for comparison, the test medication should be at least equivalent to the standard.

Finally, the inclusion of two or more dose levels (concentrations) of the drug under test may be desirable in order to provide an estimate of an effective therapeutic dose range which is free from undesirable side effects. If a crossover design is utilized, i.e., each subject serves as his own control, the sequence in which the placebo, standard, and test drugs are administered should be randomized and a sufficient "wash-out period" between tests should be permitted.

Wherever possible, objective measurements should be made in preference to subjective judgments. However, subjective measurements may be required if relevant to the symptom

or symptom complex for which the drug under test is to be used.

2. *Testing period provided for Category III conditions.* The Panel has determined that the available data are insufficient (Category III) to classify some conditions either as Category I or Category II. Such conditions are permitted to remain on the market, or to be introduced into the market, after the date of publication of the final monograph in the Federal Register, provided that FDA receives notification of testing in accordance with § 330.10(a)(13) (21 CFR 330.10(a)(13)). The Panel recommends that Category III conditions should be tested within 2 years.

3. *Testing guidelines for Category III combination products.* The Category III active ingredients for the labeling indication claims must be tested in accordance with the evaluation protocol specified for that particular pharmacotherapeutic classification. If, when tested alone, the Category III ingredient or ingredients can be shown to be safe and effective in accordance with the standards for evaluation established in the protocols, it will then qualify for Category I status. The combination will then contain only Category I active ingredients but still must be tested to prove that each ingredient makes a contribution to the product's claimed effect(s).

An acceptable test procedure will be one in which the proposed combination and each of the individual active ingredients at the proposed dosage level in the combination are evaluated, all in the same study, and compared to a placebo for effectiveness against the relevant labeling claim. In this way, it can be shown whether or not each active ingredient in the combination makes a contribution toward effectiveness without incurring an unnecessary decrease in safety.

G. Drug Misuse and Abuse

The potential for development of drug tolerance and addiction due to the use of oral mucosal injury drug products, even when the patient is on an unsupervised regimen, does not seem to exist. However, the Panel believes that misuse of dental care agents occurs when an agent tends to give the subject a false sense of security, thereby diminishing his desire to seek professional advice. When this possibility exists, the label warnings should alert the patient to this danger. The problem becomes especially acute in those cases where the OTC medication suppresses the signs of an infection or other painful symptoms but does not correct the underlying cause. In another example, a person who needs professional dental care may use an OTC dental care agent to enable him to postpone the needed care. Labeling of OTC oral mucosal injury drug products should include warnings against possible misuse of the specific ingredients and should specify a maximum time period for use of the product without the advice of a dentist or physician.

H. Pediatric Considerations

The Panel reviewed the conditions under which dental care products can be safely used by children. Children are defined as individuals under 12 years of age. All of the agents reviewed by the Panel are to be applied topically in the oral cavity and are only inadvertently ingested. For most drugs administered topically, the concentration required for children is equal to that needed by adults. Because the surface area treated may be smaller in a child than in an adult, the total amount of agent applied may be less in a child than in an adult; however, under many circumstances the total amount required by both age groups will be similar. If the adult dosage can be applied safely to children, no special instructions are needed for reduced dosage in children; labeling should, however, indicate that children should be supervised in their use of the agent. If ingestion of an adult dose might cause adverse effects in a child, then the quantity used by the child must be restricted through labeling. In addition, children under 5 years of age cannot be expected to reliably expectorate a dental product (Ref. 1). The dosage for children under 5 years of age must be safe for ingestion; if it is not, labeling should restrict usage to children over 5 years of age.

The Panel recommends packaging in containers with safety closures, additional safety measures whenever necessary and provision of a means for measuring dosage or for single unit dose packaging.

Reference

(1) Barnhart, W. E., et al., "Dentifrice Usage and Ingestion among Four Age Groups," *Journal of Dental Research*, 53:1317–1322, 1974.

I. Inactive Ingredients

A variety of inactive ingredients is used in the manufacture and formulation of products reviewed by the Panel. Such ingredients should be limited to agents that are considered necessary and include abrasives, preservatives, aromatics, vehicles, colorants, sweeteners, anti-oxidants, buffers, and other types of pharmaceutic aids for particular dosage forms.

The Panel did not undertake an extensive review of inactive ingredients because it is the view of the Panel that the safety and the advisability of including specific inactive ingredients in drug products should be reviewed by an appropriate Panel. Since many of these ingredients are used in the formulation of many drug products other than those reviewed by this Panel, it is not appropriate that they be dealt with specifically and solely in relation to dentifrice and dental care agents except when unusual problems arise. This is the case with edetate disodium, which is discussed in the recommendations for Relief of Oral Discomfort Drug Products to be published in a subsequent issue of the Federal Register.

For various reasons, individuals may wish to avoid using certain inactive ingredients found in drug products. Such reasons include allergic reactions, previous idiosyncratic responses, safety concerns (whether valid or not), or personal preference. It is impossible to make a free choice in this regard unless all the components of drug products are listed on the labels. Therefore, this Panel strongly recommends that FDA require full ingredient labeling of inactive as well as active ingredients in descending order of quantities present in all drug products. The Panel recognizes that although full disclosure of flavoring and coloring ingredients is desirable, this may be impractical and confusing because of the large number of ingredients which may be involved. Thus, flavoring and coloring ingredients may be listed in accordance with present regulations for labeling such ingredients in food products. The Panel recommends that FDA study the safety of flavorings and colorings, in addition to other inactive ingredients, so that regulations for such ingredients can be devised and applied to all drug products.

J. Single Active Ingredient Products

The Panel has discussed dental combination products earlier in this document. (See part II. paragraph E. above—Principles Applicable to Combination Products.) The Panel concludes that there are some combinations which are rational for concurrent therapy of multiple symptoms for a significant portion of the target population. However, for the individual who has only one condition and needs one ingredient, single active ingredients afford the opportunity to selectively treat such a condition. If a single ingredient is safe and effective for the treatment of a particular symptom, the presence of other ingredients in the

product exposes the patient to additional risk of side effects or idiosyncratic reactions.

Great variability with regard to side effects induced by drugs is seen among patients. Although these side effects and the drugs producing them are sometimes familiar to dentists, physicians, and pharmacists, it is more difficult to determine which ingredient in a combination is causing the side effect. Furthermore, use of fixed combinations, where a single ingredient product would be sufficient, will expose the consumer to additional risk of side effects and allergic reactions without added benefit. These difficulties are largely avoided with single active ingredient products, which many dentists and pharmacists prefer to recommend. There was agreement among Panel members that the availability of products containing single active ingredients would provide increased opportunity for the public and health professionals to select products appropriate to treat the symptoms.

K. Advertising

The Panel is aware that the role of FDA is to regulate labeling of OTC drugs and the role of the Federal Trade Commission is to enforce adherence to such labeling in advertising. In addition to recommending specific labeling claims, warnings, and dosages, the Panel would like to make some general comments and recommendations regarding advertising of drugs.

Advertisements extend the label beyond the pharmaceutical counter or medicine cabinet. The public may well receive most of its attitudes toward dentifrice and dental care agent remedies from advertisements, particularly television advertisements that are often directed toward children.

For this reason the Panel strongly urges the Federal Trade Commission to challenge any advertisement which (1) in any way negates or dilutes the information on the label, especially the contraindications and/or warnings; (2) suggests or leans heavily on words, phrases, and portrayals that lead the lay person to assume that the product is to be used in any manner not recommended in the monograph established below, or that it cures when in reality it only alleviates symptoms; (3) promotes the misuse of the product; (4) advertises either to the lay public or the profession that a product or ingredient is completely tested and proven safe and effective when the Panel has found that insufficient evidence is available to establish general recognition (Category III).

L. General Statements on the Determination of Safety and Effectiveness for OTC Dental Products

The Panel evaluated the safety and effectiveness of OTC dental active ingredients as well as the proper dosage ranges for OTC drug use. In reviewing the scientific literature for these ingredients, the Panel evaluated the available data as to whether or not the ingredient was safe and effective. Among those agents determined to be safe and effective, the Panel did not attempt to determine the drugs of choice for any particular indication.

1. *Determination of safety.* In deciding on the safety of a drug or combination of drugs for the intended use, both animal and human studies were considered. The animal data usually related to levels of the drug that might cause death or cause other serious adverse effects on vital tissues, such as the bone marrow, liver, and kidneys. Also the drug might cause adverse effects on teeth or irritation of the oral mucosa. Animal studies are also helpful in establishing benefit-to-risk ratios for ingredients which are commonly used.

Major attention was paid to information related to adverse drug effects in humans, both adults and children. A knowledge of the toxicology of the drug or drugs under consideration both in animal studies and from human experience make it possible to look specifically for adverse effects in one or more organs or systems. For example, manufacturers of topical anesthetics were required to show that the ingredients used in their products were safe when such ingredients were used in effective concentrations.

It was desirable that there be studies in which the drug was evaluated in its final composition and compared to its vehicle control. However, there were times when the Panel was called upon to make judgments without benefit of controlled pharmacological studies, since they were not available for many ingredients.

2. *Determination of effectiveness.* In determining effectiveness for the intended use, it was necessary to consider each pharmacotherapeutic group separately although certain general principles apply to all groups.

In terms of effectiveness, animal studies were seldom very helpful since it is difficult to find animal models which closely mimic the course of oral diseases and conditions in humans.

Major attention was paid to clinical studies especially where the double-blind technique could be employed. The inclusion of a placebo as a comparison was considered desirable and comparison of the agent with a known standard was also considered useful.

Studies utilizing objective measurements, proper controls, and statistical analysis carried considerable weight in the Panel's decision to place an ingredient in Category I. Certain drug actions make such objective measurements extremely difficult or impossible and, therefore, large well-controlled subjective studies were considered adequate. Partially controlled and uncontrolled clinical studies were of very limited value, but both were considered by the Panel. Clinical experience of a general nature, if documented by qualified experts, added somewhat to the final decision.

The Panel believes that claims of superior effectiveness for one Category I active ingredient over another Category I active ingredient of the same pharmacotherapeutic group should only be permitted on the basis of proven superiority in two or more adequately conducted clinical trials on human subjects by independent investigators comparing the agents directly in the trials. Such claims should not be permitted on the basis of laboratory data.

Misleading superiority claims may also appear as claims that state or imply actions peculiar to a particular product, when in fact those claims are applicable to all OTC drug products or all Category I ingredients of the same pharmacotherapeutic group.

III. Agents for Oral Mucosal Injury

A. General Discussion

1. *General comments.* The Panel recognizes that there is a consumer population which has an occasional need for OTC preparations to treat minor gum disorders such as trauma or irritation of a transient nature. The Panel has classified such preparations as agents for Oral Mucosal Injury. These are agents which relieve oral mucosal injury, e.g., by cleansing or promoting the healing of oral wounds (minor oral irritations). These agents may aid in the formation of new tissue. Agents for relief of oral mucosal injury have been in the marketplace for many years but have not been previously classified as such. Thus, this classification is new and is presented to aid discussion. Without this designation the drugs in this group have been claimed to perform varied and extravagent functions. The creation of the classification has enabled the Panel to recommend specific labeling so that the drugs can stay on the OTC market and be properly used by the consumer. The Panel does

not make any recommendations for professional claims for these products.

Antiseptics and antimicrobials also may possibly aid healing, but the Panel has deferred consideration of these agents to the OTC Advisory Review Panel on Oral Cavity Drug Products. Agents for Oral Mucosal Injury (OMI) are pharmacotherapeutically different from other dental care agents which the Panel classified as Agents for Relief of Oral Discomfort in that OMI agents have no direct effect on oral discomfort, e.g., no anesthetic, analgesic, or protective effect. Agents for the Relief of Oral Discomfort will be discussed in a subsequent issue of the Federal Register.

Agents for oral mucosal injury are not intended for use in the treatment of acute or chronic gingival disorders, such as gingivitis and periodontal disease. The Panel concludes that these are conditions which cannot be self-diagnosed and which require professional treatment. These claims have, therefore, been placed in Category II.

2. *Classification.* Panel has further classified agents for oral mucosal injury into oral wound cleansers and oral wound healing agents.

a. *Oral wound cleansers.* These are nonirritating preparations which assist (physically or chemically) in the removal of foreign material from small superficial oral wounds and do not delay wound healing.

Oral wound cleansers are widely used by the lay public and may be recommended by the dental and medical professions for cleansing of wounds caused by trauma, minor dental procedures, and other irritations of the oral soft tissues. Such agents generally contain oxygen-releasing compounds, such as hydrogen peroxide, or other substances which release hydrogen peroxide during use. Upon contact with tissue or salivary catalase and peroxidase, hydrogen peroxide decomposes to form water and oxygen, with resultant foaming action due to release of the oxygen gas. Oral wound cleansing action appears to be a result of this foaming activity, which physically removes debris from the wound. Evidence of effectiveness is based largely on clinical impressions.

b. *Oral wound healing agents.* These are nonirritating agents which aid in the healing of small superficial oral wounds by means other than cleansing and irrigating, or by serving as a protectant.

The general features of wound healing have been known and recognized for centuries, but the exact mechanisms involved are still poorly understood (Refs. 1 and 2). Complications of wound healing following surgery have been markedly reduced, primarily because of control of sepsis, improvements in surgical techniques, and better understanding of nutrition.

Factors involved in wound healing can be divided into two general categories: systemic and local. Systemic factors include (1) physiologic condition of the host, (2) nutrition, and (3) hormones. The local factors include (1) blood and oxygen supply, (2) presence of infection, (3) presence of foreign material, (4) mobility of tissue, (5) amount of tissue destruction, and (6) type of tissue in which injury has occurred (Ref. 3).

The process of wound healing is arbitrarily divided into three overlapping stages: (1) Inflammatory, (2) proliferative, and (3) reorganization or remodeling (Refs. 4 and 5). Many attempts have been made to find substances which would accelerate or modify these stages but none has been generally accepted. However, it is generally considered more important to avoid complications and retardation of wound healing than it is to accelerate the normal, uncomplicated rate of repair (Ref. 6). If, however, promotion of wound healing is claimed for an ingredient, it should have an effect on one or more of the three stages mentioned above.

The inflammatory response stage is ordinarily a necessary prerequisite to wound healing; to shorten this stage would only be beneficial to specific tissues, such as joint articulations where pain and swelling increase as the inflammatory process continues. The value of altering the inflammatory response of oral mucosal injury has not been established.

To modify the proliferative stage by growth stimulation is a highly complex process. While many substances inhibit cell growth without requiring tissue specificity, growth promoters ordinarily have high tissue specificity and require a multitude of co-factors (Refs. 7 and 8). To imply that a substance is a growth promoter when applied to tissues in general is misleading and without a sound and scientific basis.

The stage of reorganization or remodeling depends primarily on the synthesis and metabolism of collagen. Collagen is the main constituent of scar tissue which is the end result of most healing processes in higher vertebrates. This means that tissue repair following injury depends largely on the proper timing, rate of synthesis, and breakdown of collagen molecules, as well as their chemical and structural characteristics (Refs. 9, 10, and 11). Modifying the factors involved in this stage of healing appears to be somewhat realistic and promising (Ref. 12).

In summary, it is expected that an agent which causes promotion of oral wound healing with increase the rate of normal collagen synthesis, producing more rapid clinical improvement.

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B. Categorization of Data

1. *Category I conditions under which agents for oral mucosal injury are generally recognized as safe and effective and are not misbranded.* The Panel recommends that the Category I conditions be effective 30 days after the date of publication of the final monograph in the Federal Register.

Category I. Active Ingredients.

The Panel has classified the following agents for oral mucosal injury as active ingredients generally recognized as safe and effective and not misbranded:

Carbamide peroxide in anhydrous glycerin (as an oral wound cleanser)

Hyrogen peroxide in aqueous solution (as an oral wound cleanser)

a. *Carbamide peroxide in anhydrous glycerin.* The Panel concludes that carbamide peroxide in anhydrous glycerin is safe and effective as an oral

wound cleanser for OTC use as specified in the dosage section discussed below.

Carbamide peroxide is unstable in aqueous solution but stable when dissolved in anhydrous glycerin (Ref. 1). Anhydrous glycerin can be prepared by heating Glycerin U.S.P. at 150° C for 2 hours (Ref. 1). Carbamide peroxide in anhydrous glycerin provides a means of delivering hydrogen peroxide to the wound site. On contact with water or saliva in the mouth, carbamide peroxide readily decomposes to form approximately 70 percent urea and approximately 30 percent hydrogen peroxide. In the presence of tissue and salivary catalase and peroxidase, the hydrogen peroxide then breaks down to form water and oxygen.

(1) *Safety.* Clinical use and marketing experience have confirmed that 10 percent carbamide peroxide in anhydrous glycerin is safe for OTC use.

A concentration of 10 percent carbamide peroxide yields approximately 3 percent hydrogen peroxide; this concentration of hydrogen peroxide is within the range the panel considers safe. Glycerin, in the concentration used, and urea, in the concentration generated, are both considered safe (Refs. 2 and 3). In humans, black hairy tongue has been considered by some to be attributable to short term use of carbamide peroxide, but this view is based on a single case report (Ref. 4).

(2) *Effectiveness.* The Panel concludes that 10 percent carbamide peroxide in anhydrous glycerin is effective as an oral wound cleanser.

The principle advantage of carbamide peroxide is that it can be used as a convenient source of hydrogen peroxide. The glycerin reportedly prolongs the release of oxygen from the hydrogen peroxide (Ref. 5), but evidence for prolonged release contributing to effectiveness is not convincing (Refs. 6 through 9).

The Panel, therefore, concludes that 10 percent carbamide peroxide in glycerin is equivalent to approximately 3 percent hydrogen peroxide in effectiveness as an oral wound cleanser. (See part III. paragraph B.1.b.(2) below—Effectiveness.)

(3) *Dosage—Adults and children 2 years of age and older.* Carbamide peroxide 10 percent in anhydrous glycerin.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing oral mucosal injury active ingredients. (See part III. paragraph B.1. below—Category I Labeling.)

(5) *Directions.* Apply several drops directly to the affected area of the mouth. Allow the medication to remain in place at least 1 minute and then spit out. Use up to four times daily (after meals and at bedtime) or as directed by a dentist or physican. Children under 12 years of age should be supervised in the use of this product. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a dentist or physician.

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b. *Hydrogen peroxide in aqueous solution.* The Panel concludes that hydrogen peroxide in aqueous solution is safe and effective as an oral would cleaner for OTC use as specified in the dosage section discussed below.

(1) *Safety.* Clinal use and marketing experience have confirmed that 1.5 to 3 percent hydrogen peroxide in aqueous solution is safe for OTC use.

Aqueous solutions up to 3 percent of hydrogen peroxide are considered safe for temporary use. This conclusion is supported by animal studies and by extensive human use upon recommendation of the medical and dental professions.

The results of very frequent or prolonged application in animals are conflicting but suggest that irritation may occur (Refs. 1 through 4). Repeated human usage of high concentrations (6 to 30 percent aqueous solution) for a month or more has resulted in gingival pathology and may also cause black hairy tongue (Refs. 4 through 7). Although prolonged use of 3 percent hydrogen peroxide in aqueous solution may produce irritation, the Panel concludes that is safe for OTC use with the recommended labeling discussed below.

(2) *Effectiveness.* The Panel concludes that 1.5 to 3.0 percent hydrogen peroxide in aqueous solution is effective as an oral wound cleanser.

The removal of debris from the wound by the use of hydrogen peroxide is generally recognized by many dental and medical practitioners. A mechanical cleansing effect results from the foaming action of the oxygen bubbles released upon contact with tissue and salivary catalase and peroxidase (Refs. 8, 9, and 10).

There is little experimental evidence to support that the foaming action of the hydrogen peroxide has a beneficial therapeutic effect in terms of faster wound healing.

Consideration of the antiseptic properties of hydrogen peroxide was deferred to the OTC Advisory Review Panel on Oral Cavity Drug Products.

(3) *Dosage—Adults and children 2 years of age and older.* Hydrogen peroxide 3 percent in aqueous solution.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing oral mucosal injury active ingredients. (See part III, paragraph B.1, below—Category I Labeling.)

(5) *Directions*—(i) *For direct application.* Apply several drops of full strength (3 percent) solution to the affected area of the mouth. Allow the medication to remain in place at least 1 minute and then spit out.

(ii) *For use as an oral rinse.* Mix the full strength (3 percent) solution with an equal amount of warm water. Swish around in the mouth over the affected area for at least 1 minute and then spit out.

(iii) *For direct application and for use as an oral rinse.* Use up to four times daily (after meals and at bedtime) or as directed by a dentist or physician. Children under 12 years of age should be supervised in the use of this product. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a dentist or physician.

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Category I. Labeling

The Panel recommends the following Category I labeling for oral mucosal injury active ingredients to be generally recognized as safe and effective and not misbranded:

a. *Indications*—(1) *For oral wound cleanser drug products.*

(i) "For temporary use in the cleansing of wounds caused by minor oral irritation or injury such as that following minor dental procedures, or from dentures or orthodontic appliances."

(ii) "For temporary use in the cleansing of gum irritation due to erupting teeth (teething)."

(2) *For oral wound healing agent drug products.* The Panel has found no Category I labeling indications acceptable at this time and recommends the Category III labeling claim below. (See part III. paragraph B.3. below-Category III Labeling.)

b. *Warnings—For both oral wound cleanser and oral wound healing agent drug products.* (1) "Not to be used for a period exceeding 7 days."

The reason for limiting use to 7 days is that a lack of improvement of an apparent oral mucosal injury may indicate the presence of a serious disease, e.g., cancer or periodontal disease. Continued use of the product may delay diagnosis and treatment of such conditions. The Panel is of the opinion that the available scientific evidence indicates that there are no indications which warrant the use of any oral mucosal injury drug product beyond 7 days except under the advice of a dentist or physician.

(2) "Discontinue use and see your dentist or physician promptly if irritation persists, inflammation develops, or if fever and infection develop."

2. *Category II conditions under which agents for oral mucosal injury are not generally recognized as safe and effective or are misbranded.* The Panel recommends that the Category II conditions be eliminated from OTC oral mucosal injury drug products effective 6 months after the date of publication of the final monograph in the Federal Register.

The use of agents for oral mucosal injury under Category II conditions is unsupported by scientific data and, in some instances, by sound theoretical reasoning. The Panel concludes that the Category II active ingredient, dosage form, and labeling should be removed from the market until scientific testing supports their use.

Category II. Active Ingredient

The Panel has classified the following active ingredient for oral mucosal injury as not generally recognized as safe and effective or as misbranded:

Sodium perborate monohydrate (as a wound cleanser)

a. *Sodium perborate monohydrate.* The Panel concludes that sodium perborate monohydrate as a source of hydrogen peroxide is not justified for OTC use as an oral wound cleanser based on an unfavorable risk-to-benefit ratio.

Sodium perborate monohydrate ($NaBO_3H_2O$) (a synonym for sodium peroxyborate (NaBO2H202) monohydrate) releases hydrogen peroxide when dissolved in water. While the Panel concludes that aqueous hydrogen peroxide 1.5 to 3.0 percent is safe and effective as an oral wound cleanser, the Panel is aware that the concentrations of sodium perborate monohydrate that would be effective for OTC use as an oral wound cleanser are not safe. The amount of boron contained in one unit-of-use (1.2 g) package for preparation of a single oral rinse exceeds the maximum safe daily amount of boron for ingestion; the resulting solution releases a concentration of hydrogen peroxide less than the Panel's minimal effective concentrations. Furthermore, safety in regard to lack of tissue irritation by solutions of sodium perborate monohydrate remains to be established.

(1) *Safety.* Gleason et al. (Ref. 1) state that the toxicological aspects of the sodium perborates cannot be distinguished from those of sodium borate and boric acid, the toxicity of which has been thoroughly studied (Refs. 2 through 26). The Panel concludes that the maximum safe dosage of boron for adult humans is 0.09 g daily (Refs. 1 through 16, and 21).

On a chemical basis, boron (atomic weight 10.8) is approximately 10.8 percent of the sodium perborate monohydrate molecule (molecular weight 99.8). A single unit-of-use package of a buffered sodium perborate monohydrate oral rinse reviewed by the Panel contains approximately 1.2 g sodium perborate monohydrate (boron content of approximately 0.13 g) to be dissolved in 30 ml (1 oz) of water just prior to use as an oral rinse (Ref. 27). Oral wound cleansers containing peroxide are generally used up to four times daily; four such 30 ml rinses contain 0.52 g of boron, and if that amount were inadvertently totally ingested, the consumer would receive nearly six times the amount safe for daily ingestion.

In a recent study, one of the subjects who followed the manufacturer's directions for use of four daily rinses failed to expectorate (and therefore was presumed to have swallowed) 60 mg boron (two-thirds the maximum safe daily amount). However, the above rinse (containing approximately 3.3 percent sodium perborate, equivalent to approximately 4 percent sodium perborate monohydrate) yields a hydrogen peroxide concentration concluded by the Panel to be subtherapeutic (see below).

Although the sodium perborate monohydrate oral rinse reviewed by the Panel is buffered by sodium bitartrate, it is still quite alkaline, approximately pH 9 (Ref. 27). The potential irritancy of this formulation to the oral mucosa has not been adequately determined for the concentrations which are currently recommended by the manufacturer (equivalent to 4 percent sodium perborate monohydrate). In early studies designed to evaluate effectiveness, oral mucosal irritation was noted within 2 to 7 days when concentrations of approximately twice the manufacturer's presently recommended concentrations were used three to five times daily. While no irritation was noted in later studies conducted over a longer period of time, the concentration employed in these later studies was only one-half that presently recommended by the manufacturer.

(2) *Effectiveness.* When dissolved in water, 34 percent of the sodium perborate monohydrate molecule becomes available as hydrogen peroxide. If 1.2 g sodium perborate monohydrate is dissolved in approximately 30 mL (1 oz) of water as presently recommended (Ref. 27), a concentration of 1.3 percent hydrogen

peroxide is obtained. This concentration of hydrogen peroxide is below the 1.5 percent minimum which the Panel considers to be effective as an oral wound cleanser. (See part III. paragraph B.1.b.2. above—Effectiveness.)

(3) *Evaluation.* An oral rinse containing approximately 4.0 percent sodium perborate (obtained by dissolving 1.2 g sodium perborate monohydrate and a buffer in 30 mL water) yields a concentration of 1.3 percent hydrogen peroxide, which is less than the Panel's minimum concentration (1.5 percent) for hydrogen peroxide as an effective oral wound cleanser. If four such 30 mL rinses were inadvertently totally ingested in a day, the amount of boron ingested would be nearly six times the amount concluded by the Panel to be safe for daily ingestion. If the concentration of sodium perborate monohydrate were increased to yield a therapeutic concentration of hydrogen peroxide when the salt is dissolved in water, the risk of boron toxicity would also be increased. The Panel, therefore, concludes that the risk of boron toxicity that may be incurred by use of concentrations of sodium perborate monohydrate sufficient to yield therapeutic concentrations of hydrogen peroxide is unjustified by benefit, if any, from use of the salt as a source of hydrogen peroxide. Furthermore, safety from irritancy of oral mucosa has not been established.

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Category II. Dosage Form

The Panel has reviewed several dentifrice formulations containing ingredients which have been classified as agents for oral mucosal injury. A dentifrice is intended to be used on a toothbrush. The Panel concludes that use of a dentifrice dosage form is irrational in the treatment of oral wounds because additional trauma may result from the toothbrushing. In addition, a dentifrice usually contains an abrasive, and abrasivity of the dentifrice may also interfere with healing. This effect, however, is not as harmful as the harmful effect of the toothbrushing itself on the wound.

The Panel also notes that some dentifrices have been marketed for the treatment of gingivitis. The Panel has placed all claims stating or implying prevention, control, or treatment of gingivitis in Category II. Therefore, any dentifrice, whether promoted as an agent for oral mucosal injury or gingivitis, is Category II.

Category II. Labeling

The Panel concludes that the use of certain labeling claims related to the safety and/or effectiveness of a product are unsupported by scientific data and, in some instances, by sound theoretical reasoning. The Panel concludes that such labeling should be removed from the market.

The Panel concludes that drug products which have antiplaque, plaque control, or gingivitis claims are not currently appropriate for the OTC market because there is no general recognition of any such drug products as safe and effective for these indications at this time. Accordingly, the Panel recommends that such drug products and claims should be evaluated by FDA through the NDA procedure.

a. *Oral wound cleansers.* The Panel concludes that the following indications should not be cited for the use of oral wound cleansers because the terms are vague to the consumer; the conditions described cannot be self-diagnosed; they are serious; and self-treatment of these conditions may delay diagnosis: "aphthous ulcers," "canker sores," "periodontal disease," and "pyorrhea."

The Panel also concludes that pain relief is not a direct benefit obtained from an oral wound cleanser and, therefore, is not an acceptable indication or claim. Some examples of such labeling follow: "relieves pain * * *," "temporary relief of minor congestion and associated pain of surface inflammation," "temporary relief of distress," and "apply before a meal for pain relief."

The Panel further concludes that prevention of inflammation is not a direct benefit of oral wound cleansing and, therefore, should not be stated as either an indication or as a claim. Some examples of such labeling follow: "prophylaxis of oral inflammation" and "prevention of minor inflammation."

Since oral wound cleansers should not be used for more than 7 days without professional supervision, their use as "an aid to regular oral hygiene" is not an acceptable indication.

Additionally, the Panel believes that the direction to "massage the medication on affected area" is inappropriate since there is no evidence that massage of damaged tissue is beneficial.

The Panel concludes that in addition to the labeling citing above the following statements are not acceptable:

(1) "Not known to be irritating or sensitizing" because it implies that such reactions will never occur.

(2) "Promotes firmer and healthier gums" because therapeutic benefit has not been demonstrated and the term implies long-term OTC use beyond 7 days.

(3) "Cleanser * * * with a * * * microfoam" because the term is vague and may be misleading.

b. *Oral wound healing agents.* The Panel concludes that oral wound healing agents do not contribute directly to the relief of soreness, pain, or discomfort and that these latter terms are, therefore, not acceptable indications. In addition, the Panel believes that statements such as "clinically tested" or "hospital tested" may cause the consumer to assume that effectiveness has been established unequivocally and that other Category I ingredients are not "clinically tested." Such statements, therefore, are misleading. The phrase "assists nature" is considered ambiguous, would be difficult to prove, and is not acceptable.

c. *Oral wound cleansers and wound healing agents.* The Panel concludes that the term "gum inflammation" describes a manifestation of gingivitis or may indicate the presence of periodontal disease. These are serious conditions which require the treatment and supervision of a dentist or physician as soon as possible since these conditions cannot be self-diagnosed by the consumer.

The term "oral discomfort" is also classified as Category II when associated with oral mucosal injury agents. These agents may only indirectly provide relief of discomfort and are intended to act directly either as a cleanser or wound healing agent. Agents for relief of oral discomfort, to be discussed in a later issue of the Federal Register, include such direct action agents as local anesthetics.

3. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of Category III conditions to Category I.

The Panel concludes that adequate and reliable scientific evidence is not available at this time to permit final classification of the ingredients and conditions listed below. Marketing need not cease during this time if adequate testing is undertaken. If adequate effectiveness data are not obtained within 2 years, however, the ingredients and conditions listed in this category should no longer be marketed in OTC products. The Panel recognizes that these products have been available for a number of years without reports of serious side effects. Therefore, safety testing guidelines need not conform to those necessary for new drugs as noted elsewhere in this document. However, since oral wound healing agents are not products generally recognized as existing in the OTC marketplace, the Panel concludes that testing must provide safety and effectiveness when applicable.

Category III. Active Ingredients

The Panel concludes that the available data are insufficient to permit final classification of the following active ingredients for oral mucosal injury:

Allantoin (as a wound healing agent)
Carbamide peroxide in anhydrous glycerin (as a wound healing agent)
Chlorophyllins, water-soluble (as a wound healing agent)
Hydrogen peroxide in aqueous solution (as a wound healing agent)

a. *Allantoin.* The Panel concludes that allantoin is safe but that there are insufficient data available to permit final classification of its effectiveness for OTC use as an oral wound healing agent as specified in the proposed dosage section discussed below.

(1) *Safety.* Clinical use and marketing experience have confirmed that 2 percent allantoin is safe for OTC use.

Allantoin is a drug which has been used as a growth stimulant since 1912 (Refs. 1 and 2). A review published in 1946 (Ref. 3) indicated that allantoin had been marketed in concentrations of 0.4 to 2 percent, often in combination with chemotherapeutic agents and/or other medications. Such preparations were usually in ointment, solution, or powder form and were intended primarily for topical application to the skin and mucous membranes. The indications were mainly the healing of suppurating wounds, burns, abscesses, and ulcers, as well as a wide variety of skin conditions. Adverse reports have not been found in the literature and an evaluation published in 1972 stated that no skin reactions had been reported (Ref. 4). One report indicated that allantoin in solution was painless when applied to wounds (Ref. 5). When large doses have been administered orally, intramuscularly, or intravenously to experimental animals and man, a leucocytosis response has been reported to occur (Refs. 6 and 7).

The Panel has designated allantoin in concentrations of up to 2 percent as safe for topical application to oral mucous membranes because of its long history of topical use without apparent toxicity or other undesirable effects.

(2) *Effectiveness.* The literature indicates that allantoin was most widely used as a growth stimulant in the period of 1930 to 1950 (Refs. 3, 5, and 7 through 18). Unfortunately, in the majority of these reports, effectiveness was based on clinical impression in which modern double-blind controlled, experimental design was not employed. There have been a few more recent studies, but these also lack well-designed protocols to document effectiveness (Refs. 19 through 22). Because the evidence in the literature is insufficient to demonstrate effectiveness, the Panel concludes that more data are needed to prove that allantoin promotes healing, and contributes significantly to healing when incorporated into a combination with other agents.

(3) *Proposed dosage. Adults and children 2 years of age and older.* Allantoin 0.4 to 2.0 percent.

(4) *Labeling.* The Panel recommends the Category III labeling specified below. (See part III. paragraph B.3. below—Category III Labeling.)

(5) *Directions.* Apply directly to affected area. Use up to four times daily after meals and at bedtime or as directed by a dentist or physician. Children under 12 years of age should be supervised in the use of this product. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a dentist or physician.

(6) *Evaluation.* Data to demonstrate effectiveness as an oral wound healing agent will be required in accordance with the guidelines set forth below. (See part III. paragraph C. below—Data Required for Evaluation.)

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b. *Carbamide peroxide in anhydrous glycerin.* The Panel concludes that carbamide peroxide in anhydrous glycerin is safe but that there are insufficient data available to permit final classification of its effectiveness for OTC use as an oral wound healing agent as specified in the proposed dosage section discussed below.

(1) *Safety.* Clinical use and marketing experience have confirmed that 10 percent carbamide peroxide in anhydrous glycerin is safe for OTC use. The safety of the ingredient is discussed earlier in this document. (See part III. paragraph B.1.a.(1) above—Safety.)

(2) *Effectiveness.* When peroxides are brought into contact with the abundant catalases and peroxidases of the oral environment, the release of oxygen from peroxide is rapid and of fleeting duration. Moreover, the quantity of oxygen released by therapeutically safe concentrations is small. Ten percent carbamide peroxide yields approximately 3.0 percent hydrogen peroxide which further yields approximately 1.4 percent oxygen. Whether such relatively low transient, concentrations of oxygen increase tissue pO_2 (oxygen partial pressure, i.e., oxygen tension) to promote wound healing has not been adequately determined.

While in vitro microrespirometry, visual inspection, and subjective histological evaluations have suggested that topically applied peroxides may aid wound healing by increasing the oxygen consumption of tissues (Refs. 1 through 6), these methodologies are either obsolete or too subjective to be reliable. Microelectric methods are now used to determine the role of various oxygen concentrations in tissue metabolism (Refs. 7 and 8). These methods, which permit direct measurement of oxygen tension in the liquid phase, are more sensitive and accurate than microrespirometry for a variety of reasons reviewed by Clark and Sachs (Ref. 9). Moreover, ultramicroelectrodes can be used in vivo; such studies have documented that a pO_2 gradient occurs between a wound and an adjacent capillary (Ref. 10). Further refinements for studying the role of oxygen in wound healing in vivo have included radiometric monitoring of pO_2 in surgically created wound dead-spaces (Refs. 10 and 11) as well as in silastic tubing tonometers (Ref. 12). Such tudies have shown that protein synthesis, including the synthesis of connective tissue and collagen, increases in "hyperoxic" conditions (40 to 70 percent oxygen as compared with the 20 percent oxygen present in air); bone repair decreases in such concentrations and increases only in "hypoxic" conditions of about 14 percent oxygen (Refs. 13 through 18). Similar studies are needed to determine whether the concentration of oxygen obtained from 10 10 percent carbamide peroxide significantly increases tissue pO_2 and whether such an increase correlates with accelerated connective tissue and collagen synthesis. The tissue pO_2 determination must be done by the use of modern technology rather than by microrespirometry.

(3) *Proposed dosage—Adults and children 2 years of age and older.* Carbamide peroxide 10 percent in anhydrous glycerin.

(4) *Labeling.* The Panel recommends the Category III labeling specified below. (See part III. paragraph B.3. below—Category III Labeling.)

(5) *Directions.* Apply directly to affected area. Use up to four times daily after meals and at bedtime or as directed by a dentist or physician. Children under 12 years of age should be supervised in the use of this product. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a dentist or physician.

(6) *Evaluation.* Data to demonstrate effectiveness as an oral wound healing agent will be required in accordance with the guidelines set forth below. (See part III. paragraph C. below—Data Required for Evaluation.)

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c. *Chlorophyllins, water-soluble.* The Panel concludes that chlorophyllins, water-soluble, are safe but that there are insufficient data available to permit final classification of effectiveness for OTC use as an oral wound healing agent as specified in the proposed dosage section discussed below.

Chlorophyllins, water-soluble, are also known as potassium-sodium-copper chlorophyllin and water-soluble derivatives of chlorophyll.

(1) *Safety.* Potassium-sodium-copper chlorophyllin is a water-soluble, saponified, metal complex derivative of chlorophyll "a". The Panel concludes that this compound is safe based on reports that 100 to 200 mg daily have been ingested by sizable groups of people for 3 months to 1 year with no deleterious effects (Refs. 1, 2, and 3). A small group of patients given 500 mL of a 0.5 percent solution daily, intravenously, for 8 days in cases of subacute bacterial endocarditis developed no toxic symptoms (Ref. 1). Furthermore, topical application for treatment of leg ulcers (Ref. 4) and for wound healing after a variety of surgical procedures (Ref. 5) has caused no apparent skin irritation. Similarly, oral use of this compound has not produced undesirable side effects (Refs. 6 through 10). Finally, no toxicity was found in rats fed potassium-sodium-copper chlorophyllin for 2 years (Ref. 9).

(2) *Effectiveness.* While the mechanisms whereby water-soluble chlorophyllin produces its effect have not been defined, the medical literature contains numerous accounts of wounds and ulcerations that did not respond to other attempts to induce healing, but that did heal with chlorophyllins therapy. These accounts are anecdotal, however, and must be substantiated in adequate well-controlled studies.

Some investigators have demonstrated that water-soluble chlorophyllin stimulates the growth of fibroblasts in in vitro tissue culture (Ref. 11) and that chlorophyllin exerts a bacteriostatic effect on organisms found on oral mucosa and produces a decrease in the acid production of saliva (Ref. 12). In vivo studies include the investigation of wound healing in animals (Ref. 1) and the measurement of the decline of electrical potential during the healing process (Ref. 13). The latter procedure has been employed as an index to the rate of healing in experimental abrasions of humans.

(3) *Proposed dosage—Adults and children 2 years of age and older*—(i) *Solution:* Chlorophyllins, water-soluble, 0.2 percent in a buffered saline solution (pH 7.3 to 8.5).

(ii) *Ointment:* Chlorophyllins, water-soluble, 0.5 percent in a suitable base.

(4) *Labeling.* The Panel recommends the Category III labeling specified below. (See part III. paragraph B.3. below—Category III Labeling.)

(5) *Directions.* Apply directly to affected area. Use up to four times daily after meals and at bedtime or as directed by a dentist or physician. Children under 12 years of age should be supervised in the use of this product. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a dentist or physician.

(6) *Evaluation.* Data to demonstrate effectiveness as an oral wound healing agent will be required in accordance with the guidelines set forth below. (See part III. paragraph C. below—Data Required for Evaluation.)

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d. *Hydrogen peroxide in aqueous solution.* The Panel concludes hydrogen peroxide in aqueous solution is safe but that there are insufficient date available to permit final classification of its effectiveness for OTC use as an oral wound healing agent as specified in the proposed dosage section discussed below.

(1) *Safety.* Clincal use and marketing experience have confirmed that 1.5 to 3.0 percent hydrogen peroxide in aqueous solution is safe for OTC use. The safety of the ingredient is discussed

earlier in this document. (See part III. paragraph B.1.b.(1) above—Safety.)

(2) *Effectiveness.* The effectiveness of hydrogen peroxide as an oral wound healing agent is related to the effectiveness of peroxide as discussed under carbamide peroxide in anhydrous glycerin. (See part III. paragraph B.3.b.(2) above—Effectiveness.) There is insufficient evidence to establish effectiveness for this claim.

(3) *Proposed dosage—Adults and children 2 years of age and older.* Hydrogen peroxide 3 percent in aqueous solution.

(4) *Labeling.* The Panel recommends the Category III labeling specified below. (See part III. paragraph B.3. below—Category III Labeling.)

(5) *Directions*—(i) *For direct application.* Apply several drops of full strength (3 percent) solution to the affected area. Allow the medication to remain in place at least 1 minute and then spit out.

(ii) *For use as an oral rinse.* Mix the full strength (3 percent) solution with an equal amount of warm water. Swish around in the mouth over the affected area for at least 1 minute and then spit out.

(iii) *For direct application and for use as an oral rinse.* Use up to four times daily after meals and at bedtime or as directed by a dentist or physician. Children under 12 years of age should be supervised in the use of this product. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a dentist or physician.

(6) *Evaluation.* Data to demonstrate effectiveness a an oral wound healing agent will be required in accordance with the guidelines set forth below. (See part III. paragraph C. below—Data Required for Evaluation.)

Category III. Labeling

The Panel concludes that the following labeling claims for oral wound cleansers or oral wound healing agents are presently unsupported by sufficient scientific data to permit classification in Category I. Additional data are required as indicated elsewhere in this document. (See part III. paragraph C. below—Data Required for Evaluation.)

a. *Oral wound cleansers.* The claim of "Longer oxygen action" (Ref. 1) must be established by quantitative chemical analysis. Visual estimations of intensity and height of frothing (Refs. 1 through 4) are too imprecise to be acceptable.

b. *Oral wound healing agents.* "For temporary use to aid healing of minor oral soft tissue wound due to injury."

Labeling should not use the term "oxygenating" or otherwise imply that peroxides aid wound healing by increasing tissue oxygen consumption unless a substantial increase in tissue pO_2 (oxygen partial pressure, i.e., oxygen tension) can be demonstrated by modern methodology. If a significant increase in oxygen uptake cannot be demonstrated when safe concentrations of peroxides are applied, the therapeutic benefit of peroxides may be attributed only to the mechanical removal of necrotic tissue and oral debris, as discussed under oral wound cleansers.

References

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C. Data Required for Evaluation

The Panel has agreed that the guidelines recommended in this document for the studies required to bring a Category III drug into Category I are in keeping with the present state of the art and do not preclude the use of any advances or improved methodology in the future.

1. *General principles in the design of an experimental protocol for testing oral mucosal injury ingredients.* The effectiveness of an oral mucosal injury ingredient is dependent on its ability to act as an oral wound cleanser or as an oral wound healing agent. In order to move from Category III to Category I, the appropriate set of testing procedures identified below must be performed and found to be statistically significant in safety and effectiveness.

a. *Oral wound healing agents.* Wound healing is not an isolated, single phenomenon, but a series of complex biologic events. It involves such processes as platelet aggregation and blood clotting; an inflammatory response; alterations in the ground substance; endothelial and capillary proliferation; fibroblastic proliferation and collegen production; epithelial proliferation and surface covering (Ref. 1).

Several animal models have been employed to study wound healing. These include (1) wounds of incision of excision; (2) wound creating artificial dead spaces, e.g., polyvinyl sponges, stainless steel wire mesh cylinders; (3) wounds resulting from insertion or injection of agents causing a sterile inflammatory response, e.g., carageenin or turpentine; (4) burn wounds; and (5) wounds caused by ionizing radiation and light, e.g., X-rays, ultraviolet, or laser (Ref. 1)

Healing is not complete until the disrupted surfaces are firmly bound by scar tissue (which is the end result of most healing processes), and there is a complete surface covering implying return of function. Therefore, any measure of the rate of wound healing is a measure of the rate of epithelialization and of collagen synthesis.

The following tests are suitable for testing of oral wound healing agents. The Panel recommends that at least one skin model and one oral mucosal model be used to test the ingredient.

(1) *Skin models*—(i) *Measurement of the rate of wound closure and epithelialization.* A suggested model to study the rate of epithelialization using an excision wound is based upon the model described by Lorenzetti, Fortenberry, and Busby (Ref. 2). Excision wounds are made in a test animal with a sharp scalpel under surgically clean conditions. The area and the depth of the wound are to be kept constant using a template and confirming the excision by measurement as one proceeds with the surgery. When bleeding is under control, the wound margins are traced onto Blenderm™ tape (3M Company, Minneapolis, Minnesota) for a measurement. At this point, the test material is applied to the wound and covered with an appropriate bandage for protection; similar excised untreated wounds will serve as controls.

Wounds should be examined under blind conditions every 2 to 4 days. Measurement of the size of the wound is made by placing Blenderm tape over the wound and tracing the advancing edges of new epidermal growth with a marking pencil. The tape is then transferred to a paper where the area is traced and appropriate measurements can be made. The percent closure of the wounds from the initial wound areas is to be recorded. To compare the different test treatments, analyses of variances should be done to determine differences between tests on the same animal and differences between animals, as well as differences between dressings on different days, especially if different observers were used. For individual analysis on any one day, a *t* test can be used.

(ii) *Wound collagen formation and maturation.* Collagen metabolism is intimately associated with tissue regeneration and remodeling. The synthesis of new collagen may be

normal or defective; if defective, it will lead to incomplete healing of wounds or to excessive scar formation, both of which depend largely upon the nature of the collagen fibers as determined by the biosynthesis and maturation of the collagen molecule.

The synthesis and maturation of collagen is a complex phenomenon. There are a number of modifications of the molecule which occur after the constituent amino acids have been incorporated into peptide linkages. One modification is the hydroxylation of proline and lysine; another is the glycosylation of hydroxyglysine with galactose and the subsequent glycosylation of some of the galactosylhydroxylysine residues with glucose. Finally, the introduction of covalent cross-links, both intra- and intermolecularly, is the last step which the collagen molecule undergoes before becoming structual connective tissue.

A measure of this complex phenomenon from synthesis of collagen to its complete maturation in tissues is performed by (1) determining salt-soluble collagen, as a measure of newly synthesized collagen, (2) weak organic acid-soluble collagen, as a measure of collagen in transition from newly synthesized to completely mature collagen, and (3) insoluble collagen, as a measure of completely matured and cross-linked collagen.

Using the model system described from the determination of wound closure and epithelialization, the rate and maturation of collagen can be determined. Wounds treated with test materials can be analyzed for the progress of collagen maturation following wounding procedures.

Collagen and the state of the collagen molecule after wounding can be determined chemically by the method of Prockop and Udenfriend (Ref. 3), radiochemically by the method of Aleo, Novak, and Levy (Ref. 4), or the method of Diegelmann, Rothkopf, and Cohen (Ref. 5). The final data should represent (1) absolute and relative collagen synthesis, (2) relative rate of collagen synthesis, and (3) the extent of proline hydroxylation in treated and untreated wound tissue.

(2) *Animal oral mucosal models (oral cavity of dogs)*—(i) *Punch biopsy model.* Two independent investigators should separately test oral wound healing agents on sufficient numbers of beagle dogs to obtain a statistically significant result. It is suggested that at least ten young, healthy dogs of either sex be studied by each investigator using a crossover design for study of active medication in vehicle compared to vehicle without medication.

Dogs are randomly assigned, half to the active group and half to the placebo. Under local anesthesia, a 5 mm punch biopsy lesion is made in a standard area of oral mucosa on one side (the bicuspid area avoiding the line where the teeth incise would be suitable). After hemorrhage is stopped, the dog is returned to its cage and medication or placebo (randomly numbered with a three digit number according to assignment) is applied after 6 hours and subsequently 3 to 4 times daily at 4 to 6 hour intervals for 7 days. A rinse with warm water is used before each treatment.

The dog is examined daily for measurement of lesion size by a plastic lesion matrix. After 6 weeks the dog receives a second wound on the other side of its mouth in the same area and the paired medication treatment is used.

Mean lesion size for each treatment is calculated and statistically analyzed. The active medication should be statistically better than the placebo and should demonstrate an effect in the first 7 days.

(ii) *Other methods.* Industry and FDA are encouraged to develop other models to measure wound healing effectiveness. The Panel suggests that mucosal abrasion models currently used by FDA to test oral mucosal irritation may be adapted to measure wound healing effectiveness.

References

(1) Schilling, J. A., "Wound Healing," *Physiological Reviews*, 48:374–423, 1968.

(2) Lorenzetti, O. J., B. Fortenberry, and E. Busby, "Influence of Microcrystalline Collagen in Wound Healing II; Comparison of Several Collagen Dressings on Excised Wounds of Pigs and Rabbits," *Research Communications in Chemical Pathology and Pharmacology*, 5:431–439, 1973.

(3) Prockop, D. J., and S. Udenfriend, "A Specific Method for the Analysis of Hydroxyproline in Tissues and Urine," *Annals of Biochemistry*, 1:228–239, 1960.

(4) Aleo, J. J., R. Novak, and E. Levy, "Collagen Synthesis by Lathyrogen-Treated 3T6 Fibroblasts," *Connective Tissue Research*, 2:91–93, 1974.

(5) Diegelmann, R. F., L. C. Rothkopf, and I. K. Cohen, "Measurement of Collagen Biosynthesis During Wound Healing," *Journal of Surgical Research*, 19:239–243, 1975.

b. *Oral wound cleansers.* The Panel concurs with the testing procedures for skin wound cleansers stated in the tentative final monograph on OTC Topical Antimicrobial Products published in the Federal Register of January 6, 1978 (43 FR 1210) and has utilized these procedures with appropriate modifications.

Inherent in the product's definition is a demonstration of its ability to assist in the cleansing and removal of foreign material while causing no delay in wound healing. In addition, cleansing ingredients which are classified as "peroxides" must be able to release oxygen at the wound site.

The Panel recognizes that the testing of delay in wound healing, particularly in human subjects, is difficult. There is a need for the development of procedures to determine whether topical wounds would delay healing in human subjects. Until adequate human testing procedures are available, data from animal models will be required to support safety of a product to be labeled as an oral wound cleanser.

(1) *Animal test for delay in wound healing.* The Panel concludes that one of the following animal tests should be used to evaluate and compare the oral wound healing delay effects of oral wound cleansers:

(i) The subjects should consist of 12 young adult male New Zealand rabbits. Both antimicrobial-treated and antimicrobial-untreated control animals should be used.

(ii) The back of the rabbit should be shaved so that approximately 20 percent of the total body surface area is shaved.

(iii) The investigator should make a wound by dermal incision in the shaved area 24 hours after clipping. A sterile technique must be followed in making the dermal incision. Next, the area should be washed with 70 percent isopropyl alcohol solution. Using a scalpel, six 1-inch long freehand incisions, three on each side of the midline, approximately 0.5 to 1 mm deep, should be made through the dorsal skin. These incisions should be full thickness wounds. One-half of the wounds (three incisions) should be sutured. Treatments should begin within 1 hour after wound inducement.

The three treatment conditions should be tap water, an aqueous solution of the wound cleansing agent, and no treatment. Solutions should be prepared daily in tap water immediately before use. Each set of two incisions (1 sutured and 1 nonsutured wound) should be subject to one of the treatments. One mL of solution should be gently applied for 1 to 2 minutes daily for 14 consecutive days. These daily applications should be 6 hours apart. The applied material should be allowed to dry. After the initial application, each incision should be rinsed with tap water immediately prior to subsequent treatments and gently dried. The animals should wear collars throughout the study to prevent oral ingestion of test material.

(iv) To evaluate the test the following parameters should be utilized: Body weight should be determined for each rabbit on days 0, 7, and 14; wound-

healing progress and general conditions should be observed and described daily. This is to be supplemented by color photographs. Two animals each should be sacrificed on days 1, 3, 5, 7, 10, and 14 by air injection. Wound sections should be evaluated and compared microscopically.

(2) *Evaluation of oral wound cleansers in humans.* The Panel was not able at this time to develop a generally acceptable procedure for evaluating of oral wound cleansers and recommends that the industry and FDA consider suitable methods. The following techniques have been used for other purposes and may have some application in evaluation oral would cleansers:

(i) Determination of leucocytes in the oral rinse; an increase in the number of leucocytes compared to those obtained from a tap water rinse indicates more efficient wound cleansing. A technique for determining leucocytes in oral fluid was described by Klinkhamer (Ref. 1) and by Wright (Ref. 2).

(ii) Determination of desquamated epithelial cells from paraffin stimulated saliva. The subject rinses with an active ingredient test product or a control and removes the rinse fluid. Then paraffin in simulated saliva is collected for 5 minutes. Desquamated epithelial cells are determined from a histological slide of the saliva. An effective wound cleanser will result in a lower count of desquamated epithelial cells than the control.

(iii) Buccal scrapings of the wound are made after rinsing, an effective wound cleanser shows less desquamated epithelial cells than scrapings taken from wounds after the control rinse.

References

(1) Klinkhamer, J. M., "Human Oral Leucocytes," *Periodontics*, 1:109–117, 1963.

(2) Wright, D. E., "Leucocytes in the Saliva of Edentulous and Caries Free Subjects," *Archives of Oral Biology*, 7:581–585, 1962.

The Food and Drug Administration has determined that this document does not contain an agency action covered by 21 CFR 25.1(b) and consideration by the agency of the need for preparing an environmental impact statement is not required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701, 52 Stat. 1040–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371)), and the Administrative Procedure Act (secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)), and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended by adding new Parts 353, to read as follows:

PART 353—ORAL MUCOSAL INJURY PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Sec.
353.1 Scope.
353.3 Definitions.

Subpart B—Active Ingredients

353.10 Oral mucosal injury active ingredients.
353.20 Permitted combinations of active ingredients.

Subpart C—[Reserved]

Subpart D—Labeling

353.50 Labeling of oral mucosal injury products.

Authority: Secs. 201, 502, 505, 701, 52 Stat. 1040–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371); (5 U.S.C. 553, 554, 702, 703, 704).

Subpart A—General Provisions

§ 353.1 Scope.

An over-the-counter oral mucosal injury drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this Part 353 and each of the general conditions established in § 330.1 of this chapter.

§ 353.3 Definitions.

(a) *Oral mucosal injury.* Injury occurring to the soft tissue in the oral cavity.

(b) *Oral mucosal injury agent.* An agent that relieves oral soft tissue injury, e.g., by cleansing or promoting the healing of oral wounds (minor oral irritations).

(c) *Oral wound cleanser.* A nonirritating preparation that assists (physically or chemically) in the removal of foreign material from small superficial oral wounds and does not delay wound healing.

(d) *Oral wound healing agent.* A nonirritating agent that aids in the healing of small superficial oral wounds by means other than cleansing and irritating, or by serving as a protectant.

Subpart B—Active Ingredients

§ 353.10 Oral mucosal injury active ingredients.

The active ingredients of the product consist of the following when used within the concentration established for each ingredient:

(a) *Oral wound cleansers.* (1) Carbamide peroxide 10 percent in anhydrous glycerin.

(2) Hydrogen peroxide 3 percent in aqueous solution.

(b) *Oral wound healing agents.* [Reserved]

§ 353.20 Permitted combinations of active ingredients.

(a) Any single oral wound cleanser identified in § 353.10(a) may be combined with any single generally recognized as safe and effective oral antiseptic.

(b) Any single oral wound healing agent identified in § 353.10(b) may be combined with any single generally recognized as safe and effective oral antiseptic.

(c) Any single oral wound healing agent identified in § 353.10(b) may be combined with a denture adhesive.

Subpart C—[Reserved]

Subpart D—Labeling

§ 353.50 Labeling of oral mucosal injury products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as either an "oral wound cleanser" or an "oral wound healing agent."

(b) *Indications.* The labeling of the product contains a statement of the indications under the heading "Indications" that is limited to one or more of the following phrases:

(1) *For oral wound cleanser drug products.* (i) "For temporary use in the cleansing of wounds caused by minor oral irritation or injury such as following minor dental procedures, or from dentures or orthodontic appliances."

(ii) "For temporary use in the cleansing of gum irritation due to erupting teeth (teething)."

(2) *For oral wound healing agent drug products.* [Reserved]

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) *For products containing any ingredient identified in § 353.10(a) and (b).* (i) "Not to be used for a period exceeding 7 days."

(ii) "Discontinue use and see your dentist or physician promptly if irritation persists, inflammation develops, or if fever and infection develop."

(2) [Reserved]

(d) *Directions.* The labeling of the product contains the following statements under the heading "Directions," followed by "or as directed by a dentist or physician."

(1) *For products containing carbamide peroxide identified in § 353.10(a)(1).* Apply several drops directly to the affected area of the mouth. Allow the medication to remain in place at least 1 minute and then spit out. Use up to four times daily after meals and at bedtime or as directed by a dentist or physician. Children under 12 years of age should be supervised in the use of this product. For children under 2 years of age, there is no recommended dosage except under the advise and supervision of a dentist or physician.

(2) *For products containing hydrogen peroxide identified in § 353.10(a)(2)*—(i) *For direct application.* Apply several drops of full strength (3 percent) solution to the affected area of the mouth. Allow the medication to remain in place at least 1 minute and then spit out. Use up to four times daily after meals and at bedtime or as directed by a dentist or physician. Children under 12 years of age should be supervised in the use of this product. For children under 2 years of age, there is no recommended dosage except under the advise and supervision of a dentist or physician.

(ii) *For use as an oral rinse.* Mix the full strength (3 percent) solution with an equal amount of warm water. Swish around in the mouth over the affected area for at least 1 minute and then spit out. Use up to four times daily after meals and at bedtime or as directed by a dentist or physician. Children under 12 years of age should be supervised in the use of this product. For children under 2 years of age, there is no recommended dosage except under the advise and supervision of a dentist or physician.

Interested persons are invited to submit their comments in writing (preferably in four copies and identified with the Hearing Clerk docket number found in brackets in the heading of this document) regarding this proposal on or before January 24, 1980. Comments should be addressed to 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. Comments replying to comments may also be submitted on or before February 25, 1980. Comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: October 1, 1979.

Sherwin Gardner,

Acting Commissioner of Food and Drugs.

[FR Doc. 79-32590 Filed 11-1-79; 8:45 am]

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federal register

Friday
November 2, 1979

Part III

Department of Health, Education, and Welfare

Food and Drug Administration

Medical Devices; Classification of Anesthesiology Devices

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Part 868

[Docket No. 78N-1648]

Classification of Anesthesiology Devices; Development of General Provisions

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing general rules applicable to the classification of all anesthesiology devices. The Medical Device Amendments of 1976 require 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 anesthesiology devices, which are being published elsewhere in this issue of the Federal Register. The preamble also describes the activities of the Anesthesiology Device Classification Panel, an FDA advisory committee that makes recommendations to FDA concerning the classification of anesthesiology devices.

DATES: Comments on or before January 2, 1980. FDA proposes that the final 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-0305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

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. 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 also classified in the same class as the device to which it is substantially equivalent.

A device that FDA previously regarded as a new drug, or a newly offered device that is not substantially equivalent to a device that was in commercial distribution before the amendments, is classified by statute into class III. The two types of devices just noted 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), FDA 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 Anesthesiology Device Classification Panel (the Panel) was originally chartered on October 3, 1972, as the Panel on Review of Anesthesiology Devices.

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 referred to it by FDA 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 anesthesiology devices. The Panel also invited experts to testify and sought information on many devices from the published literature.

In November 1977, the Panel submitted to FDA a preliminary report of its recommendations. The report included a roster of current and previous Panel members and consultants and listed all meeting dates. The agency placed a copy of the report in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, and announced its availability to the public by notice published in the Federal Register of November 29, 1977 (42 FR 60792). At a meeting held on January 24, 1978, the Panel changed its previous recommendations concerning the classification of several devices. An addendum to the Panel report showing these changes has been placed in the office of the Hearing Clerk, Food and Drug Administration. Also available in the office of the Hearing Clerk are summary minutes from all Panel meetings, verbatim transcripts of meetings held after May 28, 1976 (the date of enactment of the amendments), and all references cited in individual anesthesiology 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 Anesthesiology 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 anesthesiology devices. The Panel supplemented the list using its members' knowledge of anesthesiology devices in use. Devices that were solely for experimental or investigational use or that were not generally available were not included.

FDA is proposing to establish a new Part 868 in Title 21 of the Code of

Federal Regulations. Part 868 will consist of sections identifying each anesthesiology device with a brief narrative description and stating the classification of that device. A list of the anethesiology devices appears elsewhere in this preamble.

Individual Anesthesiology Device Classification Regulations

Elsewhere in this issue of the Federal Register, FDA is issuing 149 individual proposed regulations to classify each anesthesiology device. The agency is proposing to classify 22 anesthesiology devices into class I (general controls), 119 anesthesiology devices into class II (performance standards), and 8 anesthesiology devices into class III (premarket approval). The agency 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 an anesthesiology device includes the information described below.

1. *Identification.* The Panel recommendation and proposed FDA classification regulation each include a brief narrative identification of the device. The identification statement is necessarily broad because it applies to a category or type of device rather than to a specific device. As explained in proposed § 868.1, any manufacturer of a newly offered device who files a premarket notification submission under section 510(k) of the act and Part 807 of the regulations cannot show merely that the device is accurately described by the section title and identification provisions of a classification regulation. Although a new device may be described accurately be the title and identification in a classification regulation, it is nevertheless in a 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 devices previously classified by the regulation. FDA 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 it 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, class II, class III.

For each device recommended for classification into class I, the Panel considered whether the device should be exempt from any requirements under certain sections of the act: section 510 (21 U.S.C. 360, registration), section 519 (21 U.S.C. 360i, records and reports), and section 520(f) (21 U.S.C. 360j(f), good manufacturing practice requirements). Although the Panel did not recommend that any device be exempted at this time from section 510 or section 519 of the act, the Panel did recommend that the manufacturers of several class I devices be exempted from the good manufacturing practice regulation in the manufacture of these devices. The agency's policy concerning these exemption recommendations is discussed below in the section of this proposal concerning "Exemptions for Class I Devices."

A Panel recommendation that a device be classified into class II includes the Panel's recommended priority ("high," "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," FDA 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 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 form the Panel's recommendation, FDA 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 unnecessary to provide reasonable assurance of its safety and effectiveness. The agency provides a similar explanation in the "Proposed Classification" section of the preamble to any proposal to classify an implant or a life-supporting or life-sustaining device into a class other than class III.

4. *Summary of data on which the recommendation is based.* In many cases, the Panel based its recommendations on Panel members' personal knowledge of, and clinical experience with, the devices under review. Reliance on the Panel members' clinical experience and judgment was particularly common when the Panel considered a simple device that had been used extensively and was accepted widely before the amendments were enacted. The legislative history of the amendments states that the term "data" has a special meaning in section 513(c)(2)(A) of the act, which requires that a Panel recommendation summarize the data upon which a recommendation is based. As used in this section, "data" refers not only to the results of scientific experiments but also to less formal evidence, other scientific information, or judgments of experts (House Committee on Interstate and Foreign Commerce, Medical Device Amendments of 1976, H. Rept. 94–853, 94th Congress, 2d Session (1976)). FDA has determined that clinical experience and judgment are valid scientific evidence for classifying certain devices.

In many cases, FDA sought data and information concerning the classification of a device in addition to that cited by the Panel. References to these data and information are found in the "Proposed Classification" section of the preambles to individual anesthesiology device regulations. FDA 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 regulations.

5. *Risks to health.* In identifying the risks to health presented by anesthesiology devices, the Panel recognized that few devices are completely free of risk. The Panel listed the risks it considered most significant, especially those that are unique to the use of a device. In some cases, FDA has

identified additional risks to health presented by a device. These additional risks are set out in the section of the preamble concerning the "Proposed Classification" of a particular device.

Because the classification recommendations and FDA regulations do not identify all risks to health presented by anesthesiology devices, future regulations establishing performance standards under section 514 of the act (21 U.S.C. 360d) and future regulations requiring premarket approval under section 515(b) of the act (21 U.S.C. 360e(b)) may identify additional risks to health to be addressed by FDA requirements.

Proposed Classification

Each proposed regulation to classify an anesthesiology 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 868 in which the device classification will be condified.

FDA cautions that the final classification of a device may differ from the proposal. Factors that may cause such a change include comments received in response to the proposal, new data and information, and the agency's reconsideration of existing information.

Priorities for Class II and Class III Devices

For a device that the Panel recommends be classified into class II or class III, section 513(c)(2)(A) of the Act requires that the Panel recommendation include, to the extent practicable, a recommendation for the assignment of a priority for application to the device of performance standards or premarket approval requirements. In reaching its determination on priorities, the Panel compared the relative risks and benefits of the particular device with those of other anesthesiology devices. The Panel recommended a "high priority" assignment only to those devices it believed warranted the agency's immediate attention.

FDA is not proposing at this time the establishment of priorities either for development of performance standards for class II devices or for 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. The agency, however, will establish such priorities in the future. These priorities will be based on the classification panels' recommendations, available resources, and other relevant factors. The agency's priorities will be reflected in the agency's annual budget request and other publicly available documents and may be published in the Federal Register.

To the extent it is not constrained by statute or available resources, the agency intends to impose premarket approval requirements on class III devices as soon as possible.

FDA's action of requiring submission of premaket approval applications for particular class III devices is dependent upon 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 panel. For example, when FDA classifies only a few devices within a panel's specialty area as class III, FDA may simultaneously publish regulations under section 515(b) requiring premarket approval for many class III devices considered by the Panel, regardless of whether a high or low priority has been established for the devices. Where practical, FDA will publish these regulations during the post classification grace period (at least 30 months) when a device classified into class III by FDA regulation may lawfully remain on the market without a premarket approval application. The grace period is provided for in section 501(f) of the act (21 U.S.C. 351(f)).

Exemptions for Class I Devices

Section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) provides that FDA may exempt a device recommended for classification into class I from a requirement under the following 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 practices.

Under section 510 of the act, a person "engaged in the manufacture, preparation, propagation, compounding or processing of * * * a device or devices" must register with FDA (section 510 (b) through (i)), file a list of devices (section 510(j)), and notify FDA at least 90 days before beginning commercial distribution of a device (section 510(k)). (See Part 807 (21 CFR Part 807).) Section 510(g)(4) authorizes the agency to exempt a device from section 510 if it finds that compliance with that section is not necessary for the protection of the public health. In § 807.65 (21 CFR 807.65), FDA has exempted certain classes of persons from section 510 of the act. Several device classification panels have recommended that manufacturers of certain class I devices also be exempted from all or some of the requirements of section 510. The agency has determined that protection of the public health requires that manufacturers of medical devices, other than those already exempt under § 807.65, register and list their products with FDA to ensure that the agency can identify these manufacturers and their products and conduct necessary inspections.

The agency has determined, however, for certain devices, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions. Thus, the agency is proposing to exempt certain devices from Subpart E of Part 807 of the regulations, which implements section 510(k) of the act. The agency does not, at this time, anticipate that premarket approval will be required for these devices. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice of new products within these generic types of devices.

Section 519 of the act authorizes FDA to issue regulations requiring device manufacturers, importers, and distributors to establish and maintain such records, make such reports, and provide such information as the agency may reasonably require to assure that devices are not adulterated or misbranded and to otherwise assure their safety and effectiveness. The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation under Part 820 (21 CFR Part 820), published in the Federal Register of July 21, 1978 (43 FR 31508). In the future, FDA will publish other regulations in accordance with section 519 of the act, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly issue exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempted from the requirements, and FDA will issue exemptions that are appropriate.

The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from most requirements of the device GMP regulation. As explained below,

the exemption will not extend to two device GMP records requirements.

The device GMP regulation was published in final form in the Federal Register of July 21, 1978. At the time of the Panel's recommendations, the GMP regulations had not yet been promulgated, and the agency had not yet developed criteria for exempting a class I device from GMP requirements. The agency has now decided that, if any one of the following criteria is met, FDA will consider exempting from the GMP regulation a class I device that is not labeled or otherwise represented as sterile. The agency will not, however, exempt a device from § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, or § 820.198 (21 CFR 820.198), with respect to complaint files. The criteria are:

1. FDA has determined, based on adequate information about current practices in the manufacture of the device and about user experience with the device, that application of GMP regulation is unlikely to improve the safety and effectiveness of the device.

2. FDA has determined that all possible defects relating to the safety and effectiveness of the device are readily detectable before use, either through visual examination by the user or routine testing before use, e.g., testing a clinical laboratory reagent with positive and negative controls.

3. FDA has determined that any defect in the device that is not readily detectable will not result in a device failure that could have an adverse effect on the patient or other user.

FDA has determined that no device that is labeled or otherwise represented as sterile will be exempted from the device GMP regulation. Such a device must be subject to the entire GMP regulation to ensure that manufacturers adequately reduce the bioburden (number of microorganisms) on the device and its components during the manufacturing process. This reduction is accomplished through adherence to a comprehensive quality assurance program as is required by the GMP regulation, with adequate environmental controls, trained personnel, appropriate maintenance and calibration of sterilization equipment, recordkeeping concerning lot sterility, strict packaging and labeling controls, and other quality assurance measures.

The agency also has determined that no exemption from the device GMP regulation will extend to § 820.180, with respect to general requirements concerning records, or § 820.198, with respect to complaint files. The agency believes that granting exemptions from these sections would not be in the public interest, and that compliance with these sections is not unduly burdensome for device manufactures. To ensure that device manufacturers have adequate systems for complaint investigation and followup, all such manufacturers are required to comply with the complaint file requirements of § 820.198. All device manufacturers also are required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

In general, FDA has not initiated proposals to exempt manufacturers of class I devices from requirements under section 510, 519, or 520(f) but has acted on the basis of exemption recommendations of the device classification panels. Manufacturers and other interested persons may submit comments on the appropriateness of exemptions of manufacturers of class I devices that are not the subject of panel exemption recommendations. FDA will consider granting exemptions from the requirement of premarket notification and from the GMP regulation (other than §§ 820.180 and 820.198) according to the policies and criteria discussed above. Comments requesting additional exemptions should be supported by information showing that the exemption of manufacturers of a device from the premarket notification requirement or the GMP regulation (other than §§ 820.180 and 820.198), or both, is consistent with the policies and criteria discussed above.

List of Anesthesiology Devices

The following is a list of anesthesiology devices that FDA is proposing to classify, the Code of Federal Regulations section under which the regulation classifying the device will be codified, the docket number of the proposed classification regulation, and the proposed classification of each device.

Section and device	Docket No.	Class
Subpart B—Diagnostic Devices		
868.1030 Manual algesimeter	78N-1649	I
868.1040 Powered algesimeter	78N-1650	II
868.1075 Argon gas analyzer	78N-1651	II
868.1100 Arterial blood sampling kit	78N-1652	II
868.1110 Nonindwelling blood carbon monoxide analyzer	78N-1653	II
868.1120 Indwelling blood oxyhemoglobin concentration analyzer	78N-1654	II
868.1130 Nonindwelling blood oxyhemoglobin concentration analyzer	78N-1655	II
868.1150 Indwelling blood carbon dioxide partial pressure (P_{CO}) analyzer	78N-1657	III
868.1160 Nonindwelling blood carbon dioxide partial pressure (P_{CO}) analyzer	78N-1658	II
868.1170 Indwelling blood hydrogen ion concentration (pH) analyzer	78N-1659	III
868.1180 Nonindwelling blood hydrogen ion concentration (pH) analyzer	78N-1660	II
868.1190 Nonindwelling blood nitrogen partial pressure (PN_2) analyzer	78N-1661	II
868.1200 Indwelling blood oxygen partial pressure (P_O) analyzer	78N-1662	III
868.1210 Nonindwelling blood oxygen partial pressure (P_O) analyzer	78N-1663	II
868.1250 Calibrated breathing system collection bottle	78N-1664	II
868.1260 Uncalibrated breathing system collection bottle	78N-1665	I
868.1400 Carbon dioxide gas analyzer	78N-1666	II
868.1430 Carbon monoxide gas analyzer	78N-1667	II
868.1500 Enflurane gas analyzer	78N-1668	II
868.1575 Gas collection vessel	78N-1669	II
868.1620 Halothane gas analyzer	78N-1670	II
868.1640 Helium gas analyzer	78N-1671	II
868.1670 Neon gas analyzer	78N-1672	II
868.1680 Nitrogen gas analyzer	78N-1673	II
868.1700 Nitrous oxide gas analyzer	78N-1674	II
868.1720 Oxygen gas analyzer	78N-1675	II
868.1730 Oxygen uptake computer	78N-1676	II
868.1750 Pressure plethysmograph	78N-1677	II
868.1760 Volume plethysmograph	78N-1678	II
868.1780 Inspiratory airway pressure meter	78N-1679	II
868.1800 Rhincanemometer	78N-1680	II
868.1840 Diagnostic spirometer	78N-1681	II
868.1850 Monitoring spirometer	78N-1682	II
868.1860 Peak-flow meter for spirometry	78N-1683	II
868.1870 Gas volume calibrator	78N-1684	II
868.1880 Pulmonary-function data calculator	78N-1685	II
868.1890 Predictive pulmonary-function value calculator	78N-1686	II
868.1900 Diagnostic pulmonary-function interpretation calculator	78N-1687	II
868.1910 Esophageal stethoscope	78N-1688	I
868.1920 Esophageal stethoscope with electrical conductors	78N-1689	II
868.1930 Stethoscope head	78N-1690	I
868.1965 Switching valve (gloss)	78N-1691	I
868.1975 Water vapor analyzer	78N-1692	II
Subpart C—Monitoring Devices		
868.2025 Ultrasonic air embolism monitor	78N-1693	II
868.2300 Bourdon gauge flowmeter	78N-1694	II
868.2320 Uncompensated thrope tube flowmeter	78N-1695	II
868.2340 Compensated thrope tube flowmeter	78N-1696	II
868.2350 Gas calibration flowmeter	78N-1697	II
868.2375 Breathing frequency monitor	78N-1698	II
868.2450 Lung water monitor	78N-1699	III
868.2500 Cutaneous oxygen monitor	78N-1700	II
868.2550 Pneumotachometer	78N-1702	II
868.2600 Airway pressure monitor	78N-1703	II
868.2610 Gas pressure gauge	78N-1704	II
868.2620 Gas pressure calibrator	78N-1705	II
868.2700 Pressure regulator	78N-1706	II
868.2775 Electrical peripheral nerve stimulator	78N-1707	II
868.2875 Differential pressure transducer	78N-1708	II
868.2885 Gas flow transducer	78N-1709	II

Section and device	Docket No.	Class
868.2900 Gas pressure transducer	78N-1710	II
Subpart F—Therapeutic Devices		
868.5090 Emergency airway needle	78N-1714	II
868.5100 Nasopharyngeal airway	78N-1715	II
868.5110 Oropharyngeal airway	78N-1716	II
868.5120 Anesthesia conduction catheter	78N-1717	II
868.5130 Anesthesia conduction filter	78N-1718	II
868.5140 Anesthesia conduction kit	78N-1719	II
868.5150 Anesthesia conduction needle	78N-1720	II
868.5160 Anesthesia gas machine	78N-1721	II
868.5170 Laryngotracheal topical anesthesia applicator	78N-1722	II
868.5180 Rocking bed	78N-1723	III
868.5220 Blow bottle	78N-1726	II
868.5240 Anesthesia Breathing circuit	78N-1727	II
868.5250 Breathing circuit circulator	78N-1728	II
868.5260 Breathing circuit bacterial filter	78N-1729	II
868.5270 Breathing system heater	78N-1730	II
868.5280 Breathing tube support	78N-1731	I
868.5300 Carbon dioxide absorbent	78N-1732	II
868.5310 Carbon dioxide absorber	78N-1733	II
868.5320 Reservoir bag	78N-1734	II
868.5330 Breathing gas mixer	78N-1735	II
868.5340 Nasal oxygen cannula	78N-1736	I
868.5350 Nasal oxygen catheter	78N-1737	I
868.5365 Posture chair for cardiac and pulmonary treatment	78N-1738	I
868.5375 Heat and moisture condenser (artificial nose)	78N-1739	II
868.5385 Water-seal thoracic drainage system	78N-1740	II
868.5400 Electroanesthesia apparatus	78N-1741	III
868.5420 Ether hook	78N-1743	I
868.5430 Gas scavenging apparatus	78N-1744	II
868.5440 Portable oxygen generator	78N-1745	II
868.5450 Respiratory gas humidifier	78N-1746	II
868.5460 Humidifier for home use	78N-1747	II
868.5470 Hyperbaric chamber	78N-1748	II
868.5480 Hyperthermia device	78N-1749	II
868.5490 Hypothermia device	78N-1750	II
868.5520 Automatic catheter flushing device	78N-1751	II
868.5530 Flexible laryngoscope	78N-1752	II
868.5540 Rigid laryngoscope	78N-1753	II
868.5550 Anesthetic gas mask	78N-1754	II
868.5560 Gas mask head strap	78N-1755	I
868.5570 Nonrebreathing mask	78N-1756	II
868.5580 Oxygen mask	78N-1757	I
868.5590 Scavenging mask	78N-1758	II
868.5600 Venturi mask	78N-1759	II
868.5610 Membrane lung for long-term pulmonary support	78N-1760	III
868.5620 Breathing mouthpiece	78N-1761	II
868.5630 Nebulizer	78N-1762	II
868.5640 Medicinal nonventilatory nebulizer (atomizer)	78N-1763	I
868.5650 Esophageal obturator	78N-1764	II
868.5655 Portable liquid oxygen unit	78N-1765	II
868.5665 Electric-powered percussor	78N-1766	II
868.5675 Rebreathing device	78N-1767	I
868.5680 Incentive spirometer	78N-1768	II
868.5700 Oxygen tent	78N-1769	I
868.5710 Electrically powered oxygen tent	78N-1770	II
868.5720 Bronchial tube	78N-1771	II
868.5730 Tracheal tube	78N-1772	II
868.5740 Tracheal/bronchial differential ventilation tube	78N-1773	II
868.5750 Inflatable tracheal tube cuff	78N-1774	II
868.5760 Cuff spreader	78N-1775	I
868.5770 Tracheal tube fixation device	78N-1776	II
868.5780 Tube introduction forceps	78N-1777	II
868.5790 Tracheal tube stylet	78N-1778	II
868.5810 Airway connector	78N-1780	II
868.5820 Dental protector	78N-1781	II
868.5830 Autotransfusion apparatus	78N-1782	III
868.5840 Blood transfusion microfilter	78N-1783	II
868.5860 Pressure tubing and accessories	78N-1784	II
868.5870 Nonrebreathing valve	78N-1785	II
868.5880 Anesthetic vaporizer	78N-1786	II
868.5895 Continuous ventilator	78N-1787	III
868.5905 Noncontinuous ventilator	78N-1788	II
868.5915 Manual emergency ventilator	78N-1789	II
868.5925 Powered emergency ventilator	78N-1790	III
868.5935 External negative pressure ventilator	78N-1791	II
868.5955 Intermittent mandatory ventilation attachment	78N-1793	II
868.5965 Positive end expiratory pressure breathing attachment	78N-1794	II
868.5975 Ventilator tubing	78N-1795	II
868.5995 Tea drain (water trap)	78N-1796	II
Subpart G—Miscellaneous Devices		
868.6100 Anesthetic cabinets, tables or trays	78N-1797	I
868.6175 Cardiopulmonary emergency cart	78N-1798	I
868.6225 Nose clip	78N-1799	I
868.6250 Portable air compressor	78N-1800	II
868.6275 Gas cylinder	78N-1801	II
868.6285 Gas cylinder holder	78N-1802	II
868.6400 Calibration gas	78N-1805	II
868.6700 Anesthesia stool	78N-1806	I
868.6810 Tracheobronchial suction catheter	78N-1810	I
868.6820 Patient position support	78N-1807	II
868.6935 Medical gas yoke assembly	78N-1808	II

Devices Considered by Two or More Panels

Many devices were reviewed by two or more device classification panels. For these devices, FDA will publish each panel's recommendations and a single proposed classification regulation. The following devices were considered by the Anesthesiology Device Classification Panel and by other panels:

1. The General and Plastic Surgery Device Classification Panel recommend that continuous oxygen analyzers be classified into class III. The General Hospital and Personal Use Device Classification Panel recommended that neonatal invasive oxygen analyzers be classified into class III. The Anesthesiology Device Classification Panel recommended that indwelling blood oxygen partial pressure (P_{O_2}) analyzers be classified into class III. FDA has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying the indwelling blood oxygen partial pressure (P_{O_2} analyzer into class III, and is publishing the Panels' recommendations in a proposal appearing elsewhere in this issue of the Federal Register.

2. The Dental Device Classification Panel recommended that anesthesia flowmeters be classified into class II. The Anesthesiology Device Classification Panel recommended that back pressure compensated thorpe tube flowmeters be classified into class II. FDA has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying compensated thorpe tube flowmeters into class II, and is publishing the two Panels' recommendations in a proposal appearing elsewhere in this issue of the Federal Register.

3. The General Hospital and Personal Use Device Classification Panel recommended that the manual pulmonary resuscitator be classified into class II. The Anesthesiology Device Classification Panel recommended that the manual emergency ventilator be classified into class II. FDA has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying the manual emergency ventilator into class II, and is publishing the two Panels' recommendations in a proposal appearing elsewhere in this issue of the Federal Register.

4. The General Hospital and Personal Use Device Classification Panel recommended that the neonatal ventilator be classified into class II. The Anesthesiology Device Classification Panel recommended that the continuous ventilator be classified into class III. FDA has determined that these devices are the same. Therefore, the agency is proposing a single regulation classifying the continuous ventilator into class II and is publishing the two Panels' recommendations in a proposal appearing elsewhere in this issue of the Federal Register.

5. The General Hospital and Personal Use Device Classification Panel recommends that nasal cannulas be classified into class I. The Anesthesiology Device Classification Panel recommends that nasal oxygen cannulas be classified into class I. FDA has determined that these devices are the same. Therefore, the agency is proposing a single regulation classifying nasal oxygen cannulas into class I and is publishing both Panels' recommendations in a proposal appearing elsewhere in this issue of the Federal Register.

6. The Dental Device Classification Panel recommends that gas machine analgesia/anesthesia be classified into class II. The Anesthesiology Device Classification Panel recommends that anesthesia gas machines be classified into class II. FDA has determined that these devices are the same. Therefore, the agency is proposing a single regulation classifying anesthesia gas machines into class II and is publishing both Panels' recommendations in a

proposal appearing elsewhere in this issue of the Federal Register.

7. The Dental Device Classification Panel recommends that compressed gas cylinders and valves be classified into class II. The Anesthesiology Device Classification Panel recommends that gas cylinders be classified into class II. FDA has determined that these devices are the same. Therefore, the agency is proposing a single regulation classifying gas cylinders into class II and is publishing both Panels' recommendations in a proposal appearing elsewhere in this issue of the Federal Register.

8. The General Hospital and Personal Use Device Classification Panel recommends that oxygen masks be classified into class II. The Anesthesiology Device Classification Panel recommends that oxygen masks be classified into class II. The FDA has determined that these devices are the same. Therefore, the agency is proposing a single regulation classifying oxygen masks into class II and is publishing both Panels' recommendations in a proposal appearing elsewhere in this issue of the Federal Register.

9. The General Hospital and Personal Use Device Classification Panel recommends that venturi oxygen masks be classified into class II. The Anesthesiology Device Classification Panel recommends that venturi masks be classified into class II. FDA has determined that these devices are the same. Therefore, the agency is proposing a single regulation classifying venturi masks into class II and is publishing both Panels' recommendations in a proposal appearing elsewhere in this issue of the Federal Register.

10. The General and Plastic Surgery Device Classificaiton Panel recommends that respiratory monitors be classified into class II. The Anesthesiology Device Classification Panel recommends that ventilatory frequency monitors be classified into class II. FDA has determined that these devices are the same. Therefore, the agency is proposing a single regulation classifying ventilatory frequency monitors into class II and is publishing both Panel recommendations in a proposal appearing elsewhere in this issue of the Federal Register.

11. The General Hospital and Personal Use Device Classification Panel recommends that mechanical oxygen regulators be classified into class II. The Anesthesiology Device Classification Panel recommends that pressure regulators be classified into class II. FDA has determined that these devices are the same. Therefore, the agency is proposing a single regulation classifying pressure regulators into class II and is publishing both Panels' recommendations in a proposal appearing elsewhere in this issue of the Federal Register.

12. The Dental Device Classification Panel recommends that emergency oxygen and resuscitation units be classified into class II. The Anesthesiology Device Classification Panel recommends that powered emergency ventilators be classified into class II. FDA has determined that these devices are the same. Therefore, the agency is proposing a single regulation classifying powered emergency ventilators into class II and is publishing both Panels' recommendations in a proposal appearing elsewhere in this issue of the Federal Register.

13. The Neurological Device Classification Panel recommends that electroanaesthesia stimulators be classified into class III. The Anesthesiology Device Classification Panel recommends that electroanesthesia apparatus be classified into class III. FDA has determined that these devices are the same. Therefore, the agency is proposing a single regulation classifying electroanesthesia apparatus into class III and is publishing both Panels' recommendations in a proposal appearing elsewhere in this issue of the Federal Register.

14. The General Hospital and Personal Use Device Classification Panel recommends that pediatric aerosol tents be classified into class II. The Anesthesiology Device Classification Panel recommends that electrically powered oxygen tents be classified into class II. FDA has determined that these devices are the same. Therefore, the agency is proposing a single regulation classifying electrically powered oxygen tents into class II and is publishing both Panels' recommendations in a proposal appearing elsewhere in this issue of the Federal Register.

15. The Cardiovascular Device Classification Panel recommends that pH catheter probes be classified into class II (Federal Register of March 9, 1979, 44 FR 13303). The Anesthesiology Device Classification Panel recommends that the indwelling blood hydrogen ion concentration (pH) analyzer be classified into class III. FDA has determined that these devices are the same. Therefore, the agency is proposing a single regulation classifying indwelling blood hydrogen ion concentration analyzer into class III and is publishing both Panels' recommendations in a proposal appearing elsewhere in this issue of the Federal Register. The pH catheter probe will be deleted from the published final orders of the Cardiovascular Device Classification Panel.

16. The Anesthesiology Device Classification Panel and the other panels listed below made classification recommendations concerning the following devices:

Device	Other panel(s)
Transcutaneous ultrasonic blood flowmeter.	Cardiovascular.
Indwelling blood flow transducer	Cardiovascular.
Blood pressure monitor amplifier and associated electronics.	Cardiovascular.
Indwelling blood pressure monitor	Cardiovascular.
Nonindwelling blood pressure monitor	Cardiovascular.
Indwelling blood pressure transducer	Cardiovascular.
Nonindwelling blood pressure transducer	Cardiovascular.
Electrocardiographic monitor	Cardiovascular.
Pulse rate monitor	Cardiovascular.
Mechanical cardiac resuscitator	Cardiovascular.
Rigid bronchoscope aspirating tube	Ear, nose, and throat.
Nonrigid bronchoscope	Ear, nose, and throat.
Rigid nonventilating bronchoscope	Ear, nose, and throat.
Rigid ventilating bronchoscope	Ear, nose, and throat.
Bronchoscope biopsy brush (nonrigid)	Ear, nose, and throat.
Bronchoscope foreign body claw (nonrigid).	Ear, nose, and throat.
Bronchoscope biopsy curette (nonrigid)	Ear, nose, and throat.
Bronchoscope biopsy curette (rigid)	Ear, nose, and throat.
Bronchoscope biopsy forceps (nonrigid)	Ear, nose, and throat.
Bronchoscope biopsy forceps (rigid)	Ear, nose, and throat.
Bronchoscope tubing	Ear, nose, and throat.
Tracheostomy tube	Ear, nose, and throat.
Arm board	General and plastic surgery.
Electrosurgical unit	General and plastic surgery.
Portable aspiration pump	General and plastic surgery.
Conductive patient restraint	General and plastic surgery.
Conductive shoe and shoe cover	General and plastic surgery.
Operating room table and attachments	General and plastic surgery.
Manual infusion apparatus	General hospital.
Powered infusion apparatus	General hospital.
Patient cart	General hospital.
Infusion rate monitor	General hospital.
Spinal-fluid pressure monitor	General hospital.
AC-powered spinal fluid pressure monitor	General hospital.
Nasogastric tube	General hospital.
Temperature monitor (self-contained)	General hospital.
Temperature monitor (w/probe)	General hospital.
Suction regulator	General hospital.
Transfusion set	General hospital.
Rigid suction tip	General hospital.
Sterile specimen trap	General hospital.
Flexible aspirating tube	General hospital.
Electrophrenic pacer	Neurology.
Bicycle ergometer	Physical medicine.
Treadmill	Physical medicine.
Grip strength dynamometer	Orthopedic.
Electromagnetic blood warmer	Hematology.
Nonelectromagnetic blood warmer	Hematology.

FDA is not at this time publishing the Anesthesiology Device Classification Panel's recommendations to classify the devices listed above. FDA will publish

these recommendations, and proposed classification regulations, when the agency publishes the recommendations of other panels that reviewed the devices. Some of these other Panels' recommendations have already been published in the Federal Register as noted below:

Neurology—November 28, 1978 (43 FR 54640–55732) (proposals). September 4, 1979 (44 FR 51726–51776) (final orders).
Cardiovascular—March 9, 1979 (44 FR 13284–13434) (proposals).
General Hospital—August 24, 1979 (44 FR 49844–49954) (proposals).
Physical Medicine—August 28, 1979 (44 FR 50458–50537) (proposals).
Hematology—September 11, 1979 (44 FR 52950–53083) (proposals).

FDA has determined that the following devices reviewed by the Anesthesiology Device Classification Panel are identical to devices reviewed by the Neurological Device Classification Panel and the Cardiovascular Device Classification Panel: electroencephalograph; surface electrodes; needle electrode; transcutaneous blood oxyhemoglobin concentration analyzer; and bit block. FDA has also determined that these anesthesiology devices should be regulated under the regulations proposed or adopted for the counterpart devices reviewed by the other two panels. FDA will not, therefore, issue proposed regulations based on the Anesthesiology Device Classification Panel's recommendations. Because, however, the proposed and final neurological device classification regulations, and the proposed cardiovascular device classification regulations, were published before FDA determined that the devices in question were identical, the agency did not publish the Anesthesiology Device Classification Panel's recommendations at that time. Accordingly, the agency is publishing, below, the recommendations of the Anesthesiology Device Classification Panel concerning these devices, as required by the amendments. Interested persons are invited to comment, in accordance with the procedure set forth at the end of this notice, on the agency's determinations that the devices described below are identical to the neurological or cardiovascular devices referred to.

1. The Anesthesiology Device Classification Panel recommends that the electroencephalograph be classified into class II because it believes that the electroencephalograph should accurately reproduce the electroencephalogram. The Panel based its recommendation on the Panel members' clinical experience with this device. The Panel identified electrical shock as a risk to health from use of this device.

FDA has determined that the electroencephalograph classified by the Anesthesiology Device Classification Panel is identical to the device considered by the Neurological Device Classification Panel. On November 28, 1978, FDA published in the Federal Register (43 FR 55653) a proposed regulation, based on that Panel's recommendation, classifying the electroencephalograph into class II.

2. The Anesthesiology Device Classification Panel recommends that a surface electrode be classified into class II because it believes the surface electrode should accurately reproduce physiologic signals and use only acceptable materials. The Panel based its recommendation on the Panel members' clinical experience with this device. The Panel identified electrical shock and biocompatability as risks to health associated with the use of this device.

The agency has determined that the surface electrode classified by the Anesthesiology Device Classification Panel is identical to the device considered by the Neurological Device Classification Panel. On November 28, 1978, FDA published in the Federal Register (43 FR 55650) a proposed regulation based on that Panel's recommendation, classifying the cutaneous electrode into class II.

3. The Anesthesiology Device Classification Panel recommends that the needle electrode be classified into class II because it believes that the needle electrode should accurately reproduce physiologic signals and use only acceptable materials. The Panel based its recommendation on the Panel members' clinical experience with this device. The Panel identified electrical shock and biocompatability as risks to health associated with the use of this device.

FDA has determined that the needle electrode classified by the Anesthesiology Device Classification Panel is identical to the device considered by the Neurological Device Classification Panel. On November 28, 1978, FDA published in the Federal Register (43 FR 55652) a proposed regulation, based on that Panel's recommendation, classifying the needle electrode into class II.

4. The Anesthesiology Device Classification Panel recommends that the transcutaneous blood oxyhemoglobin concentration analyzer be classified into class II because it believes that the design of the device should be controlled to assure accurate and reproducible blood oxyhemoglobin concentration values. The Panel based its recommendation on the Panel members' clinical experience with this device. The Panel identified local irritation or burns and erroneous data leading to inappropriate therapy as risks to health associated with this device.

FDA has determined that the transcutaneous blood oxyhemoglobin concentration analyzer classified by the Anesthesiology Device Classification Panel is identical to the device considered by the Cardiovascular Device Classification Panel. On March 9, 1979, FDA published in the Federal Register (44 FR 13346) a proposed regulation, based on that Panel's recommendation, classifying the ear oximeter into class II.

5. The Anesthesiology Device Classification Panel recommends that a bite block be classified into class II because it believes that a bite block should adequately protect the patient's teeth and use only acceptable materials. The Panel based its recommendation on the Panel members' clinical experience with this device. The Panel identified trauma and infection as risks to health associated with the use of this device.

FDA has determined that the bite block classified by the Anesthesiology Device Classification Panel is identical to the device considered by the Neurological Device Classification Panel. On November 28, 1978 FDA published in the Federal Register (43 FR 55652) a proposed regulation, based on that Panel's recommendation, classifying a bite block into class II.

Devices Reviewed by the Panel but for Which No Regulation Is Proposed

FDA is not issuing proposed regulations classifying the following devices reviewed by the Anesthesiology Device Classification Panel:

1. The Anesthesiology Device Classification Panel recommends that the ether dropper, a device used to administer ether anesthetic, be classified into class II because it believes that the device should accurately dispense the correct amount of ether.

FDA agrees with the Panel recommendation, but is unaware of any such product in commercial distribution. The agency requests the submission of any information regarding the commercial distribution of the ether dropper.

2. The Anesthesiology Device Classification Panel recommends that airway suction kits, a device in kit form used to remove secretions from the respiratory tract, be classified into class

II because it believes that the device should comply with a sterility standard.

The devices usually used for removing secretions from the respiratory tract (e.g., tracheobronchial suction catheter) are the subjects of individual proposed classification regulations published in this issue of the Federal Register. Accordingly, there is no need to publish a separate regulation for those devices when sold as a "kit."

3. The Anesthesiology Device Classification Panel recommended that both attached and unattached cigarette filters be classified into class III (premarket approval) because it believes that insufficient information exists to determine that general controls or standards would be adequate to provide reasonable assurance of the safety and effectiveness of these devices.

On October 2, 1978, Action on Smoking and Health (ASH) filed a petition requesting that FDA recognize its jurisdiction over cigarette filters and regulate them as medical devices. FDA is not now issuing a proposed classification regulation for cigarette filters pending a decision on the ASH petition and a determination of the regulatory status of cigarette filters.

4. The Anesthesiology Device Classification Panel recommends that acupuncture needles be classified into class II and that acupuncture point locators and electroacupuncture stimulators be classified into class III.

FDA is not publishing a proposed regulation to classify these devices because the devices have already been classified into class III by statute and such a proposal is therefore unnecessary.

FDA believes that these devices have not been shown to be safe and effective for any therapeutic or diagnostic use. In recommending that acupuncture needles be classified into class II, the Panel considered risks of infection and trauma from needle breakage, but not risks presented by lack of effective therapy or diagnosis. In the Federal Register of March 9, 1973 (38 FR 6419), FDA published a notice explaining that FDA believed that the safety and effectiveness of acupuncture devices had not yet been established by adequate scientific studies to support the many uses for which the devices were being promoted. The agency concluded that until safety and effectiveness are established, acupuncture devices would be considered misbranded if the device labeling contains any claims of therapeutic or diagnostic effectiveness, or fails to include a statement of the investigational nature of the device and certain other information. The agency has not received any information to justify a conclusion different from that announced in 1973. Thus, FDA considers acupuncture devices still to be in investigational status and not to have been in commercial distribution before the amendments, for purposes of section 513 of the act. Under section 513 (b)(1) and (f), FDA does not publish for comment proposed classification regulations for devices that were not in commercial distribution before the amendments (other than postamendments devices that are substantially equivalent to those in commercial distribution before the amendments). Proposed classification regulations are unnecessary for these devices because section 513(f) of the statute itself classifies them into class III, unless reclassified by FDA orders. Because devices classified into class III by section 513(f) of the act were not in commercial distribution before the amendments, the devices are subject immediately to the premarket approval requirements of section 515 without benefit of the statutory grace period under section 501(f)(2)(A) for preamendments class III devices and postamendments, substantially equivalent devices.

The agency will, at a later date, publish final regulations describing the statutory class III status for certain devices so classified by section 513(f) of the act, as well as the status of devices reclassified by orders under section 513(f), and those formerly considered new drugs and classified into class III by section 520(1) of the act.

Because FDA believes that acupuncture devices should remain in investigational status until safety and effectiveness have been demonstrated, sponsors and investigators of acupuncture devices will be required to comply with the final regulation governing applications for an investigational device exemption (IDE) when that regulation is promulgated and becomes effective. A proposed IDE regulation was published in the Federal Register of August 20, 1976 (41 FR 35282). Upon receipt of comments, the proposed regulation was revised, and a tentative final regulation was published in the Federal Register of May 12, 1978 (43 FR 20726). Sponsors and investigators of acupuncture devices should be prepared to comply with the final IDE regulation when it becomes effective.

FDA also has issued proposed general regulations on the responsibilities of sponsors and monitors of clinical investigations in the Federal Register of September 27, 1977 (42 FR 49612); standards for investigational review boards for clinical investigations in the Federal Register of August 8, 1978 (43 FR 31585), reproposed in the Federal Register of August 14, 1979 (44 FR 47699); obligations of clinical investigators of regulated articles in the Federal Register of August 8, 1978 (43 FR 35210); and informed consent in the Federal Register of August 14, 1978 (44 FR 47713). Sponsors and investigators should refer to these proposals for additional guidance in conducting investigational studies involving acupuncture devices.

Life Supporting or Life Sustaining Devices Proposed for Classification in Class II

The Panel has identified 38 devices the Panel believes are life supporting or life sustaining devices. The Panel believes that premarket approval is unnecessary for these 38 devices. The agency agrees that some of these devices are life supporting or sustaining, but that some may not be in that category. The agency has concurred in the Panel's recommendations that these devices be classified into Class II. For each of these 38 devices, the Panel specifically found that it is unnecessary to classify the device in Class III because there is sufficient information to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device.

Because of the unusually large number of life supporting or life sustaining devices proposed for classification in Class II, FDA believes that it is important to emphasize two features of anesthesiology and respiratory therapy devices that contribute to this result. First, anesthesiology and respiratory therapy devices are, by nature, intended for use in connection with the life supporting functions of the body. Consequently, a larger percentage of such devices are life supporting than is the case in other therapeutic categories. Second, although many devices used in anesthesiology are life supporting, the principles governing their operation are well known and accepted in the medical community. All are devices with which the members of the Panel have had sufficient experience to determine whether there is enough information to develop a performance standard to assure their safety and effectiveness. Many of the devices have been in use for decades. Many are the subject of existing performance standards written by, or standards that are currently under development by, various institutions.

Environmental Impact

FDA has carefully considered the environmental effects of proposed § 868.1 and the proposed anesthesiology 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 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 of Food and Drugs (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 868, Subpart A, to read as follows:

PART 868—ANESTHESIOLOGY DEVICES

Subpart A—General Provisions

Sec.
868.1 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

§ 868.1 Scope.

(a) This part sets forth the classification of anethesiology 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, and anesthesiology device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed in one subpart only.

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administation.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33334 Filed 11–1–79; 8:45 am]
BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1649]

Medical Devices; Classification of Manual Algesimeters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying manual algesimeters into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into the class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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:

James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of manual algesimeters:

1. Identification: A manual algesimeter is a mechanical device used to determine a patient's sensitivity to pain after using an anesthetic agent, e.g., by pricking with a sharp point.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempted from good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that manual algesimeters 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 Panel does not believe that this device requires performance standards to control the identified risks to health. The Panel recommends that the manufacturer not be required to comply with the good manufacturing practice requirement because the good manufacturing practice regulations would not improve the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Skin trauma: Sharp edges or surface imperfections may cause trauma to the patient's skin.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that manual algesimeters be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of a manual algesimeter be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21

CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of a manual algesimeter must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of a manual algesimeter must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 by adding new Subpart B and new § 868.1030, to read as follows:

Subpart B—Diagnostic Devices

§ 868.1030 Manual algesimeter.

(a) *Identification.* A manual algesimeter is a mechanical device used to determine a patient's sensitivity to pain after using an anesthetic agent, e.g., by pricking with a sharp point.

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 19, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33335 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1650]

Medical Devices; Classification of Powered Algesimeters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered algesimeters into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into the class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panal Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of powered algesimeters:

1. Identification: A powered algesimeter is a device using electrical stimulation to determine a patient's sensitivity to pain after administration of an anesthetic agent.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be low priority.

3. Summary of reasons for recommendation: The Panel recommends that the powered algesimeter be classified into class II (performance standards) because the design of, and the materials used in, the device must be adequate to assure that neither the patient nor the operator are shocked or burned from excessive leakage current. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panal believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this and related devices.

5. Risks to health: (a) Electrical shock: If the device is not properly designed, the patient or operator may receive an electrical shock. (b) Excessive muscle contraction: Excessive current or improper output parameters can cause the patient to have excessive muscle contractions.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that powered algesimeters be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The Agency also believes that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1040, to read as follows:

§ 868.1040 Powered algesimeter.

(a) *Identification.* A powered algesimeter is a device using electrical stimulation to determine a patient's sensitivity to pain after administration of an anesthetic agent.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m. Monday through Friday.

Dated: September 19, 1979.

William F. Randolph

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33336 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1651]

Medical Devices; Classification of Argon Gas 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 argon gas analyzers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of argon gas analyzers:

1. Identification: An argon gas analyzer is a device used to measure the connection of argon in a gas mixture to aid in determining the patient's ventilatory status. The device may use techniques such as mass spectrometry or thermal conductivity.

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 argon gas analyzers be classified into class II (performance standards) because the device must accurately measure the argon gas concentration to ensure that the patient's ventilatory status will be properly assessed. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Inappropriate therapy: Inaccurate measurement of the argon gas concentration may cause the patient's condition to be incorrectly diagnosed and treated.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that argon gas analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 by adding new Subpart B including § 868.1075, to read as follows:

SUBPART B—DIAGNOSTIC DEVICES

§ 868.1075 Argon gas analyzer.

(a) *Identification.* An argon gas analyzer is a device used to measure the concentration of argon in a gas mixture to aid in determining the patient's ventilatory status. The device may use techniques such as mass spectrometry or thermal conductivity.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 19, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33337 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1652]

Medical Devices; Classification of Arterial Blood Sampling 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 arterial blood sampling kits into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of arterial blood sampling kits:

1. Identification: An arterial blood sampling kit is a device, in kit form, used to obtain arterial blood samples from a patient for blood gas determinations. The kit may include a syringe, needle, cork, and heparin.

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 arterial blood sampling kits be classified into class II (performance standards) to assure that the device is sterile to prevent infection, and that the kit contains the proper amount of heparin and that the syringe does not leak, leading to inaccurate oxygen tension measurements. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Inappropriate therapy: An improper amount of heparin in the syringe, or atmospheric contamination caused by leakage of the syringe, may cause errors in the measurement of arterial oxygen tension resulting in inappropriate therapy. (b) Infection: If the device is not sterile, infection may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that arterial blood sampling kits be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1100, to read as follows:

§ 868.1100 Arterial blood sampling kit.

(a) *Identification.* An arterial blood sampling kit is a device, in kit form, used to obtain arterial blood samples from a patient for blood gas determinations. The kit may include a syringe, needle, cork, and heparin.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 19, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33338 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1653]

Medical Devices; Classification of Nonindwelling Blood Carbon Monoxide 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 nonindwelling blood carbon monoxide analyzers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nonindwelling blood carbon monoxide analyzers:

1. Identification: A nonindwelling blood carbon monoxide analyzer is a device used to measure, in vitro, the concentration of carboxyhemoglobin (a compound formed from hemoglobin when exposed to carbon monoxide) in blood, to aid in determining the patient's physiological status.

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 nonindwelling blood carbon monoxide analyzers be classified into class II (performance standards) to assure that the carboxyhemoglobin concentration in the patient's blood is accurately measured. The measurement is necessary to assess the decrease in the oxygen-carrying capacity of the patient's blood to assure proper diagnosis of the patient's condition. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Inappropriate therapy: Inaccurate measurement of the patient's blood carbon monoxide concentration may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that nonindwelling blood carbon monoxide analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1110, to read as follows:

§ 868.1110 Nonindwelling blood carbon monoxide analyzer.

(a) *Identification.* A nonindwelling blood carbon monoxide analyzer is a device used to measure, in vitro, the concentration of carboxyhemoglobin (a compound formed from hemoglobin when exposed to carbon monoxide) in blood to aid in determining the patient's physiological status.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 19, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33339 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1654]

Medical Devices; Classification of Indwelling Blood Oxyhemoglobin Concentration 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 indwelling blood oxyhemoglobin concentration analyzers into class III (premarket approval). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1979. FDA propses that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of indwelling blood oxyhemoglobin concentration analyzers:

1. Identification: An indwelling blood oxyhemoglobin concentration analyzer is a photoelectric device used to measure, in vivo, the oxygen-carrying capacity of hemoglobin in blood to aid in determining the patient's physiological status.

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 indwelling the blood oxyhemoglobin concentration analyzers be classified into class III (premarket approval) because the device presents a potential unreasonable risk of illness or injury to the patient. The Panel believes that insufficient information exists to determine that general controls or standards would be adequate to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the lack of published clinical data relating to the safety of, and the problems associated with this device, and on the lack of widespread clinical experience in using the device.

5. Risks to health: (a) inappropriate therapy: Inaccurate measurement of the blood oxyhemoglobin concentration may cause an incorrect diagnosis,

leading to inappropriate therapy. (b) Thrombus or embolus formation: If the analyzer materials are incompatible with the blood, thrombus or embolus (clot) formation may result. (c) Electrical shock: If the device is not designed properly the patient may recieve an electrical shock. (d) Vascular occlusion: If the device sensor is too large, it may occlude the blood vessel in which it is placed, thus stopping blood flow through that vessel.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that indwelling blood oxyhemoglobin concentration analyzer devices be classified into class III (premarket approval). The agency believes that the device presents a potential unreasonable risk of illness or injury because the design of, and the materials used in, the device may contribute to thrombus or embolus formation, and because erroneous oxyhemoglobin concentration measurements may lead to institution of inappropriate patient therapy. The agency also 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 for 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1120 as follows:

§ 868.1120 Indwelling blood oxyhemoglobin concentration analyzer.

(a) *Identification.* An indwelling blood oxyhemoglobin concentration analyzer is a photoelectric device used to measure, in vivo, the oxygen-carrying capacity of hemoglobin in blood to aid in determining the patient's physiological status.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 19, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33349 Filed 11-1-79; 8:45 am]
BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1655]

Medical Devices; Classification of Nonindwelling Blood Oxyhemoglobin Concentration 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 nonindwelling blood oxyhemoglobin concentration analyzers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nonindwelling blood oxyhemoglobin concentration analyzers:

1. Identification: A nonindwelling blood oxyhemoglobin concentration analyzer is a device used to measure, in vitro, the oxygen-carrying capacity of hemoglobin in blood to aid in determining the patient's physiological status.

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 nonindwelling blood oxyhemoglobin concentration analyzers be classified into class II (performance standards) because the accurate measurement of the patient's blood oxyhemoglobin concentration to assess its oxygen-carrying capacity is necessary to assure proper patient diagnosis. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, nonindwelling blood oxyhemoglobin concentration analyzers.

5. Risks to health: Inappropriate therapy: Inaccurate measurement of the blood exyhemoglobin concentration in a blood sample may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that nonindwelling blood oxyhemoglobin concentration analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1130, to read as follows:

§ 868.1130 Nonindwelling blood oxyhemoglobin concentration analyzer.

(a) *Identification.* A nonindwelling blood oxyhemoglobin concentration anaylzer is a device used to measure, in vitro, the oxygen-carrying capacity of hemoglobin in blood to aid in determining the patient's physiological status.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 19, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33341 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1657]

Medical Devices; Classification of Indwelling Blood Carbon Dioxide Partial Pressure (P_{CO_2}) 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 indwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzers into class III (premarket approval). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of indwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzers:

1. Identification: An indwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzer is a device which consists of a catheter-tip P_{CO_2} transducer (e.g., P_{CO_2} electrode) that is used to measure, in vivo, the partial pressure of carbon dioxide in blood to aid in determining the patient's circulatory, ventilatory, and metabolic status.

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 recommendations: The Panel recommends that indwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzers be classified into class III (premarket approval) because the device presents a potential unreasonable risk of illness or injury to the patient. The Panel also believes that insufficient information exists to determine that general controls or standards would be adequate to provide reasonable assurance of safety or effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the lack of published clinical data, relating to the safety of, and the problems associated with, this device, and on the lack of widespread clinical experience with the device.

5. Risks to health: (a) Inappropriate therapy: If the device is improperly calibrated, the P_{CO_2} measurement may be erroneous, causing an incorrect diagnosis that leads to inappropriate therapy. (b) Thrombus and embolus formation: The analyzer materials may be incompatible with the blood, causing thrombus and embolus (clot) formation. (c) Electrical shock: If the device is improperly designed, users may receive an electrical shock.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that indwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzers be classified into class III (premarket approval). The agency believes that the device presents a potential unreasonable risk of illness or injury because the design of, and the materials used in, the device may contribute to thrombus or embolus formation and erroneous P_{CO_2} measurements may lead to inappropriate patient therapy. The agency 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 for 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1150, to read as follows:

§ 868.1150 Indwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzer.

(a) *Identification.* An indwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzer is a device which consists of a catheter-tip P_{CO_2} transducer (e.g., P_{CO_2} electrode) and is used to measure, in vivo, the partial pressure of carbon dioxide in blood to aid in determining the patient's circulatory, ventilatory, and metabolic status.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading

of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 19, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33342 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1658]

Medical Devices; Classification of Nonindwelling Blood Carbon Dioxide Partial Pressure (P_{CO_2}) 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 nonindwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nonindwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzers:

1. Identification: A nonindwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzer is a device used to measure, in vitro, the partial pressure of carbon dioxide in blood to aid in determining the patient's circulatory, ventilatory, and metabolic status. The device may use techniques such as chemical titration, electrochemical methods, or mass spectrometry.

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 nonindwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzers be classified into class II (performance standards) because the partial pressure of carbon dioxide in a patient's blood must be accurately measured to assure proper diagnosis of the patient's condition. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Inappropriate therapy: Inaccurate measurement of the partial pressure of carbon dioxide in the patient's blood may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that nonindwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1160, to read as follows:

§ 868.1160 Nonindwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzer.

(a) *Identification.* A nonindwelling blood carbon dioxide partial pressure (P_{CO_2}) analyzer is a device used to measure, in vitro, the partial pressure of carbon dioxide in blood to aid in determining the patient's circulatory, ventilatory, and metabolic status. The device may use techniques such as chemical titration, electrochemical methods, or mass spectrometry.

(b) *Classification.* Class II (performance standards). Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 19, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33343 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1659]

Medical Devices; Classification of Indwelling Blood Hydrogen Ion Concentration (pH) 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 indwelling blood hydrogen ion concentration (pH) analyzers into class III (premarket approval). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class III and the recommendation of the Cardiovascular Device Classification Panel that the device be classified into class II. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket

approval application at a date to be set in a future regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides backgroud information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel and the Cardiovascular Device Classification Panel, FDA advisory committees, made the following recommendations regarding the classification of indwelling blood hydrogen ion concentration (pH) analyzers:

1. Identification: An indwelling blood hydrogen ion concentration (pH) analyzer is a device which consists of a catheter-tip pH electrode that is used to measure, in vivo, the hydrogen ion concentration (pH) in blood to aid in determining the patient's acid-base balance.

2. Recommended Classification: The Anesthesiology Device classification Panel recommends that indwelling blood hydrogen ion concentration analyzers be classified in Class III (premarket approval). The Anesthesiology Device Classification Panel recommends that premarket approval of this device be a medium priority. The Cardiovascular Device Classification Panel recommends that the device be classified in Class II (performance standards). The Cardiovascular Panel recommends that establishing performance standards be a low priority.

3. Summary of reasons for recommendation: The Anesthesiology Device Classification Panel recommends that indwelling blood hydrogen ion concentration (pH) analyzers be classified into class III (premarket approval) because the device presents a potential unreasonable risk of illness or injury to the patient. The Panel believes that insufficient information exists to determine that general controls or standards would be adequate to provide reasonable assurance of the safety and effectiveness of the device. The Cardiovascular Device Classification 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 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. Certain performance characteristics of the pH catheter probe, such as electrical isolation, accuracy, and stability, 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 would provide reasonable assurance of safety and effectivenss of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Anesthesiology Device Classification Panel based its recommendation on the lack of published clinical data relating to the safety of, and the problems associated with, this device, and on the lack of widespread clinical experience in using the device. The Cardiovascular Device Classification Panel based its recommendation on the potential hazards associated with the inherent properties of the device and on the Panel members knowledge of, and clinical experience with, the device.

5. Risks to health: Both the Anesthesiology Device Classification Panel and the Cardiovascular Device Classification Panel identified the following risks to health: (a) Inappropriate therapy: If the device is improperly calibrated, erroneous pH measurements may cause an incorrect diagnosis, leading to inappropriate therapy. (b) Thrombus or embolus formation: The analyzer materials may be incompatible with the blood, leading to thrombus on embolus (clot) formation. (c) Electrical shock: If the device is improperly designed, the patient may receive an electrical shock.

Proposed Classification

FDA agrees with the Anesthesiology Device Classification Panel recommendation and is proposing that indwelling blood hydrogen ion concentration (pH) analyzers be classified into class III (premarket approval). FDA disagrees with the Cardiovascular Device Classification Panel recommendation that indwelling blood hydrogen ion concentration (pH) analyzers be classified into class II (performance standards). The agency believes the device presents a potential unreasonable risk of illness or injury because the design of, and the materials used in the device may contribute to thrombus or embolus formation and because erroneous pH mesurement may lead to inappropriate patient therapy. The agency believes that insufficient information exists to determine that general controls would provide reasonable assurance of the safety and effectiveness of the device and that insufficient information exists to establish a performance standard for 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1170, to read as follows:

§ 868.1170 Indwelling blood hydrogen ion concentration (pH) analyzer.

(a) *Identification.* An indwelling blood hydrogen ion concentration (pH) analyzer is a device which consists of a catheter-tip pH electrode that is used to measure, in vivo, the hydrogen ion concentration (pH) in blood to aid in determining the patient's acid-base balance.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 2, 1980, submit to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600

Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 19, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33344 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1660]

Medical Devices; Classification of Nonindwelling Blood Hydrogen Ion Concentration (pH) 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 nonindwelling blood hydrogen ion concentration (pH) analyzers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulations. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nonindwelling blood hydrogen-ion concentration (pH) analyzers:

1. Identification: A nonindwelling blood hydrogen ion concentration (pH) analyzer is a device that uses electrochemical electrodes to measure, in vitro, the hydrogen ion concentration of blood to aid in determining the patient's acid-base balance.

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 reason for recommendation: The Panel recommends that nonindwelling blood hydrogen ion concentration (pH) analyzers be classified into class II (performance standards) because the patient's blood pH must be accurately measured to assure proper diagnosis of the patient's condition. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's person knowledge of, and clinical experience with, the device.

5. Risks to health: Inappropriate therapy: Inaccurate measurement of the blood hydrogen ion concentration (pH) may cause an incorrect diagnosis, leading to inappropriate therapy.

Propose Classification

FDA agrees with the Panel recommendation and is proposing that nonindwelling blood hydrogen ion concentration (pH) analyzers be classified into class II. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 549-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1180, to read as follows:

§ 868.1180 Nonindwelling blood hydrogen ion concentration (pH) analyzer.

(a) *Identification.* A nonindwelling blood hydrogen ion concentration (pH) analyzer is a device that uses electrochemical electrodes to measure, in vitro, the hydrogen ion concentration of blood to aid in determining the patient's acid-base balance.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 19, 1979.

William F. Randloph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33345 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1661]

Medical Devices; Classification of Nonindwelling Blood Nitrogen Partial Pressure (PN_2) 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 non-indwelling blood nitrogen partial pressure (PN_2) analyzers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nonindwelling blood nitrogen partial pressure (PN_2) analyzers:

1. Identification: A nonindwelling blood nitrogen partial pressure (PN_2) analyzer is a device used to measure, in vitro, the partial pressure of nitrogen in blood to aid in determining the patient's circulatory, ventilatory, and metabolic status.

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 nonindwelling blood nitrogen partial pressure (PN_2) analyzers be classified into class II (performance standards) because the partial pressure of nitrogen in a patient's blood must be accurately measured to assure proper diagnosis of the patient's condition. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, nonindwelling blood nitrogen partial pressure (PN_2) analyzers.

5. Risks to health: Inappropriate therapy: Inaccurate measurement of the partial pressure of nitrogen in the patient's blood may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that nonindwelling blood nitrogen partial pressure (PN_2) analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 the authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1190, to read as follows:

§ 868.1190 Nonindwelling blood nitrogen partial pressure (PN_2) analyzer.

(a) *Identification.* A nonindwelling blood nitrogen partial pressure (PN_2) analyzer is a device used to measure, in vitro, the partial pressure of nitrogen in blood to aid in determining the patient's circulatory, ventilatory, and metabolic status.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 19, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33346 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1662]

Medical Devices; Classification of Indewelling Blood Oxygen Partial Pressure (P_{o_2}) 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 indwelling blood oxygen partial pressure (P_{o_2}) analyzers into class III (premarket approval). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel, the General and Plastic Surgery Device Classification Panel, and the General Hospital and Personal Use Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation.

The Anesthesiology Device Classification Panel, the General and Plastic Surgery Device Classification Panel, and the General Hospital and Personal Use Device Classification Panel, FDA advisory committees, made the following recommendation regarding the classification of indwelling blood oxygen partial pressure (P_{O_2}) analyzers:

1. Identification: An indwelling blood oxygen partial pressure (P_{O_2}) analyzer is a device which consists of a catheter-tip P_{O_2} transducer (e.g., P_{O_2} electrode) that is used to measure, in vivo, the partial pressure of oxygen in blood to aid in determining the patient's circulatory, ventilatory, and metabolic status.

2. Recommended classification: Class III (premarket approval). The Anesthesiology Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the General and Plastic Surgery Device Classification Panel recommend that indwelling blood oxygen partial pressure (P_{O_2}) analyzers be classified into class III (premarket approval). The Anesthesiology Device Classification Panel recommends that premarket approval of this device be a medium priority. The General Hospital Device Classification Panel and the General and Plastic Surgery Device Classification Panel recommend that premarket approval of this device be a high priority.

3. Summary of reasons for recommendation: The Anesthesiology Device Classification Panel recommends that indwelling blood oxygen partial pressure (P_{O_2}) analyzers be classified into class II because the device presents a potential unreasonable risk of illness or injury. The Panel believes that insufficient information exists to determine that general controls or performance standards would be adequate to provide reasonable assurance of the safety or effectiveness of the device. The General Hospital and Personal Use Device Classification Panel cited insufficient information concerning the device and the potential for misdiagnosis of P_{O_2} as reasons for recommending classification into class III. The General and Plastic Surgery Device Classification Panel cited the high incidence of blood clot formation resulting from use of the device and insufficient information to establish an adequate performance standards for the device as reasons for its recommendation that the device be classified into class III.

4. Summary of data on which the recommendation is based: The Anesthesiology Device Classification Panel, the General Hospital and Personal Use Device Classification Panel, and the General and Plastic Surgery Device Classification Panel based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the device. The Panels also based their recommendations on the lack of published clinical data available relating to the safety of, and the problems associated with, this device, and on the lack of widespread clinical experience in using the device.

5. Risks to health: Both the Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel identified the following risks to health: (a) Inappropriate therapy: If the deivce is improperly calibrated, erroneous measurement of the blood P_{O_2} may cause an incorrect diagnosis of the patient's condition, leading to inappropriate therapy. (b) Embolus formation: Analyzer materials may be incompatible with the blood, causing thrombus or embolus formation. (c) Bleeding: The P_{O_2} analyzer may puncture the blood vessel, resulting in potentially fatal bleeding. (d) Electrical shock: If the device is improperly designed, the patient may receive an electrical shock. In addition to the foregoing, the General and Plastic Surgery Device Classification Panel identified the following risks to health: (e) Infection: If the device is not sterile, infection may result. (f) Bleeding: Poor mechanical integrity of the catheter-electrode components may cause them to disassemble accidentally, resulting in severe blood loss from the patient.

Proposed Classification

FDA agrees with the Panels' recommendations and is proposing that indwelling blood oxygen partial pressure (P_{O_2}) analyzers be classified into class III (premarket approval). The agency believes the device presents a potential unreasonable risk of illness or injury because the design of, and the materials used in, the device may contribute to thrombus or embolus formation and because erroneous blood oxygen partial pressure measurements may lead to institution of inappropriate patient therapy. The agency believes that premarket approval is necessary for this device because general controls or performance standards are insufficient to control the above described risks to health and thus cannot 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1200, to read as follows:

§ 868.1200 Indwelling blood oxygen partial pressure (P_{O_2}) analyzer.

(a) *Identification.* An indwelling blood oxygen partial pressure (P_{O_2}) analyzer is a device which consists of a catheter-tip P_{O_2} transducer (e.g., P_{O_2} electrode) that is used to measure, in vivo, the partial pressure of ozygen in blood to aid in determining the patient's circulatory, ventilatory, and metabolic status.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 6500 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 19, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33347 Filed 11-1-79; 8:45 am]
BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1663]

Medical Devices; Classification of Nonindwelling Blood Oxygen Partial Pressure (P_{O_2}) 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 nonindwelling blood oxyen partial pressure (P_{O_2}) analyzers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nonindwelling blood oxygen partial pressure (P_{O_2}) analyzers:

1. Identification: A nonindwelling blood oxygen partial pressure (P_{O_2}) analyzer is a device used to measure, in vitro, the partial pressure of oxygen in blood to aid in determining the patient's circulatory, ventilatory, and metabolic status. The device may use techniques such as electrochemical electrodes, gas chromatography, or mass spectrometry.

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 nonindwelling blood oxygen partial pressure (P_{O_2}) analyzers be classified into class II (performance standards) because the partial pressure of oxygen in a patient's blood must be accurately measured to assure proper diagnosis of the patient's condition. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Inappropriate therapy: Inaccurate measurement of the partial pressure of oxygen in the patient's blood may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that nonindwelling blood oxygen partial pressure (P_{O_2}) analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1210, to read as follows:

§ 868.1210 Nonindwelling blood oxygen partial pressure (P_{O_2}) analyzer.

(a) *Identification.* A nonindwelling blood oxygen partial pressure (P_{O_2}) analyzer is a device used to measure, in vitro, the partial pressure of oxygen in blood to aid in determining the patient's circulatory, ventilatory, and metabolic status. The device may use techniques such as electrochemical electrodes, gas chromatography, or mass spectrometry.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33348 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1664]

Medical Devices; Classification of Calibrated Breathing System Collection Bottles

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying calibrated breathing system collection bottles into class II (performance standards). The FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of calibrated breathing system collection bottles:

1. Identification: A calibrated breathing system collection bottle is a calibrated container that is used to collect fluids aspirated from a patient and that is capable of protecting the vacuum source by stopping the vacuum when the container overflows.

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 calibrated breathing system collection bottle be classified into class II (performance standards) to assure that the graduations on the bottle are correctly calibrated. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Inaccurate measurement: Inaccurate graduations on the bottle will cause inaccurate measurement of the volume of aspirated fluid. (b) Inadequate suction: Inadequate sealing of the bottle will decrease its effectiveness, due to air leakage. (c) Contamination of main vacuum system: Failure of the automatic cutoff may result in contamination of the main vacuum system, increasing the risk of patient infections.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that calibrated breathing system collection bottles be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1250, to read as follows:

§ 868.1250 Calibrated breathing system collection bottle.

(a) *Identification.* A calibrated breathing system collection bottle is a calibrated container that is used to collect fluids aspirated from a patient and that is capable of protecting the vacuum source by stopping the vacuum when the container overflows.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33349 Filed 11-1-79; 8:45 am]
BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1665]

Medical Devices; Classification of Uncalibrated Breathing System Collection Bottles

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying uncalibrated breathing system collection bottles into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of uncalibrated breathing system collection bottles:

1. Identification: An uncalibrated breathing system collection bottle is a container that is used to collect fluids aspirated from a patient and that is capable of protecting the vacuum source by stopping the vacuum when the container overflows.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that uncalibrated breathing system collection bottles 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 Panel does not believe that this device requires performance standards to control the identified risks to health. The Panel recommends that the manufacturer not be required to comply with the good manufacturing practice requirements because compliance with those requirements would not improve the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Inadequate suction: Inadequate sealing of the bottle will decrease its effectiveness due to air leakage. (b) Contamination of the main vacumm system: Failure of the automatic cutoff may result in contamination of the main vacumm system, increasing the risk of patient infections.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that uncalibrated breathing system collection bottles be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of an uncalibrated breathing system collection bottle be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820. 198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of an uncalibrated breathing system collection bottle must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigations and followup. The agency also believes that manufacturers of an uncalibrated breathing system collection bottle must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1260, to read as follows:

§ 868.1260 Uncalibrated breathing system collection bottle.

(a) *Identification.* An uncalibrated breathing system collection bottle is a container that is used to collect fluids aspirated from a patient and that is capable of protecting the vacuum source by stopping the vacuum when the container overflows.

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33350 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1666]

Medical Devices; Classification of Carbon Dioxide Gas 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 carbon dioxide gas analyzers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of carbon dioxide gas analyzers:

1. Identification: A carbon dioxide gas analyzer is a device used to measure the concentration of carbon dioxide in a gas mixture to aid in determining the patient's ventilatory, circulatory, and metabolic status. The device may use techniques such as chemical titration, absorption of infrared radiation, gas chromatography, and mass spectrometry.

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 carbon dioxide gas analyzers be classified into class II (performance standards) because the carbon dioxide concentration in a patient's breath must be accurately measured to assure proper diagnosis of the patient's condition. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: Inappropriate therapy: Inaccurate measurement of the carbon dioxide concentration may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that carbon dioxide gas analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1400, as follows:

§ 868.1400 Carbon dioxide gas analyzer.

(a) *Identification.* A carbon dioxide gas analyzer is a device used to measure the concentration of carbon dioxide in a gas mixture to aid in determining the patient's ventilatory, circulatory, and metabolic status. The device may use techniques such as chemical titration, absorption of infrared radiation, gas chromatography, and mass spectrometry.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33351 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1667]

Medical Devices; Classification of Carbon Monoxide Gas 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 carbon monoxide gas analyzers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of carbon monoxide gas analyzers:

1. Identification: A carbon monoxide gas analyzer is a device used to measure the concentration of carbon monoxide in a gas mixture to aid in determining the patient's ventilatory status. The device may use techniques such as infrared absorption and gas chromatography.

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 carbon monoxide gas analyzers be classified into class II (performance standards) because the carbon monoxide concentration in a patient's breath must be accurately measured to assure proper diagnosis of the patient's condition. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: Inappropriate therapy: Inaccurate measurement of the carbon monoxide concentration in a gas mixture may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that carbon monoxide gas analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1430, to read as follows:

§ 868.1430 Carbon monoxide gas analyzer.

(a) *Identification.* A carbon monoxide gas analyzer is a device used to measure the concentration of carbon monoxide in a gas mixture to aid in determining the patient's ventilatory status. The device may use techniques such as infrared absorption and gas chromatography.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be

identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33352 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1668]

Medical Devices; Classification of Enflurane Gas 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 enflurane gas analyzers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of enflurane gas analyzers:

1. Identification: An enflurane gas analyzer is a device used to measure the concentration of enflurane anesthetic in a gas mixture.

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 enflurane gas analyzer be classified into class II (performance standards) because the device must accurately measure the concentration of enflurane anesthetic in a gas mixture to assure that the patient is properly anesthetized. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Memory and pain: If the device's calibration is faulty and the patient receives too low a concentration of enflurane to be properly anesthetized, the patient may experience pain during surgery and remember the surgery afterwards. (b) Cardiopulmonary arrest: Excessive depth of anesthesia caused by faulty calibration may induce cardiopulmonary arrest and possibly death.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that enflurane gas analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1500, to read as follows:

§ 868.1500 Enflurane gas analyzer.

(a) *Identification.* An enflurane gas analyzer is a device used to measure the concentration of enflurane anesthetic in a gas mixture.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33353 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78-1669]

Medical Devices; Classification of Gas Collection Vessels

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying gas collection vessels into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gas collection vessels:

1. Identification: A gas collection vessel is a containerlike device used to collect a patient's exhaled gases for subsequent analysis. It does not include a sampling pump.

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 gas collection vessels be classified into calss II (performance standards) because the design of, and the materials used in, the device must be controlled to assure that the patient's exhaled gases are sampled properly and to prevent gas leaks or absorption of the sampled gas in the device. Improper sampling or sample storage may result in an inaccurate analysis of the sampled gases that could cause an incorrect diagnosis, leading to inappropriate therapy. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Inappropriate therapy: System leaks or absorption of the sampled gas in the device may result in the inaccurate measurement of the sampled gas. The inaccurate measurement may cause an incorrect diagnosis of the patient's condition, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that gas collection vessels be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1575, to read as follows:

§ 868.1575 Gas collection vessel.

(a) *Identification.* A gas collection vessel is a container-like device used to collect a patient's exhaled gases for subsequent analysis. It does not include a sampling pump.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, 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 any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33354 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1670]

Medical Devices; Classification of Halothane Gas 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 halothane gas analyzers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of halothane gas analyzers:

1. Identification: A halothane gas analyzer is a device used to measure the concentration of halothane anesthetic in a gas mixture. The device may use techniques such as mass spectrometry or absorption of infrared and ultraviolet radiation.

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 halothane gas analyzers be classified into class II (performance standards) because the device must accurately measure the concentration of halothane anesthetic in a gas mixture to assure that the patient is properly anesthetized. The Panel believes that general controls will not

provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Memory and pain: If the device's calibration is faulty and the patient receives too low a concentration of halothane to be properly anesthetized, the patient may experience pain during surgery and/or remember the surgery afterwards. (b) Cardiopulmonary arrest: Excessive depth of anesthesia caused by faulty calibration, may induce cardiopulmonary arrest and possible death.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that halothane gas analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1620, to read as follows:

§ 868.1620 Halothane gas analyzer.

(a) *Identification.* A halothane gas analyzer is a device used to measure the concentration of halothane anesthetic in a gas mixture. The device may use techniques such as mass spectrometry or absorption of infrared and ultraviolet radiation.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33355 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1671]

Medical Devices; Classification of Helium Gas 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 helium gas analyzers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of helium gas analyzers:

1. Identification: A helium gas analyzer is a device used to measure the concentration of helium in a gas mixture during pulmonary function testing. The device may use techniques such as thermal conductivity, gas chromatography, or mass spectrometry.

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 helium gas analyzers be classified into class II (performance standards) because the helium concentration in a gas mixture must be accurately measured to assure proper diagnosis of the patient's condition. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Inappropriate therapy: Inaccurate measurement of the helium gas concentration may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that helium gas analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1640, to read as follows:

§ 868.1640 Helium gas analyzer.

(a) *Identification.* A helium gas analyzer is a device used to measure the concentration of helium in a gas mixture during pulmonary function testing. The device may use techniques such as thermal conductivity, gas chromatography, or mass spectrometry.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33356 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1672]

Medical Devices; Classification of Neon Gas 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 neon gas analyzers into class II (performance standards). FDA is also publishing the recommendation of 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 furture development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of neon gas analyzers:

1. Identification: A neon gas analyzer is a device used to measure the concentration of neon in a gas mixture exhaled by a patient. The device may use techniques such as mass spectrometry or thermal conductivity.

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 neon gas analyzers be classified into class II (performance standards) because the neon concentration in a gas mixture must be accurately measured to assure proper diagnosis of the patient's condition. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Inappropriate therapy: Inaccurate measurement of the neon gas concentration may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the neon gas analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1670, to read as follows:

§ 868.1670 Neon gas analyzer.

(a) *Identification.* A neon gas analyzer is a device used to measure the concentration of neon in a gas mixture exhaled by a patient. The device may use techniques such as mass spectrometry or thermal conductivity.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33357 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1673]

Medical Devices; Classification of Nitrogen Gas 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 nitrogen gas analyzers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nitrogen gas analyzers:

1. Identification: A nitrogen gas analyzer is a device used to measure the concentration of nitrogen in respiratory gases to aid in determining the patient's ventilatory status. The device may use techniques such as gas chromatography or mass spectrometry.

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 nitrogen gas analyzers be classified into class II (performance standards) because the nitrogen concentration in a patient's breath must be accurately measured to assure proper diagnosis of the patient's condition. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Inappropriate therapy: Inaccurate measurement of the nitrogen gas concentration may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that nitrogen gas analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1690, to read as follows:

§ 868.1690 Nitrogen gas analyzer.

(a) *Identification.* A nitrogen gas analyzer is a device used to measure the concentration of nitrogen in respiratory gases to aid in determining the patient's ventilatory status. The device may use techniques such as gas chromatography or mass spectrometry.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33358 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1674]

Medical Devices; Classification of Nitrous Oxide Gas 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 nitrous oxide gas analyzers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, An FDA advisory committee, made the following recommendation regarding the classification of nitrous oxide gas analyzers:

1. Identification: A nitrous oxide gas analyzer is a device used to measure the concentration of nitrous oxide anesthetic in a gas mixture. The device may use techniques such as infrared absorption or mass spectrometry.

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 nitrous oxide gas analyzers be classified into class II (performance standards) because the device's accurancy must be adequate to assure that the patient is properly anesthetized. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Hypoxemia: Patient hypoxemia (deficient blood oxygenation) may be caused by an excessive concentration of nitrous oxide due to faulty analyzer calibration. (b) Memory and pain: If the device's calibration is faulty and causes the patient to receive too low a concentration of nitrous oxide to be properly anesthetized, the patient may experience pain during surgery and/or remember the surgery afterwards. (c) Cardiopulmonary arrest: Excessive depth of anesthesia caused by faulty analyzer calibration could lead to cardiopulmonary arrest.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that nitrous oxide gas analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1700, to read as follows:

§ 868.1700 Nitrous oxide gas analyzer.

(a) *Identification.* A nitrous oxide gas analyzer is a device used to measure the concentration of nitrous oxide anesthetic in a gas mixture. The device may use techniques such as infrared absorption or mass spectrometry.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33359 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1675]

Medical Devices; Classification of Oxygen Gas 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 oxygen gas analyzers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of oxygen gas analyzers:

1. Identification: An oxygen gas analyzer is a device used to measure the concentration of oxygen in respiratory gases by techniques such as mass spectrometry, polaragraphy, thermal conductivity, or gas chromatography. This generic type of device also includes paramagnetic analyzers.

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 oxygen gas analyzers be classified into class II (performance standards) because the device should accurately display the oxygen concentration of the gases being supplied to the patient. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel noted that an American National Standards Institute Committee has drafted a proposed standard for this device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Hypoxia or hyperoxia: If the oxygen concentration of the gases breathed by the patient are inaccurately measured, the patient may receive too much oxygen, resulting in hyperoxia, or too little oxygen, resulting in hypoxia.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that oxygen gas analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health

presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1720, to read as follows:

§ 868.1720 Oxygen gas analyzer.

(a) *Identification.* An oxygen gas analyzer is a device used to measure the concentration of oxygen in respiratory gases by techniques such as mass spectrometry, polaragraphy, thermal conductivity, or gas chromatography. This generic type of device also includes paramagnetic analyzers.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33360 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1676]

Medical Devices; Classification of Oxygen Uptake 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 oxygen uptake computers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of oxygen uptake computers:

1. Identification: An oxygen uptake computer is a device used to compute the amount of oxygen consumed by the patient and may include components for determining expired gas volume and composition.

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 oxygen uptake computers be classified into class II (performance standards) because the device must accurately compute the amount of oxygen consumed by the patient. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel noted that the National Fire Protection Association has been involved in developing standards for this device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: In appropriate therapy: Inaccurate measurement of oxygen consumption may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the oxygen uptake computers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1730, to read as follows:

§ 868.1730 Oxygen uptake computer.

(a) *Identification.* An oxygen uptake computer is a device used to compute the amount of oxygen consumed by the patient and may include components for determining expired gas volume and composition.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33361 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1677]

Medical Devices; Classification of Pressure 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 plethysmographs into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of pressure plethysmographs:

1. Identification: A pressure Plethysmograph is a device used to determine a patient's airway resistance and lung volumes by measuring pressure changes while the patient is in an airtight box.

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 pressure plethysmographs be classified into class II (performance standards) because the mechanical design of, the device must be controlled to assure that the patient is able to open the chamber from the inside in the event that the operator is incapacitated. The electrical design of the device must be adequate to assure that the user does not receive an electrical shock. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Suffocation: The patient may suffocate if unable to open the chamber from the inside in the event that the operator is incapacitated. (b) Electrical shock: If the device is not designed properly, the user may recieve an electrical shock.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that pressure plethysmographs be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1750, to read as follows:

§ 868.1750 Pressure plethysmograph.

(a) *Identification.* A pressure plethysmograph is a device used to determine a patient's airway resistance and lung volumes by measuring pressure changes while the patient is in an airtight box.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33362 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1678]

Medical Devices; Classification of Volume 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 volume plethysmographs into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of volume plethysmographs:

1. Identification: A volume plethysmograph is an airtight box, in which the patient sits, that is used to determine the patient's lung volume changes.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standards for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that volume plethysmographs be classified into class II (performance standards) because the mechanical design of the device must be controlled to assure that the patient is able to open the chamber from the inside in the vent that the operator is incapacitated. The electrical design of the device must be adequate to assure that the user does not receive an electrical shock. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Suffocation: The patient may suffocate if unable to open the chamber from the inside in the event that the operator is incapacitated. (b) Electrical shock: If the device is not properly designed, the user may receive an electrical shock.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that volume plethysmographs be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1760, to read as follows:

§ 868.1760 Volume plethysmograph.

(a) *Identification.* A volume plethysmograph is an airtight box, in which the patient sits, that is used to determine the patient's lung volume changes.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33363 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1679]

Medical Devices; Classification of Inspiratory Airway Pressure Meters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying inspiratory airway pressure meters into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of inspiratory airway pressure meters:

1. Identification: An inspiratory airway pressure meter is a device used to measure the amount of pressure produced in a patient's airway during maximal inspiration.

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 inspiratory airway pressure meters be classified into class II (performance standards) because the device must accurately measure a patient's inspiratory pressure. The design of, and the materials used in, the device must be controlled to prevent asphyxiation of the patient. In addition, there must be assurance that the device can be cleaned and sterilized to prevent infection due to contamination of the device. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Asphyxia: Improper design or use of this device may cause asphyxiation of the patient. (b) Inappropriate therapy: Inaccurate calibration or inspiratory pressure measurement may cause an incorrect diagnosis, leading to inappropriate therapy. (c) Patient infection: If the device is not cleaned or sterilized properly, infection may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that inspiratory airway pressure meters be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1780, to read as follows:

§ 868.1780 Inspiratory airway pressure meter.

(a) *Identification.* An inspiratory airway pressure meter is a device used to measure the amount of pressure produced in a patient's airway during maximal inspiration.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33364 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1680]

Medical Devices; Classification of Rhinoanemometers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rhinoanemometers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into the class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panal Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rhinoanemometers:

1. Identification: A rhinoanemometer is a device used to quantify the amount of nasal congestion by measuring the airflow through, and differential pressure across, a patient's nasal passages.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be low priority.

3. Summary of reasons for recommendation: The Panel recommends that rhinoanemometers be classified into class II (performance standards) because the device design must be controlled to assure that is accurately measures the degree of nasal congestion. The Anesthesiology Device Classification Panel recommended at its August 16, 1977 meeting that this device be classified into class I (general controls) because, at that time, the Panel believed that general controls were sufficient to assure the safety and effectiveness of the device. However, during its January 24, 1978 meeting, the Panel reconsidered its original decision, and recommended that the device be classified into class II because the device provides a quantifiable output that must be accurate. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' review of the literiature on this device (Refs. 1 and 2), and on the Panel members' knowldge of related devices (i.e., pneumotachometers and differential pressure transducers).

5. Risks to health: (a) Injury: Sharp edges or other poor design characteristics may cause trauma upon insertion of the device. (b) Inappropriate therapy: Inaccurate determination of gas flow and pressure may cause the patient's condition to be incorrectly diagnosed, resulting in inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that rhinoanemometers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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. Kern, E. B., "Rhinoanemometry," *Otolaryngologic Clinics of North America*, 6[3]: 863–874, 1973.

2. Undritz, W., "The Rhinoanemometer," *Acta Laryngolic*, 14: 513–524, 1930.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1800, to read as follows:

§ 868.1800 Rhinoanemometer.

(a) *Identification.* A rhinoanemometer is a device used to quantify the amount of nasal congestion by measuring the airflow through, and differential pressure across, a patient's nasal passages.

b. *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33365 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1681]

Medical Devices; Classification of Diagnostic Spirometers

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 spirometers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of diagnostic spirometers:

1. Identification: A diagnostic spirometer is a device used in pulmonary function testing to measure the volume of gas moving in and/or out of the patient's lungs.

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 diagnostic spirometers be classified into class II (performance standards) because the device must generate accurate ventilatory volume or flow data, and because the design of, and the materials used in, the device must be controlled to assure that the device can be disinfected to prevent contamination and infection of patients. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel considered the 1976 American Thoracic Society (ATS) pulmonary spirometry standard (Ref. 1).

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, diagnostic spirometers. These devices have been widely used for many years.

5. Risks to health: (a) Inappropriate therapy: Inaccurate measurement of ventilatory flow data may cause an incorrect diagnosis, leading to inappropriate therapy. (b) Infection: Inability to disinfect the device may result in contamination and infection of patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the diagnostic spirometers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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. American Thoracic Society, Pulmonary Spirometry Standard, 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1840, to read as follows:

§ 868.1840 Diagnostic spirometer.

(a) *Identification.* A diagnostic spirometer is a device used in pulmonary function testing to measure the volume of gas moving in and/or out of the patient's lungs.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may

submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33366 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1682]

Medical Devices; Classification of Monitoring Spirometers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying monitoring spirometers into class II (performance standards). The FDA is also publishing the recommendation of 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.

DATE: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of monitoring spirometers:

1. Identification: A monitoring spirometer is a device used to measure continuously a patient's tidal volume (volume of gas inhaled by the patient during each respiration cycle) or minute volume (the tidal volume multiplied by the rate of respiration for 1 minute) for the evaluation of the patient's ventilatory status.

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 spirometers be classified into class II (performance standards) because this device must accurately measure a patient's tidal and minute volume and because the design of, and the materials used in, the device must be controlled to assure that it can be adequately cleaned and disinfected and that it will not cause a fire or explosion if use with oxygen or inflammable agents. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel noted that certain sections of National Fire Protection Association Standards would apply to this device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Inappropriate therapy: Inaccurate measurement of tidal and minute volume may cause an incorrect diagnosis, leading to inappropriate therapy.

(b) Infection: Inability to disinfect the device may result in contamination and infection of patients.

(c) Burns and trauma: Use of oxygen or other inflammable agents in a spirometer not designed for such use may cause a fire or explosion.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that monitoring spirometers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1850, to read as follows:

§ 868.1850 Monitoring spirometer.

(a) *Identification.* A monitoring spirometer is a device used to measure continuously a patient's tidal volume (volume of gas inhaled by the patient during each respiration cycle) or minute volume (the tidal volume multiplied by the rate of respiration for 1 minute) for the evaluation of the patient's ventilatory status.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33367 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1683]

Medical Devices; Classification of Peak-Flow Meters for Spirometry

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying peak-flow meters for spirometry into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of peak-flow meters for spirometry:

1. Identification: A peak-flow meter for spirometry is a device used to measure a patient's maximum ventilatory flow rate.

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 peak-flow meters for spirometry be classified into class II (performance standards) because the design of, and the materials used in, the device must be controlled to assure that the device does not generate misleading flow-rate data due to an obstruction or excessive resistance in the device, and to assure that the device can be adequately sterilized to prevent infection. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Inappropriate therapy: Inaccurate measurement of maximum ventilatory flow rate may cause an incorrect diagnosis, leading to inappropriate therapy. (b) Infection: If the device is not sterilized properly, infection may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the peak-flow meters for spirometry be classified into class II (performance standards). The agency believes that a performance standards is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1860, to read as follows:

§ 868.1860 Peak-flow meter for spirometry.

(a) *Identification.* A peak-flow meter for spirometry is a device used to measure a patient's maximum ventilatory flow rate.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33368 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1684]

Medical Devices; Classification of Gas Volume Calibrators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying gas volume calibrators into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gas volume calibrators:

1. Identification: A gas volume calibrator is a device that is used to calibrate the output of gas volume

measurement instrumentation by delivering a known gas volume.

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 gas volume calibrators be classified into class II (performance standards) because the device's accuracy must be adequate to assure proper calibration of spirometers and other gas measurement equipment. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Inappropriate therapy: Improper calibration of gas measurement equipment may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that gas volume calibrators be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1870, to read as follows:

§ 868.1870 Gas volume calibrator.

(a) *Identification.* A gas volume calibrator is a device that is used to calibrate the output of gas volume measurement instrumentation by delivering a known gas volume.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33369 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 79N–1685]

Medical Devices; Classification of Pulmonary-Function Data Calculators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pulmonary-function data calculators into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of pulmonary-function data calculators:

1. Identification: A pulmonary-function data calculator is a device used to calculate pulmonary-function values based on actual physical data obtained during pulmonary-function testing.

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 pulmonary-function data calculators be classified into class II (performance standards) because the calculated pulmonary-function values must be accurate to assure proper diagnosis of the patient's conditions. The Panel recommends that the standard require that the labeling for pulmonary-function data calculators include the equations used for calculations of data. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, pulmonary-function data calculators.

5. Risks to health: Inappropriate therapy: Inaccuracies in the calculated pulmonary-function values may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that pulmonary-function data calculators be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient

information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1880, to read as follows:

§ 868.1880 Pulmonary-function data calculator.

(a) *Identification.* A pulmonary-function data calculator is a device used to calculate pulmonary-function values based on actual physical data obtained during pulmonary-function testing.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33370 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1686]

Medical Devices; Classification of Predictive Pulmonary-Function Value Calculators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying predictive pulmonary-function value calculators into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into the class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of predictive pulmonary-function value calculators:

1. Identification: A predictive pulmonary-function value calculators is a device used to calculate normal pulmonary-function value based on empirical equations.

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 predictive pulmonary-function value calculators be classified into class II (performance standards) because the predicted pulmonary-function values must be accurate to assure proper diagnosis of the patient's condition. The Panel recommends that the standard require that the labeling for the device include the empirical equations used for calculation of data. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: Inappropriate therapy: Inaccurancies in the calculation of predicted pulmonary function values may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that predictive pulmonary-function value calculators be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1890, to read as follows:

§ 868.1890 Predictive pulmonary-function value calculator.

(a) *Identification.* A predictive pulmonary-function value calculator is a device used to calculate normal pulmonary-function values based on empirical equations.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33371 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 868

[Docket No. 78N-1687]

Medical Devices; Classification of Diagnostic Pulmonary-Function Interpretation Calculators

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 pulmonary-function interpretation calculators into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (JFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of diagnostic pulmonary-function interpretation calculators:

1. Identification: A diagnostic pulmonary-function interpretation calculator is a device that interprets pulmonary study data to determine the clinical significance of pulmonary-function values.

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 diagnostic pulmonary-function interpretation calculators be classified into class II (performance standards) because accurate interpretation of pulmonary-function data by the device is necessary to assure the proper diagnosis of the patient's condition. The Panel recommends that the standard require that the labeling for the device include the interpretation method used for the calculations of data. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: Inappropriate therapy: Inaccurate interpretation of pulmonary-function data may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that diagnostic pulmonary-function interpretation calculators be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1900, to read as follows:

§ 868.1900 Diagnostic pulmonary-function interpretation calculator.

(a) *Identification.* A diagnostic pulmonary-function interpretation calculator is a device that interprets pulmonary study data to determine the clinical significance of pulmonary-function values.

(b) *Classificaiton.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33372 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1688]

Medical Devices; Classification of Esophageal 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 esophageal stethoscopes into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia

Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of esophageal stethoscopes:

1. Identification: An esophageal stethoscopes is an unpowered device that is inserted into the patient's esophagus to enable the user to listent to heart and breath sounds.

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 esophageal stethoscopes 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 Panel does not believe that this device requires performance standards to control the identified risks to health.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Injury: Improper size or shape of the device, or the use of improper materials in the device may result in trauma to the patient's airways or esophagus when the device is inserted. (b) Infection: If the device is not sterilized properly, infection may result.

Proposed Classification

FDA agrees with the Panel recommendations and is proposing that esophageal stethoscopes be classified into class I (general controls), with no exemptions. The agency 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1910, to read as follows:

§ 868.1910 Esophageal stethoscope.

(a) *Identification.* An esophageal stethoscope is an unpowered device that is inserted into the patient's esophagus to enable the user to listen to heart and breath sounds.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackers in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

FR Doc. 79-33373 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1689]

Medical Devices; Classification of Esophageal Stethoscopes With Electrical Conductors

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying esophageal stethoscopes with electrical conductors into class II (performance standards). FDA is also publishing the recommendation of 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 clasifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of esophageal stethoscopes with electrical conductors:

1. Identification: An esophageal stethoscope with electrical conductors is a device that is inserted into the esophagus to listen to heart and breath sounds and to monitor electrophysiological signals. The device may also incorporate a thermistor for temperature measurement.

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 esophageal stethoscope with electrical conductors be classified into class II (performance standards) because the electrical design of the device must be adequate to assure that the patient does not receive an electrical shock or burn and because the size, shape, and materials of the device must be controlled to assure that the patient's airways and esophagus are not damaged. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Burns and electrical shock: Improper design of the device may result in the patient receiving an electrical shock or burn. (b) Injury: Improper size or shape of the device, or the use of improper materials in the device, may result in trauma to

the patient's airways or esophagus when the device is inserted. (c) Infection: if the device is not sterilized properly, infection may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the esophageal stethoscopes with electrical conductors be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1920, to read as follows:

§ 868.1920 Esophageal stethoscope with electrical conductors.

(a) *Identification.* An esophageal stethoscope with electrical conductors is a device that is inserted into the esophagus to listen to heart and breath sounds and to monitor electrophysiological signals. The device may also incorporate a thermistor for temperature measurement.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33374 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1690]

Medical Devices; Classification of Stethoscope Heads

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying stethoscope heads into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Devise Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of stethoscope heads:

1. Identification: A stethoscope head is a weighted chest piece used during anesthesia to listen to heart, breath and other physiological sounds.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from good manufacturing practice regulation under section 520(f) of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that stethoscope heads 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 Panel recommends that the manufacturer not be required to comply with the good manufacturing practice requirements because any defects in the device are readily detectable.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Skin trauma. The patient's skin may be injured if the chest piece has sharp edges.

Proposed Classification

FDA agrees with the Panel and is proposing that stethoscope heads be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of a stethoscope head be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of a stethoscope head must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of a stethoscope head must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1930, to read as follows:

§ 868.1930 Stethoscope head.

(a) *Identification.* A stethoscope head is a weighted chest piece used during anesthesia to listen to heart, breath, and other physiological sounds.

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33375 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1691]

Medical Devices; Classification of Switching Valves (Ploss)

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying switching valves (ploss) into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of switching valves (ploss):

1. Identification: A switching valve (ploss) is a three-way valve located between a stethoscope placed over the heart, a blood pressure cuff, and an earpiece. The valve allows the user to eliminate one sound channel and listen to only heart or korotoff (blood pressure) sounds through the other channel.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that switching valves (ploss) 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 Panel recommends that the manufacturer not be required to comply with the good manufacturing practice requirements because any defects in the device are readily detectable.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that switching valves (ploss) be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of a switching valve (ploss) be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufactureres of a switching valve (ploss) must still be required to comply with the complaint file requirments of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of a switching valve (ploss) must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1965, to read as follows:

§ 868.1965 Switching valve (ploss).

(a) *Identification.* A switching valve (ploss) is a three-way valve located between a stethoscope placed over the heart, a blood pressure cuff, and an earpiece. The valve allows the user to eliminate one sound channel and listen

to only heart of korotkoff (blood pressure) sounds through the other channel.

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33376 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1692]

Medical Devices; Classification of Water Vapor 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 water vapor analyzers into class II (performance standards). The FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of water vapor analyzers:

1. Identification: A water vapor analyzer is a device used to measure the concentration of water vapor in a patient's expired gases by using techniques such as mass spectrometry

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 water vapor analyzers be classified into class II (performance standards) because the water vapor concentration in a patient's breath must be accurately measured to assure proper diagnosis of the patient's condition. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Misdiagnosis: Inaccurate measurement of water vapor concentration in the expired gases may cause an incorrect diagnosis, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that water vapor analyzers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart B by adding new § 868.1975, to read as follows:

§ 868.1975 Water vapor analyzer.

(a) *Identification.* A water vapor analyzer is a device used to measure the concentration of water vapor in a patient's expired gases by using techniques wuch as mass spectrometry.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20357, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33377 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1693]

Medical Devices; Classification of Ultrasonic Air Embolism 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 ultrasonic air embolism monitors into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ultrasonic air embolism monitors:

1. Identification: An ultrasonic air embolism monitor is a device used to detect air bubbles in a patient's blood stream. It may use Doppler or other ultrasonic principles.

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 ultrasonic air embolism monitors be classified into class II because the Panel believes that the reliability of the device must be adequate to assure accurate detection of air emboli. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Failure to detect air emboli: If the ultrasonic air embolism monitor fails to detect air emboli, it could result in the air emboli blocking the flow of blood in the patient's blood vessels, causing serious complications or death. (b) Electrical shock: If the device is not designed properly, the patient or operator may receive an electrical shock.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that ultrasonic air embolism monitors be classified into class II (performance standards). The Biological Effects of Ultrasound Subcommittee of FDA's Obstetrical and Gynecological Device Classification Panel has also reviewed the possible adverse effects of diagnostic ultrasound devices. (The Subcommittee was established because of FDA's special concerns about the obstetrical use of ultrasound, based upon several studies involving laboratory animals that showed various biological effects from prenatal ultrasound exposures (Ref. 1).) The Subcommittee concluded that there is sufficient information available to establish a standard for diagnostic ultrasound devices generally (Refs. 2, 3, and 4).

In the Federal Register of February 13, 1979 (44 FR 9542), FDA published a notice of intent announcing that it is considering an action program to reduce exposure to diagnostic ultrasound as much as practicable, consistent with the need for essential diagnostic information. One action the agency will consider taking is promulgation of a performance standard under the Radiation Control for Health and Safety Act of 1978 (Pub. L. 90-602, 42 U.S.C. 2636 et seq.). The agency believes that a performance standard under the Radiation Control for Health and Safety Act is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (HFA-305), Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday:

1. Stratmeyer, M. E., "Research Directions in Ultrasound Bioeffects—A Public Health View," Proceedings of a Symposium on Biological Effects and Characterization of Ultrasound Sources, HEW Publication (FDA 78-8044, 1978).

2. Minutes of the Biologic Effects of Ultrasound Subcommittee of the OB-GYN Device Classification Panel (First Meeting), Jan. 22-23, 1976.

3. Minutes of the Biologic Effects of Ultrasound Subcommittee of the OB-GYN Device Classification Panel (Second Meeting), Oct. 28, 1976.

4. Minutes of the Biologic Effects of Ultrasound Subcommittee of the OB-GYN Device Classification Panel (Third Meeting), Oct. 4, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 by adding new Subpart C and new § 868.2025, to read as follows:

Subpart C—Monitoring Devices

§ 868.2025 Ultrasonic air embolism monitor.

(a) *Identification.* An ultrasonic air embolism monitor is a device used to detect air bubbles in a patient's blood stream. It may use Doppler or other ultrasonic principles.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this 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: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33378 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1694]

Medical Devices; Classification of Bourdon Gauge Flowmeter

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying bourdon gauge flowmeters into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Springs, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of bourdon gauge flowmeters:

1. Identification: A bourdon gauge flowmeter is a device used in conjunction with respiratory equipment to sense gas pressure. The device is calibrated to indicate gas flow rate with the outflow open to the atmosphere.

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 bourdon gauge flowmeters be classified into class II because the Panel believes that the device must accurately measure gas flow rates to assure that gases are delivered at the correct rates to the patient and/or respiratory devices. The Panel believes that general controls will not provide sufficient control over this characteristic. The panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, bourdon gauge flowmeters.

5. Risks to health: Inappropriate therapy: The patient may receive incorrect therapy if the device does not measure gas flow rates accurately.

Proposed Classification

FDA agrees with the Panel recommendation and it proposing that bourdon guage flowmeters be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Therefore, under the Federal Food, Drug, and Comestic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2300, to read as follows:

§ 868.2300 Bourdon gauge flowmeter.

(a) *Identification.* A bourdon gauge flowmeter is a device used in conjunction with respiratory equipment to sense gas pressure. The device is calibrated to indicate gas flow rate with the outflow open to the atmosphere.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this 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: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33379 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1695]

Classification of Uncompensated Thorpe Tube 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 uncompensated thorpe tube flowmeters into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of uncompensated thorpe tube flowmeters:

1. Identification: A uncompensated thorpe tube flowmeter is a device used to indicate and control gas flow rate accurately. The device includes a vertically mounted tube and is calibrated when the outlet of the flowmeter is open to the atmosphere.

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 uncompensated thorpe tube flowmeters be classified into class II because the Panel believes that the device must accurately measure gas flow rates to assure that correct gas volumes and concentrations are delivered to the patient. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Inappropriate therapy: Inaccuracy or a change in outlet pressure may cause the device to display incorrect flow data, resulting in the delivery of improper gas therapy to the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that uncompensated thorpe tube flowmeters be classified into class II (performance standards). The agency believes that a performance standards is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2320, to read as follows:

§ 868.2320 Uncompensated thorpe tube flowmeter.

(a) *Identification.* An uncompensated thorpe tube flowmeter is a device used to indicate and control gas flow rate accurately. The device includes a vertically mounted tube and is calibrated when the outlet of the flowmeter is open to the atmosphere.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33380 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1696]

Medical Devices; Classification of Compensated Thorpe Tube 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 compensated thorpe tube flowmeters into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel and the Dental 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.

EFFECTIVE DATE: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel and the Dental Device Classification Panel, FDA advisory committees, made the following recommendation regarding the classification of compensated thorpe tube flowmeters:

1. Identification: A compensated thorpe tube flowmeter is a device used to control and measure gas flow rate accurately. The device includes a vertically mounted tube, with the outlet of the flowmeter calibrated to a reference pressure.

2. Recommended classification: Class II (performance standards). Both the Anesthesiology Device Classification Panel and the Dental Device Classification Panel recommend that this device be classified into class II (performance standards). The Anesthesiology Device Classification Panel recommends that establishing a performance standard for this device be a medium priority. The Dental Device Classification Panel recommended that establishing a performance standard for the device be a low priority.

3. Summary of reasons for recommendation: Both the Anesthesiology Device Classification Panel and the Dental Device Classification Panel recommend that compensated thorpe tube flowmeters be classified into class II because the Panels believe that the accuracy of the device must be controled to assure that the device displays accurate gas flow rate data. The Panels believe that general controls will not provide sufficient control over the accuracy of the device. The Panels believe that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: Both Panels based their recommendation on the Panel members' personal knowledge of, and clinical experience with, this device. The Panels noted that compensated thorpe tube flowmeters have been widely used for many years.

5. Risks to health: The Anesthesiology Device Classification Panel identified the following risk to health: (a) Inappropriate therapy: Inaccuracy or nonlinearity may cause the device to display inaccurate flow data, resulting in the delivery of improper gas flows or other inappropriate therapy to the patient. The Dental Device Classification Panel identified the following risk to health: (b) Incorrect amount of gas delivered: Malfunction may cause an incorrect amount of anesthetic gas to be delivered to the patient.

Proposed Classification

FDA agrees with the Panels' recommendation and is proposing that compensated thorpe tube flowmeters be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2340, to read as follows:

§ 868.2340 Compensated thorpe tube flowmeter.

(a) *Identification.* A compensated thorpe tube flowmeter is a device used to control and measure gas flow rate accurately. The device includes a vertically mounted tube, with the outlet of the flowmeter calibrated to a reference pressure.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this 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: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33381 Filed 11-1-79; 8:45 am]
BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1697]

Medical Devices; Classification of Gas Calibration 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 gas calibration flowmeters into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into the class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panal Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gas calibration flowmeters:

1. Identification: A gas calibration flowmeter is a device that is used to calibrate flowmeters and accurately measure gas flow.

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 gas calibration flowmeters be classified into class II to assure that gas flowmeters are correctly calibrated so that the data generated by them will be accurate. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: Inappropriate gas concentration: Inaccurate calibration of gas flowmeters or lack of flowmeter accuracy may lead to incorrect gas flow data resulting in delivery of inappropriate and possibly hazardous breathing mixtures to the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that gas calibration flowmeters be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2350, to read as follows:

§ 868.2350 Gas calibration flowmeter.

(a) *Identification.* A gas calibration flowmeter is a device that is used to calibrate flowmeters and accurately measure gas flow.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing 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: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33382 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1698]

Medical Devices; Classification of Breathing Frequency 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 breathing frequency monitors into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980; FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel and the General and Plastic Surgery Device Classification Panel, FDA advisory committees, made the following recommendation regarding the classification of breathing frequency monitors:

1. Identification: A breathing (ventilatory) frequency monitor is a device used to measure a patient's respiratory rate. The device provides an audible or visible alarm when the respiratory rate is outside predetermined limits.

2. Recommended classification: Class II (performance standards). The Anesthesiology Device Classification Panel and the General and Plastic Surgery Device Classification Panel recommend that this device be classified into class II. The Anesthesiology Device Classification Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for the recommendation: The Panels recommend that the breathing frequency monitor be classified into class II because the Panels believe that the device must accurately and reliably detect and alert users to changes in a patients's breathing frequency. The Panels believe that general controls will not provide sufficient control over these characteristics. The Panels believe that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panels based their recommendation on the Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: The Anesthesiology Device Classification Panel identified the following risks to health: (a) Undetected abnormal respiratory conditions: Failure of the device or alarm may cause abnormal conditions to go undiscovered and result in serious patient injury or death. (b) Inappropriate therapy: The patient may receive incorrect therapy if the device does not monitor the patient's breathing frequency accurately and reliably. The General and Plastic Surgery Device Classification Panel identified no hazards from this device.

Proposed Classification

FDA agrees with the Panels' recommendations and is proposing that breathing frequency monitors be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2375, to read as follows:

§ 868.2375 Breathing frequency monitor.

(a) *Identification.* A breathing (ventilatory) frequency monitor is a device used to measure a patient's respiratory rate. The device provides an audible or visible alarm when the respiratory rate is outside predetermined limits.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this 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: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33383 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1699]

Medical Devices; Classification of Lung Water 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 lung water monitors into class III (premarket approval). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to require 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 would include premarket approval information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of lung water monitors:

1. Identification: A lung water monitor is a device used to monitor the trend of fluid volume changes in a patient's lung by measuring changes in thoracic electrical impedance (resistance to alternating current) by means of electrodes placed on the patient's chest.

2. Recommended classification: Class III (premarket approval). The Panel recommends that premarket approval for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that lung water monitors be classified into class III because the Panel believes that the device presents a potential unreasonable risk of illness or injury. The Panel believes that insufficient information exists to determine whether general controls or performance standards would be adequate to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and experience with, the device, and the lack of clinical data. The Panel notes that there is no acceptable quantitative procedure for measuring changes in lung fluid volume.

5. Risks to health: (a) Incorrect diagnosis: If the device is not calibrated or does not accurately measure changes in lung fluid volume, misdiagnosis of the patient's condition may result in inappropriate therapy. (b) Electrical shock: If the device malfunctions or is not properly grounded, the patient may receive an electrical shock. (c) Allergic reaction: The adhesive backing on the electrodes applied to the chest may cause skin irritation.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that lung water monitors be classified into class III (premarket approval). The agency concurs with the Panel that the device presents potential unreasonable risks of illness or injury to the patient and 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 of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2450, to read as follows:

§ 868.2450 Lung water monitor.

(a) *Identification.* A lung water monitor is a device used to monitor the trend of fluid volume changes in a patient's lung by measuring changes in thoracic electrical impedance (resistance to alternating current) by means of electrodes placed on the patient's chest.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this 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: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33384 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1700]

Medical Devices; Classification of Cutaneous Oxygen 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 cutaneous oxygen monitors into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of cutaneous oxygen monitors:

1. Identification: A cutaneous oxygen monitor is a device used to monitor relative changes in the cutaneous (skin) oxygen tension by using a noninvasive sensor (e.g., Clark-type polarographic electrode) placed on the patient's skin.

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 cutaneous oxygen monitors be classified into class II because the Panel believes that the design and materials of the device must be controlled to assure that the patient is not burned due to excessive heating of the sensor, that the device accurately measures the cutaneous oxygen tension, that skin injury or allergic reaction does not occur from the use of electrode gels or adhesives, and that the patient does not receive an electrical shock. The Panel believes that the output of the device should be validated by the user against arterial blood-oxygen tension, both initially and with any subsequent change in electrode site. The Panel recommends that the manufacturer be required by FDA to specify in the labeling for the device any conditions known to interfere with the oxygen tension measurement. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on testimony and data presented to the Panel. On June 2, 1977 Mr. Lonny Wolgemuth, representing Litton Medical Electronics, addressed the Panel regarding the Litton Oxymonitor, a device for measuring the cutaneous oxygen tension. The presentation addressed the history of development of the device, its operational principles, applications for use of the device, and alternative methods for the measurement of oxygen tension (PO_2).

Dr. Howard Hochberg, representing Roche Medical Electronics, addressed the Panel on January 24, 1978 concerning the Roche cutaneous oxygen monitor. Dr. Hochberg referenced the utility of the device as a trend monitor and the low incidence of burns reported to date. He concluded his presentation by recommending that the device be classified into class III (premarket approval), contending that there is not enough information to develop a performance standard because the technology for the device is still being developed.

The Panel members raised questions during both of the above presentations concerning the safety and effectiveness of the device. The Panel members' concerns centered on (1) the incidence of and extent of skin injury due to the electrode temperature relative to body weight when the device is used on infants, (2) ranges of linearity, and (3) the position of the electrode on the patient.

Based on these presentations and the data available in the medical literature, the Panel members determined that sufficient data exist on which to base a performance standard.

5. Risks to health: (a) Burns: If the sensor temperature is too high or if the position of the electrode on the patient is not changed periodically, the patient may be burned. (b) Inappropriate therapy: If the device does not measure the patient's oxygen tension accurately, the patient may receive inappropriate therapy. (c) Skin reaction: The electrolyte or adhesive used with the sensor may cause an adverse skin reaction. (d) Electrical shock: If the device is not designed properly, the patient may receive an electrical shock.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that cutaneous oxygen monitors be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device.

FDA originally placed the cutaneous oxygen monitor into class III (premarket approval) based on premarket notifications made to the agency under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) and Part 807 of the regulations (21 CFR Part 807). FDA was not aware at that time that a substantially equivalent product had been in commercial distribution prior to the date of enactment of the Medical Device Amendment (May 28, 1976). Subsequently, an application for premarket approval and a petition for reclassification were submitted to FDA. Also, new information was presented to FDA showing that the cutaneous oxygen monitor had been in commercial distribution before May 28, 1976. Accordingly, FDA notified the manufacturers whose submissions on this device were pending that the device was substantially equivalent to a device in commercial distribution prior to enactment of the Medical Device Amendments of 1976 and, therefore, could be marketed without premarket approval or approval of a reclassification petition. The pending submissions were withdrawn by the manufacturers and the cutaneous oxygen monitor was referred to the Anesthesiology Device Classification Panel for a classification recommendation.

During the Panel discussions, differing opinions were expressed about the classification of cutaneous oxygen monitors because the device uses a relatively new technique for measuring oxygen tension. The device uses an external cutaneous electrode to heat the patient's skin and underlying tissues to temperatures greater than 43° C to enable oxygen tension to be measured. Questions were expressed during the Panel's deliberations as to whether there was enough information available to develop a performance standard that would assure the safety and effectiveness of the device. Although the agency tentatively agrees with the Panel and proposes to classify the cutaneous oxygen monitor into class II (performance standards), comments are requested on whether there is sufficient information available to establish a performance standard that will assure the safety and effectiveness of the device without requiring that it undergo premarket clearance by FDA.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2500 as follows:

§ 868.2500 Cutaneous oxygen monitor.

(a) *Identification.* A cutaneous oxygen monitor is a device used to monitor relative changes in the cutaneous (skin) oxygen tension by using a noninvasive sensor (e.g., Clark-type polarographic electrode) placed on the patient's skin.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above offices between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33285 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1702]

Medical Devices; Classification of Pneumotachometers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pneumotachometers into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device 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 device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of pneumotachometers:

1. Identification: A pneumotachometer is a device used to determine gas flow by measuring the pressure differential across a known resistance. The device may use a set of capillaries or a metal screen for the resistive element.

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 pneumotachometers be classified into class II because the Panel believes the accuracy of the device must be adequate to assure that the device does not generate incorrect data. In addition, the Panel believes that the design and materials of the device must be controlled to assure that when used in a breathing circuit or mechanical ventilator, the device does not increase air-flow resistance excessively or promote infection due to an inability of the user to clean and sterilize the device. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Inappropriate therapy: Inaccurate determination of gas flow may cause the patient's condition to be incorrectly diagnosed, resulting in incorrect therapy. (b) High flow resistance: If the device is used in a breathing circuit, poor design may cause excessive flow resistance that could result in inadequate ventilation of the patient. (c) Infection: If the device is not clean or sterile, infection may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that pneumotachometers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for 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 of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2550, to read as follows:

§ 868.2550 Pneumotachometer.

(a) *Identification.* A pneumotachometer is a device used to determine gas flow by measuring the pressure differential across a known resistance. The device may use a set of capillaries or a metal screen for the resistive element.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this 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: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33386 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1703]

Medical Devices; Classification of Airway Pressure 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 airway pressure monitors into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposed elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesioloogy Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of airway pressure monitors:

1. Identification: An airway pressure monitor is a device used to measure the pressure in a patient's upper airway. The device may include a pressure gauge and an alarm.

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 airway pressure monitors be classified into class II because the Panel believes that the device must accurately measure a patient's airway pressure, and changes in that pressure, so that hospital personnel will be alerted to abnormal conditions. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The Panel noted that a standard for pressure gauges is being developed by the American National Standards Institute.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, airway pressure monitors.

5. Risks to health: Inadequate ventilation: Failure of the device to accurately measure airway pressure and pressure changes may result in inadequate ventilation or other inappropriate patient therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that airway pressure monitors be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2600, to read as follows:

§ 868.2600 Airway pressure monitor.

(a) *Identification.* An airway pressure monitor is a device used to measure the pressure in a patient's upper airway. The device may include a pressure gauge and an alarm.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this 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: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33387 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1704]

Medical Devices; Classification of Gas 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 gas pressure gauges into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980.

FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gas pressure gauges:

1. Identification: A gas pressure gauge (e.g., bourdon tube pressure gauge) is a device used to measure the gas pressure in a gas delivery system.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that gas pressure gauges be classified into class II because the Panel believes that the device must be accurate to asssure proper gas delivery pressures. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The Panel noted that standards for this device have been developed by committees of the Compressed Gas Association and the British Standards Institution.

4. Summary of data on which the recommendation is based: The Panel based it recommendation on the Panel members' personal knowledge of, and clinical experience with, gas pressure gauges. There has been extensive clinical experience and widespread use of these devices for many years.

5. Risks to health: Inappropriate therapy: An inaccurate pressure guage may lead to improper functioning of respiratory equipment and resulting inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that gas pressure gauges be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2610, to read as follows:

§ 868.2610 Gas pressure gauge.

(a) *Identification.* A gas pressure gauge (e.g., Bourdon tube pressure gauge) is a device used to measure gas pressure in a gas delivery system.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this 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: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33388 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1705]

Medical Devices; Classification of Gas Pressure Calibrators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying gas pressure calibrators into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gas pressure calibrators:

1. Identification: A gas pressure calibrator is a device used to calibrate pressure-measuring instruments by generating a known gas pressure.

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 gas pressure calibrators be classified into class II to assure that the gas pressure generated by this device is accurate so that the device can be used to calibrate correctly instruments used in the care and treatment of patients. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The Panel noted that standards are being developed by the

Compressed Gas Association (CGA) and the American National Standards Institute (ANSI).

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, gas pressure calibrators.

5. Risks to health: Inappropriate therapy: Inaccurate calibration of gas pressure gauges may lead to improper operation of various medical devices used in the support and care of the patient, and the patient may receive incorrect therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that gas pressure calibrators be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2620, to read as follows:

§ 868.2620 Gas pressure calibrator.

(a) *Identification.* A gas pressure calibrator is a device used to calibrate pressure-measuring instruments by generating a known gas pressure.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this 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: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33389 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1706]

Medical Devices; Classification of Pressure Regulators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pressure regulators into class II (performance standards). FDA is also publishing the recommendations of the Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel, FDA advisory committees, made the following recommendation regarding the classification of pressure regulators:

1. Identification: A pressure regulator is a device, often called a pressure-reducing valve, that is used to convert a gas pressure from a high variable pressure to a lower, more constant working pressure. This device includes mechanical oxygen regulators.

2. Recommended classification: Class II (performance standards). Both the Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel recommend that this device be classified into class II. The Anesthesiology Device Classification Panel recommends that establishing a performance standard for this device be a low priority. The General Hospital and Personal Use Device Classification Panel recommends that establishing a performance standard be a medium priority.

3. Summary of reasons for recommendation: The Panels recommend that pressure regulators be classified into class II because the Panels believe the design and materials of the device must be controlled to assure that the device delivers a reliable constant pressure, to assure that the diaphragm has adequate strength to prevent rupture, to assure that the device uses standard fittings, and to assure that the device can be cleaned and sterilized to prevent infection. The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: Both Panels based their recommendation on their Panel members' personal knowledge of, and clinical experience with, the device, and widespread use of the device during the past 30 years. The Anesthesiology Device Classification Panel also noted that portions of standards for anesthesia and respiratory equipment developed by the National Fire Protection Association, the Compressed Gas Association, the Interstate Commerce Commission (Department of Transportation), and the Underwriters Laboratories apply to gas pressure regulators.

5. Risks to health: The Anesthesiology Device Classification Panel identified the following risks to health: (a) Overpressurization: Rupture of the regulator diaphragm could allow high gas pressure to be introduced into the patient's airway, possibly resulting in

rupture of a lung. (b) Inappropriate therapy: If the pressure regulator does not supply gas at the correct pressure to the devices supporting the patient, the patient may receive incorrect therapy. (c) Leaks: If the pressure regulator does not have standard fittings, leaks may develop, resuting in an inadequate delivery of gases. (d) Infection: If the regulator is not adequately cleaned or sterilized, contamination of equipment and cross-infection between patients may occur.

The General Hospital and Personal Use Device Classification Panel identified the following risks to health for mechanical oxygen regulators: (a) Hypoxia/hyperoxia: If the regulator does not provide accurate gas pressure or flow the patient may receive too little or too much oxygen. (b) Contamination: If the device is not supplied with proper cleaning instructions, contaminants may be added to the gas stream going to the patient. (c) Leaks: The regulator fittings should be compatible with appropriate gas sources to prevent leaks.

Proposed Classification

FDA agrees with the Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel recommendation and is proposing that pressure regulators be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessay to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by 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 of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2700, to read as follows:

§868.2700 Pressure regulator.

(a) *Identification.* A pressure regulator is a device, often called a pressure-reducing valve, that is used to convert a gas pressure from a high variable pressure to a lower, more constant working pressure. This device includes mechanical oxygen regulators.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this 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: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33390 Filed 11-1-79 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1707]

Medical Devices; Classification of Electrical Peripheral 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 electrical peripheral nerve stimulators into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of electrical peripheral nerve stimulators:

1. Identification: An electrical peripheral nerve stimulator (neuromuscular blockade monitor) is a device used to apply an electrical current to a patient to test the level of pharmacological effect of anesthetic drugs and gases.

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 electrical peripheral nerve stimulators be classified into class II because the Panel believes that the electrical current may cause burns or electrical shock to the body if the output parameters are not controlled. The Panel believes that the device is safe when used with well-established output parameters. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, electrical peripheral nerve stimulators used in anesthesia.

5. Risks to health: (a) Electrical shock: If the device is not designed properly, the patient or operator may receive an electrical shock. (b) Local burns: Improper electrode surface area or excessive current density can cause burns to the patient's body. (c) Excessive muscle contractions: Improper output parameters can cause excessive muscle contractions in the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that

electrical peripheral nerve stimulators be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2775, to read as follows:

§ 868.2775 Electrical peripheral nerve stimulator.

(a) *Identification.* An electrical peripheral nerve stimulator (neuromuscular blockade monitor) is a device used to apply an electrical current to a patient to test the level of pharmacological effect of anesthetic drugs and gases.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this 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: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33391 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1708]

Medical Devices; Classification of Differential 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 differential pressure transducers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of differential pressure transducers:

1. Identification: A differential pressure transducer is a two-chambered device often used during pulmonary function testing. It generates an electrical signal for subsequent display or processing that is proportional to the difference in gas pressures in the two chambers.

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 differential pressure transducers be classified into class II because the Panel believes that the device should produce a signal that accurately reflects the pressure differential between the two chambers. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device. These devices have been widely used for many years.

5. Risks to health: Inappropriate therapy: If the device does not accurately measure the difference in pressures, a patient's condition may be incorrectly diagnosed, leading to inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that differential pressure transducers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2875, to read as follows:

§ 868.2875 Differential pressure transducer.

(a) *Identification.* A differential pressure transducer is a two-chambered device often used during pulmonary function testing. It generates an electrical signal for subsequent display or processing that is proportional to the difference in gas pressures in the two chambers.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing

Clerk docket number found in brackets in the heading of this 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: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33392 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1709]

Medical Devices; Classification of Gas Flow 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 gas flow transducers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gas flow transducers:

1. Identification: A gas flow transducers is a device used to convert gas flow rate into an electrical signal for subsequent display or processing.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that gas flow transducers be classified into class II because the Panel believes that the device must generate electrical signals that accurately reflect the gas flow being detected. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The Panel noted the development of standards for this device by committees of the American National Standards Institute and the National Fire Protection Association.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Inappropriate therapy: If the device does not accurately show gas flow rate for display and evaluation by the physician, the patient may receive incorrect treatment.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that gas flow transducers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2885, to read as follows:

§ 868.2885 Gas flow transducer.

(a) *Identification.* A gas flow transducer is a device used to convert gas flow rate into an electrical signal for subsequent display or processing.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this 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: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33393 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1710]

Medical Devices; Classification of Gas 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 gas pressure transducers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gas pressure transducers:

1. Identification: A gas pressure transducer is a device used to convert gas pressure into an electrical signal for subsequent display or processing.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that gas pressure transducers be classified into class II because the Panel believes that the device must generate electrical signals that accurately describe the gas pressure being detected. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Inappropriate therapy: If the device does not accurately show pressure signals for display and evaluation by the user, the patient may receive incorrect treatment.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that gas pressure transducers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart C by adding new § 868.2900, to read as follows:

§ 868.2900 Gas pressure transducer.

(a) *Identification.* A gas pressure transducer is a device used to convert gas pressure into an electrical signal for subsequent display or processing.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this 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: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33394 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1714]

Medical Devices; Classification of Emergency Airway Needles

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying emergency airway needles into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of emergency airway needles:

1. Identification: An emergency airway needle is a device used to puncture the cricothyroid membrane to provide an emergency airway during upper airway obstruction.

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 emergency airway needles be classified into class II (performance standards) because the Panel believes that the design of the device should be controlled to minimize the risk of hemorrhage when the device is inserted. The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, emergency airway needles..

5. Risks to health: Hemorrhage (bleeding): If the device is of an inappropriate size, shape, or length, hemorrhaging may occur when it is inserted through the cricothyroid membrane.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the emergency airway needles be classified into class II. Although the device is life supporting, the agency believes that premarket approval is unnecessary because this is a simple device with which there has been significant experience and because no reported problems attributed to the device would be diminished by subjecting the device to premarket approval. The agency believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency believes that general controls alone are insufficient to control the risks to health presented by 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5090, to read as follows:

§ 868.5090 Emergency airway needle.

(a) *Identification.* An emergency airway needle is a device used to puncture the cricothyroid membrane to provide an emergency airway during upper airway obstruction.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this 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: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33395 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1715]

Medical Devices; Classification of Nasopharyngeal Airways

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nasopharyngeal airways into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nasopharyngeal airways:

1. Identification: A nasopharyngeal airway is a device used to facilitate breathing by means of a tube inserted into the patient's pharynx through the nose to provide a patent airway.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the nasopharyngeal airway be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device should be controlled to assure that the device does not promote infection or obstruct or damage the patient's airway. The Panel believes that general controls will not provide sufficient control over these characteristics. Although this deviced is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, nasopharyngeal airways.

5. Risks to health: (a) Epistaxis (nosebleed), obstruction, and tissue damage: If the airway is not shaped properly or is too large or too rigid, it may obstruct the air passage, damage the tissue within the nose, or cause epistaxis.

(b) Infection: If the device is not sterile, infection may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the nasopharyngeal airways be classified into class II (performance standards). Although the device is life supporting, the agency believes that class III (premarket approval) is unnecessary for this device because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device, nasopharyngeal airway, using the principles applicable to the standards for the oropharyngeal airway and the tracheal tube, which are similar to the nasopharyngeal airway and which are the subjects of proposed classification regulations published elsewhere in this issue of the Federal Register. The agency also believes that general controls alone are insufficient to control the risks to health presented by 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 of Food and Drugs proposes to amend Part 868 in Subpart F

by adding new § 868.5100, to read as follows:

§ 868.5100 Nasopharyngeal airway.

(a) *Identification.* A nasopharyngeal airway is a device used to facilitate breathing by means of a tube inserted into the patient's pharynx through the nose to provide a patent airway.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33396 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1716]

Medical Devices; Classification of Oropharyngeal Airways

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying oropharyngeal airways into class II (performance standards). FDA is also publishing the recommendation of 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 future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of oropharyngeal airways:

1. Identification: An oropharyngeal airway is a device inserted into the pharynx through the mouth to provide a patent airway.

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 oropharyngeal airways be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the device has a proper anatomical shape and sufficient strength and hardness to prevent damage to soft tissue and teeth, and breakage of the device. The Panel believes that general controls alone will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device. The Panel members noted the widespread use of these devices during the past 25 years by both professional and lay personnel. The use of oropharyngeal airways in emergency resuscitation has been taught to lay personnel through the American Red Cross, the Boy Scouts of America, and various volunteer rescue groups. The American National Standards Institute's Z-79 Committee has written a standard (Z-79.3) addressing the physical characteristics of oropharyngeal airways. (Ref. 1)

5. Risks to health: (a) Soft tissue trauma: Damage to the tissues of the mouth may result from improper insertion or improper anatomical shape of the device. (b) Trauma to teeth: If the airway device is too hard, it may damage the teeth.

(c) Inadequate ventilation: If the airway device is composed of a material that is too soft, it could be blocked or broken by the patient's teeth, rendering the device ineffective.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the oropharyngeal airways be classified into class II. Although the device is life supporting, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by 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. American National Standards Institute, American National Standard for Oropharyngeal Airways, Z-79.3, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-548 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 890 in Subpart F by adding new § 868.5110, to read as follows:

§ 868.5110 Oropharyngeal airway.

(a) *Identification.* An oropharyngeal airway is a device inserted into the pharynx through the mouth to provide a patent airway.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket

number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33397 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1717]

Medical Devices; Classification of Anesthesia Conduction Catheters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying anesthesia conduction catheters into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of anesthesia conduction catheters:

1. Identification: An anesthesia conduction catheter is a flexible tubular device used to inject local anesthetics to provide continuous regional anesthesia.

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 anesthesia conduction catheters be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure adequate mechanical strength to prevent breakage of the catheter when it is removed from the patient. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device. Anesthesia conduction catheters have been widely used for over 33 years.

5. Risks to health: (a) Thromboembolic complications: If the catheter is not strong enough, it may break during extraction from the patient and cause complications such as embolism or thrombus (blood clot) formation. (b) Adverse tissue reaction: If the materials in the catheter are not biocompatible, adverse tissue reaction may occur due to leaching of chemicals from the device.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that anesthesia conduction catheters be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5120, to read as follows:

§ 868.5120 Anesthesia conduction catheter.

(a) *Identification.* An anesthesia conduction catheter is a flexible tubular device used to inject local anesthetics to provide continuous regional anesthesia.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments, are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33398 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1718]

Medical Devices; Classification of Anesthesia Conduction 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 anesthesia conduction filters into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of anesthesia conduction filters:

1. Identification: An anesthesia conduction filter is a microporous filter used while administering injections of local anesthetics to minimize particulate (foreign material) contamination of the injected fluid.

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 anesthesia conduction filters be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure both that the filter mesh size adequately prevents foreign bodies from entering a patient, and that the materials used in the filter are biocompatible. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, anesthesia conduction filters.

5. Risks to health: (a) Foreign body reaction: An excessively large mesh size may allow larger particulate matter to enter the patient and cause foreign body reactions. (b) Adverse tissue reaction: If the filter material is not biocompatible, or if toxic substances leach from the filter, an adverse tissue reaction may occur in the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that anesthesia conduction filters be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5130, to read as follows:

§ 868.5130 Anesthesia conduction filter.

(a) *Identification.* An anesthesia conduction filter is a microporous filter used while administering injections of local anesthetics to minimize particulate (foreign material) contamination of the injected fluid.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33399 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1719]

Medical Devices; Classification of Anesthesia Conduction 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 anesthesia conduction kits into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of anesthesia conduction kits:

1. Identification: An anesthesia conduction kit is a device used to administer conduction anesthesia. The device may contain syringes, needles, and drugs.

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 anesthesia conduction kits be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the strength of

the needles or catheters is adequate to prevent breakage and to assure that the components and anesthetic agents can be adequately cleaned and sterilized to prevent sepsis (infection), particulate contamination of the spinal fluid, and chemical contamination. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel noted that a committee of the Association for the Advancement of Medical Instrumentation (AAMI) is developing needle standards.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Trauma: If the needles or catheters break during the procedure, trauma to the patient may result. (b) Sepsis (infection) and particulate contamination: If the device is not clean and sterile, sepsis or particulate contamination of the spinal fluid may result. (c) Adverse tissue reaction: Chemical contamination of the local anesthetic agent may cause adverse tissue reactions in the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that anesthesia conduction kits be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5140, to read as follows:

§ 868.5140 Anesthesia conduction kit.

(a) *Identification.* An anethesia conduction kit is a device used to administer conduction anesthesia. The device may contain syringes, needles, and drugs.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33400 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1720]

Medical Devices; Classification of Anesthesia Conduction Needles

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying anesthesia conduction needles into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of anesthesia conduction needles:

1. Identification: An anesthesia conduction needle is a device used to inject local anesthetics into a patient to provide regional anesthesia.

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 anesthesia conduction needles be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the device is strong enough to prevent breakage, that the needle and needle tip are properly shaped to prevent damage to blood vessels, and that the hub is designed to prevent leakage when changing needles on a syringe. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, anesthesia conduction needles.

5. Risks to health: (a) Blood vessel damage or thrombus (blood clot): Improper needle or needle-tip shape or strength may cause thrombus formation or vessel damage. (b) Leakage: Leakage of anesthetics may occur when changing needles on a syringe if the hub is not properly designed. (c) Breakage: If the needle breaks while in the patient, complications may ensue.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that anesthesia conduction needles be classified into class II (performance standards). The agency believes that a

performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5150, to read as follows:

§ 868.5150 Anesthesia conduction needle.

(a) *Identification.* An anesthesia conduction needle is a device used to inject local anesthetics into a patient to provide regional anesthesia.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 20, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33401 Filed 11–1–79; 8:45 am]
BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1721]

Medical Devices; Classification of Anesthesia Gas Machines

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying anesthesia gas machines into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel and the Dental Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel and the Dental Device Classification Panel, an FDA advisory committees, made the following recommendation regarding the classification of anesthesia gas machines:

1. Identification: An anesthesia gas machine is a device used to administer, continuously or intermittently, a general inhalation anesthetic or analgesic agent to a patient and to maintain a patient's ventilation. The device may include a gas flowmeter, vaporizer, ventilator, breathing circuit with bag, and emergency gas supply.

2. Recommended classification: Class II (performance standards). Both the Anesthesiology Device Classification Panel and Dental Device Classification Panel recommend that this device be classified into class II (performance standards). The Anesthesiology Device Classification Panel recommends that establishing a performance standard be a high priority. The Dental Device Classification Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Anesthesiology Device Classification Panel and the Dental Device Classification Panel recommend that the anesthesia gas machine be classified into class II (performance standards) because the Panels believe that the design of the device must be controlled to assure that the patient is properly anesthetized and ventilated. The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which recommendation is based: The Anesthesiology Device Classification Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device. The Anesthesiology Panel also noted the widespread use of this device during the past 50 years and the development of a standard for continuous flow anesthesia machines by the Z–79 Committee of the American National Standards Institute (Ref. 1). The Dental Device Classification Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and the potential hazards to the patient associated with the use of the device.

5. Risks to health: The Anesthesiology Device Classification Panel noted the following risks to health: (a) Inappropriate therapy: Incorrect calibration of the device may lead to delivery of an incorrect gas mixture to the patient. (b) Inappropriate dosage: Poor design or malfunction could result in leaks in the system that cause the patient to receive less than the appropriate gas volume. (c) Injury: Fire and explosion from flammable or explosive anesthetic agents may result in severe injury to the patient. (d) Inadequate ventilation: Mechanical failure causing obstruction of the air pathway may result in the patient receiving inadequate ventilation. (e) Overdistension of lung tissue: Mechanical failure resulting in overpressurization of the patient's pulmonary system may lead to overdistension of lung tissue (pneumothorax). The Dental Device Classification Panel identified the following additional risk to health: (f) Brain damage, cardiac arrest, or death: Mechanical failure of the device's valves and flowmeters may cause brain damage, cardiac arrest, or death.

Proposed Classification

FDA agrees with the Panel and is proposing that anesthesia gas machines be classified into class II (performance standards). Although the device is life supporting, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency believes that general controls alone are insufficient to control the risks to health presented by 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. "Proposed Minimum Performance and Safety Requirements for Components and Systems of Continuous Flow Anesthesia Machines," American National Standards Institute, Z-79.8, draft, 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5160 to read as follows:

§ 868.5160 Anesthesia gas machine.

(a) *Identification.* An anesthesia gas machine is a device used to continuously or intermittently administer a general inhalation anesthetic or analgesic agent to a patient and to maintain a patient's ventilation. The device may include a gas flowmeter, vaporizer, ventilator, breathing circuit with bag, and emergency gas supply.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA—305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs

[FR Doc. 79-33402 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1722]

Medical Devices; Classification of Laryngotracheal Topical Anesthesia Applicators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying laryngotracheal topical anesthesia applicators into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910. 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of laryngotracheal topical anesthesia applicators:

1. Identification: A laryngotracheal topical anesthesia applicator is a device used to apply topical anesthetics to a patient's laryngotracheal area.

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 laryngotracheal topical anesthesia applicators be classified into class II (performance standards) because the Panel believes that the design and construction of, and the materials used in, the device must be adequate to assure that all of the components are secure, to prevent the patient from aspirating disconnected device components. In addition, the device should be both sterile and of the proper size and shape to avoid causing trauma to the patient's airway. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, topical anesthesia applicators and related devices.

5. Risks to health: (a) Aspiration of components: Disconnection of the components may result in accidental aspiration of components. (b) Trauma: Improper size, shape, or rigidity of the device may cause trauma to the patient's airway upon insertion. (c) Infection: If the device is not sterile, infection may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that laryngotracheal topical anesthesia applicators be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5170, to read as follows:

§ 868.5170 Laryngotracheal topical anesthesia applicator.

(a) *Identification.* A laryngotracheal topical anesthesia applicator is a device used to apply topical anesthetics to a patient's laryngotracheal area.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33403 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1723]

Medical Devices; Classification of Rocking Beds

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rocking beds into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rocking beds:

1. Identification: A rocking bed is a device used to temporarily help patient ventilation (breathing) by repeatedly tilting the patient, thereby using the weight of the abdominal contents to move the diaphragm.

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 rocking beds be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the patient is properly supported and restrained to prevent injury from falling. The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is unnecessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, rocking beds.

5. Risks to health: Injury: The patient may fall out of the bed and be injured.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that rocking beds be classified into class II (performance standards). Although the device is life supporting, the agency believes that premarket approval is unnecessary because there has been significant experience with the device and because no reported problems attributed to the device would be diminished by subjecting the device to premarket approval. The agency believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5180, to read as follows:

§ 868.5180 Rocking bed.

(a) *Identification.* A rocking bed is a device used to temporarily help patient ventilation (breathing) by repeatedly tilting the patient, thereby using the weight of the abdominal contents to move the diaphragm.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33404 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1726]

Medical Devices; Classification of Blow Bottles

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for

public comment a proposed regulation classifying blow bottles into class I (general controls), FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of blow bottles:

1. Identification: A blow bottle is a device used to induce a forced expiration from a patient. The patient blows into the device to move a column of water from one bottle to another.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that blow bottles 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 presents no risks to health, and the integrity of the device can be easily determined by examining it. Therefore, the Panel recommends that the manufacturer not be required to comply with the good manufacturing practice requirements.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel's recommendation and is proposing that blow bottles be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of a blow bottle be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act, FDA is proposing that a manufacturer of this device who does not label or otherwise represent it as sterile be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records and reports, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of a blow bottle, even when it is not labeled or otherwise represented as sterile, must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of a blow bottle must still be required to comply with the general requirements concerning records and reports in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate. A manufacturer of a blow bottle that is labeled or otherwise represented as sterile is, in the manufacture of this device, subject to the GMP regulation in its entirety.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5220, to read as follows:

§ 868.5220 Blow bottle.

(a) *Identification.* A blow bottle is a device used to induce a forced expiration from a patient. The patient blows into the device to move a column of water from one bottle to another.

(b) *Classification.* Class I (general controls). If the device is not labeled or otherwise represented as sterile, it is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33405 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1727]

Medical Devices; Classification of Anesthesia Breathing Circuits

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying anesthesia breathing circuits into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of anesthesia breathing circuits:

1. Identification: An anesthesia breathing circuit is a device used to administer medical gases to a patient during anesthesia. It provides both an inhalation and exhalation route and may include a connector, adaptor, and Y-piece.

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 anesthesia breathing circuits be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure leak-free connections and components, to prevent inadequate ventilation, to prevent fire hazards, and to assure low resistance to gas flow in the breathing circuit. The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is unnecessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, breathing circuits. Breathing circuits have been used for the past 35 years. They are well accepted by the medical community worldwide, and their performance characteristics are clearly understood.

5. Risks to health: (a) Failure to deliver gas: If the breathing circuit becomes obstructed or disconnected, gas delivery to the patient may be reduced, leading to hypoxia (lack of oxygen) or insufficient anesthesia. (b) Increased breathing effort: If the circuit exhibits excessive resistance to gas flow or if excessive pressures develop within the circuit, the patient may have difficulty breathing. (c) Burns: If the circuit leaks flammable gases, fire, and explosion may result.

Proposed Classification

FDA agrees with the Panel recommendation and proposes that anesthesia breathing circuits be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5240, to read as follows:

§ 868.5240 Anesthesia breathing unit.

(a) *Identification.* An anesthesia breathing circuit is a device used to administer medical gases to a patient during anesthesia. It provides both an inhalation and exhalation route and may include a connector, adaptor, and Y-piece.

(b) *Classification.* Class II (performance standards). Interested persons, may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m. Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33400 Filed 11-01-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1728]

Medical Devices; Classification of Breathing Circuit Circulators

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying breathing circuit circulators into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device by classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory

committee, made the following recommendation regarding the classification of breathing circuit circulators:

1. Identification: A breathing circuit circulator is a turbine device attached to a closed breathing circuit. The device is used to circulate anesthetic gases continuously by maintaining the unidirectional valves in an open position and reducing mechanical dead space and resistance in the breathing 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 breathing circuit circulators be classified into class II (performance standards) because the Panel believes that the design of the device must be controlled to assure that the device is installed correctly and provides adequate circulation to prevent rebreathing, and that any gas turbulence produced by the device does not cause excessive flow resistance. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device and related devices.

5. Risks to health:

(a) Impeded breathing: Reverse attachment of the circulator device to the breathing circuit may cause closure of breathing circuit valves, impeding the patient's breathing.

(b) Difficulty in breathing: Excessive flow resistance due to turbulence or inadequate circulation may cause difficulty in breathing.

(c) Rebreathing: Inadequate circulation may result in rebreathing of exhaled gases.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that breathing circuit circulators be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5250, to read as follows:

§ 868.5250 Breathing circuit circulator.

(a) *Identification.* A breathing circuit circulator is a turbine device attached to a closed breathing circuit. The device is used to circulate anesthetic gases continuously by maintaining the unidirectional valves in an open position and reducing mechanical dead space and resistance in the breathing circuit.

(b) *Classification.* Class II (performance standards). Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33407 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1729]

Medical Devices; Classification of Breathing Circuit Bacterial 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 breathing circuit bacterial filters into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of breathing circuit bacterial filters:

1. Identification: A breathing circuit bacterial filter is a device used to remove microbiological and particulate matter from the gases in the breathing circuit.

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 breathing circuit bacterial filters be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the filter does not add excessive flow resistance or promote bacterial contamination of the breathing circuit. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel

members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Increased breathing resistance: Absorption of water by the filter may impede gas flow in the breathing circuit thereby requiring increased patient effort. (b) Bacterial contamination: A reversal of airflow through the filter may cause bacterial contamination of the gases in the breathing circuit.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that breathing circuit bacterial filters be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5260, to read as follows:

§ 868.5260 Breathing circuit bacterial filter.

(a) *Identification.* A breathing circuit bacterial filter is a device used to remove microbiological and particulate matter from the gases in the breathing circuit.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33408 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1730]

Medical Devices; Classification of Breathing System Heaters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying breathing system heaters into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of breathing system heaters:

1. Identification: A breathing system heater is a device used to warm respiratory gases before they enter the patient's airway. The device may include a temperature controller.

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 breathing system heaters be classified into class II (performance standards) because the Panel believes that the heat output of this important and widely used device must be such that the gases are heated to a proper temperature. Overheating can cause hyperthermia and thermal burns, and inadequate heating can cause hypothermia. Improper heating may be caused by an inadequate heat controller or improper heat output where there is no controller. The electrical design must be adequate to assure that the patient or operator does not receive an electrical shock. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based it recommendation on the Panel members' personal knowledge of, and clinical experience with, breathing system heaters. The Panel noted that appropriate sections of electrical safety standards may apply.

5. Risks to health: (a) Hyperthermia and burns: If the breathing gases are overheated because of inadequate controls or excessive heat output, burns or hyperthermia may result. (b) Hypothermia: If the gases are underheated as a result of inadequate controls or insufficient heat output, hypothermia may result. (c) Electrical shock: If the device is not designed properly the patient or operator may receive an electrical shock.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that breathing system heaters be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart F

by adding new § 868.5270, to read as follows:

§ 868.5270 Breathing system heater.

(a) *Identification.* A breathing system heater is a device used to warm respiratory gases before they enter a patient's airway. The device may include a temperature controller.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33409 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1731]

Medical Devices; Classification of Breathing Tube Supports

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying breathing tube supports into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James. R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of breathing tube supports:

1. Identification: A breathing tube support is a device used to support and anchor a patient's breathing tube(s).

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 breathing tube supports be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that when the device is used in an explosive atmosphere, an explosion does not occur from the build-up of static electrical charges due to the use of nonconductive materials or improper grounding. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel noted that standards or sections of the standards developed by the Association of Operating Room Nurses (AORN) and the National Fire Protection Association (NFPA) may apply to this device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, breathing tube supports. There has been widespread use of these devices for many years.

5. Risks to health: Explosion: If the device is used in the presence of flammable gases, the build-up of static electricity from the use of nonconductive materials and/or improper grounding may result in an explosion.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that breathing tube supports be classified into class I (general controls) with no exemptions. Because users are familiar with these simple devices and have used them successfully for many years without significant problems, the agency believes that a performance standard is unnecessary. The agency believes that general controls, including appropriate labeling regarding the conductivity or nonconductivity of the device and warnings against use of the nonconductive device in the presence of flammable anesthetic agents, are sufficient to control the risks to health presented by the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 710(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5280, to read as follows:

§ 868.5280 Breathing tube support.

(a) *Identification.* A breathing tube support is a device used to support and anchor a patient's breathing tube(s).

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33410 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1732]

Medical Devices; Classification of Carbon Dioxide Absorbents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying carbon dioxide absorbents into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of carbon dioxide absorbents:

1. Identification: Carbon dioxide absorbent is a device consisting of an absorbent material (e.g., soda lime) used to remove carbon dioxide from the gases in a breathing 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 carbon dioxide absorbents be classified into class II (performance standards) because the Panel believes that the properties of this device must be controlled to assure that the device has an adequate carbon dioxide absorbing capacity to prevent hypercapnia (excess carbon dioxide in the blood) of the patient, to assure that dust caused by excessive flakiness is not introduced into the airway, and to assure that excessive resistance to gas flow does not result in inadequate ventilation.

The Panel believes that general controls will not provide sufficient control over these characteristics. Although the Panel believes that this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, carbon dioxide absorbents. Carbon dioxide absorbent material is listed in the United States Pharmacopeia (U.S.P.).

5. Risks to health: (a) Hypercapnia (excess carbon dioxide in the blood): If the device lacks sufficient absorption capacity, patient hypercapnia could result. (b) Inadequate ventilation: If the carbon dioxide absorbent adds excessive resistance to the breathing circuit, the patient may be inadequately ventilated. (c) Cross infection: If the device cannot be disinfected, a patient using the device may contract an infection after its use by another patient. (d) Airway irritation: If the carbon dioxide absorbent material is excessively flaky, particles or dust may be introduced into the patient's airway, possibly causing irritation of the patient's airway.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that carbon dioxide absorbents be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because this is a simple device with which there has been significant experience and because no reported problems attributed to the device would be diminished by subjecting the device to premarket approval. The agency believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5300, to read as follows:

§ 868.5300 Carbon dioxide absorbent.

(a) *Identification.* Carbon dioxide absorbent is a device consisting of an absorbent material (e.g., soda lime) used to remove carbon dioxide from the gases in the breathing circuit.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33411 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1733]

Medical Devices; Classification of Carbon Dioxide Absorbers

AGENCY: Food and Drug Administration

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying carbon dioxide absorbers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of carbon dioxide absorbers:

1. Identification: A carbon dioxide absorber is a device used in a breathing circuit as a container for carbon dioxide absorbent. It may include a canister and water drain.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standards for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the carbon dioxide absorber be classified into class II (performance standards) because the Panel believes that the design of the device should be controlled to assure that the absorber does not leak, causing inadequate carbon dioxide removal, and that dust or other irritants are not delivered to the patient. The Panel believes that general controls will not provide sufficient control over these characterisics. Although the Panel believes that this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficent information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device and the widespread use of the device during the past 25 years.

5. Risks to health: (a) Airway irritation: If the absorber allows dust to enter the breathing system, the dust could cause an allergic reaction and irritation of the patient's airway. (b) Inadequate carbon dioxide removal: Gas leakage in the absorber could result in an inadequate removal of carbon dioxide from the exhaled gas, possibly causing hypercapnia (excess carbon dioxide in the blood).

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that carbon dioxide absorbers be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecesaary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5310, to read as follows:

§ 868.5310 Carbon dioxide absorber.

(a) *Identification.* A carbon dioxide absorber is a device used in a breathing circuit as a container for carbon dioxide absorbent. It may include a canister and water drain.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980. submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33412 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1734]

Medical Devices; Classification of Reservoir 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 reservoir bags into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following

recommendation regarding the classification of reservoir bags:

1. Identification: A reservoir bag is a device, usually made of conductive rubber, used in a breathing circuit as a reservoir for breathing gas and to assist, control, and/or monitor a patient's ventilation.

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 reservoir bags be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the bag has a leak-free connection with the breathing circuit and proper elasticity to prevent the patient from being inadequately ventilated. The Panel believes that general controls will not provide sufficient control over these characteristics. Although the Panel believes that reservoir bags are life-supporting devices, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the devices because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and its widespread use during the past 25 years. The Panel also cited the American National Standards Institute's Z-79 Committee Standard for Anesthetic Reservoir Bags (Z-79.4, 1974) (Ref. 1) and noted that Underwriters Laboratory (UL) and the National Fire Protection Association (NFPA) standards also may apply to the device.

5. Risks to health: (a) Inadequate ventilation: If the reservoir bag is not properly connected to the other components in the breathing circuit, leaks may develop, resulting in an inadequate delivery of breathing gas to the patient. In addition, if the reservoir bag is not sufficiently elastic, excessive pressure may develop in the breathing circuit, resulting in inadequate ventilation of the patient. (b) Burns, explosion: If the device is used in the presence of flammable gases, the build-up of static electricity from the use of nonconductive materials may result in an explosion.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that reservoir bags be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a performance standard to provide reasonable assurance of the safety and effectiveness of this device. The agency also believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by 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. American National Standards Institute, Anesthetic Reservoir Bags, Z-79.4, 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5320, to read as follows:

§ 868.5320 Reservoir bag.

(a) *Identification.* A reservoir bag is a device, usually made of conductive rubber, used in a breathing circuit as a reservoir for breathing gas and to assist, control, and/or monitor a patient's ventilation.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33413 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1735]

Medical Devices; Classification of Breathing Gas Mixers

AGENCY: Food and Drug Administration

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying breathing gas mixers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of breathing gas mixers:

1. Identification: A breathing gas mixer is a device used in conjuction with a respiratory support apparatus to

facilitate and control the mixing of gases that are to be breathed by a patient.

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 breathing gas mixers be classified into class II (performance standards) because the Panel believes that the design of the device should be controlled to assure that the patient receives the correct mixture of gases for breathing. The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is unnecessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Incorrect gas mixtures: If the device is designed so that more than one type of gas can be connected to the same fitting, or if the device is not calabrated properly, the patient may breathe an incorrect gas mixture.

Proposed Classification

FDA agrees with the Panel and is proposing that breathing gas mixers be classified into class II (performance standards). Although the device is life supporting, the agency believes that premarket approval is unnecessary because the principles applicable to the mixing of two or more gases are well understood. The agency believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5330, to read as follows:

§ 868.5330 Breathing gas mixer.

(a) *Identification.* A breathing gas mixer is a device used in conjuction with a respiratory support apparatus to facilitate and control the mixing of gases that are to be breathed by a patient.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33414 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1736]

Medical Devices; Classification of Nasal Oxygen 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 nasal oxygen cannulas into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The 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 nasal oxygen cannulas:

1. Identification: A nasal oxygen cannula is a two-pronged device used to administer oxygen to a patient through the nose.

2. Recommended classification: Class I (general controls). Both the Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel recommend that this device be classified into class I (general controls). The Anesthesiology Device Classification Panel recommends that the device be exempted from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)). The General Hospital and Personal Use Device Classification Panel recommends that this device be exempt from the registration regulation under section 510 of the act (21 U.S.C. 360) and from the good manufacturing practice regulation under section 520(f) of the act.

3. Summary of reasons for recommendation: The Panels recommend that the nasal oxygen cannula 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 user can easily determine whether the device is safe and effective by examining it.

4. Summary of data on which the recommendation is based: Both Panels based their recommendation on their Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: The Anesthesiology Device Classification Panel identified no risks to health. The General Hospital and Personal Use Device Classification Panel identified the following risks to health: (a) Infection: If the device is not

sterile, infection may result. (b) Tissue reactions: If the materials used in the device are not biocompatible, they may cause tissue reaction.

Proposed Classification

FDA agrees with the recommendation of both Panels and is proposing that nasal oxygen cannulas be classified into class I (general controls). FDA disagrees with the recommendation of both Panels that manufacturers of nasal oxygen cannulas be exempt from the good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)). The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent production of a nasal oxygen cannula having defects that could harm users.

FDA disagrees with the General Hospital and Personal Use Device Classification Panel recommendation that manufacturers of nasal oxygen cannulas be exempt from the registration regulation under section 510 of the act (21 U.S.C. 360). Under section 510(g)(4), the agency may exempt a manufacturer from section 510 only upon a finding that compliance with this section is not necessary for the protection of the public health. In the case of a nasal oxygen cannula, the agency cannot make the required finding. To protect the public health, the agency needs to require manufacturers of this device to register and to list their products with FDA, so that the agency is able to identify the firms manufacturing this device and to conduct necessary inspections. Premarket notification by these manufacturers assures that FDA learns of new products, and of significant modifications of existing products, for which premarket approval is required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5340, to read as follows:

§ 868.5340 Nasal oxygen cannula.

(a) *Identification.* A nasal oxygen cannula is a two-pronged device used to administer oxygen to a patient through the nose.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33415 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1737]

Medical Devices; Classification of Nasal Oxygen 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 nasal oxygen catheters into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nasal oxygen catheters:

1. Identification: A nasal oxygen catheter is a device that is inserted through a patient's nostril to administer oxygen.
2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).
3. Summary of reasons for recommendation: The Panel recommends that nasal oxygen catheters 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 Panel recommends that the manufacturer not be required to comply with the good manufacturing practice requirements because any defects in the device are readily detectable.
4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.
5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that nasal oxygen catheters be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. FDA disagrees with the Panel's recommendation that manufacturers of nasal oxygen catheters be exempt from the good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)). The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent production of nasal oxygen catheters having defects that could harm users.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21

U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5350, to read as follows:

§ 868.5350 Nasal oxygen catheter.

(a) *Identification.* A nasal oxygen catheter is a device that is inserted through a patient's nostril to administer oxygen.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33416 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1738]

Medical Devices; Classification of Posture Chairs for Cardiac and Pulmonary Treatment

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying posture chairs for cardiac and pulmonary treatment into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of posture chairs for cardiac and pulmonary treatment:

1. Identification: A posture chair for cardiac and pulmonary treatment is a device used to assist in the rehabilitation and mobilization of patients with chronic heart and lung disease.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that posture chairs for cardiac and pulmonary treatment 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 Panel recommends that the manufacturer not be required to comply with the good manufacturing practice requirements because undetected defects in the device would not have an adverse effect on the patient.

4. Summary of data on which the recommendation is based: The Panel based it recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that posture chairs for cardiac and pulmonary treatment be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of a posture chair for cardiac and pulmonary treatment be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device, and that any defect in the device that is not readily detectible will not result in a device failure that could have an adverse effect on the patient or other user. The agency believes, however, that manufacturers of a posture chair for cardiac and pulmonary treatment must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of a posture chair for cardiac and pulmonary treatment must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5365, to read as follows:

§ 868.5365 Posture chair for cardiac and pulmonary treatment.

(a) *Identification.* A posture chair for cardiac and pulmonary treatment is a device used to assist in the rehabilitation and mobilization of patients with chronic heart and lung disease.

(b) *Classification.* Class I (general controls).

The device is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198 with respect to complaint files.

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33417 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1739]

Medical Devices; Classification of Heat and Moisture Condensers (Artificial Nose)

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying heat and moisture condensers (artificial nose) into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of heat and moisture condensers (artificial nose):

1. Identification: A heat and moisture condenser (artificial nose) is a device positioned over a tracheotomy (a surgically created opening in the throat) or tracheal tube (a tube inserted into the trachea) to warm and humidify gases breathed in by a patient.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that heat and moisture condensers be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure low resistance to gas flow, proper dead space (space not utilized for gas exchange with the blood) according to the size of the patient for whom it is designed, standard connector fittings, and proper size and shape to prevent premature obstruction by secretions. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, heat and moisture condensers.

5. Risks to health: (a) Inadequate ventilation (breathing): Inadequate ventilation may be caused by excessive resistance to gas flow, improper dead space, or connectors that do not fit. (b) Obstruction by secretions: Improper size or shape may cause premature obstruction of the tracheotomy by secretions.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that heat and moisture condensers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5375, to read as follows:

§ 868.5375 Heat and moisture condenser (artificial nose).

(a) *Identification.* A heat and moisture condenser (artificial nose) is a device positioned over a tracheotomy (a surgically created opening in the throat) or tracheal tube (a tube inserted into the trachea) to warm and humidify gases breathed in by a patient.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 21, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33418 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1740]

Medical Devices; Classification of Water-Seal Thoracic Drainage 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 water-seal thoracic drainage systems into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of water-seal thoracic drainage systems:

1. Identification: A water-seal thoracic drainage system is a device used to restore subatmospheric intrapleural pressure (pressure in the space between the lungs and the chest wall) and to drain fluid from the pleural space, by means of a chest tube. The device is usually connected to a suction system.

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 water-seal thoracic drainage systems be classified into class II (performance standards) because the Panel believes that standards are necessary to assure that the device supplies adequate suction for drainage of the pleural space, and because it believes that the materials used in the device are controlled to assure a good connection between the device and the patient to prevent pneumothorax (accumulation of gas in the pleural space). The Panel believes that general controls would not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, water-seal thoracic drainage systems. In addition, the Panel members are aware that there have been few reported malfunctions or failures of this type of device (e.g., as reported in the FDA Medical Device Experience Monitoring Network files) relative to the number of these devices in use.

5. Risks to health: (a) Failure to establish subatmospheric intrapleural pressure: A loss of suction could reduce the effectiveness of the device in establishing a subatmospheric intrapleural pressure and in providing adequate drainage from the pleural space. (b) Pneumothorax (an accumulation of gas in the pleural space): Disconnection of the device from the patient may cause a pneumothorax, resulting in impaired lung function.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that water-seal thoracic drainage systems be classified into class II. Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5385, to read as follows:

§ 868.5385 Water-seal thoracic drainage system.

(a) *Identification.* A water-seal thoracic drainage system is a device used to restore subatmospheric intrapleural pressure (pressure in the space between the lungs and the chest wall) and to drain fluid from the pleural space, by means of a chest tube. The device is usually connected to a suction system.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 33419 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1741]

Medical Devices; Classification of Electroanesthesia 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 electroanesthesia apparatus into class III (premarket approval). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel and the Neurological Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to require each manufacturer

of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel and the Neurological Device Classification Panel, FDA advisory committees, made the following recommendation regarding the classification of electroanesthesia apparatus:

1. Identification: An electroanesthesia apparatus is a device used for the induction and maintenance of anesthesia during surgical procedures by means of an alternating or pulsed electric current that is passed through electrodes fixed to the patient's head.

2. Recommended classification: Class III (premarket approval). Both the Anesthesiology Device Classification Panel and the Neurological Device Classification Panel recommend that the electroanesthesia apparatus be classified into class III (premarket approval). Both Panels recommend that premarket approval for this device be a low priority.

3. Summary of reasons for recommendation: Both the Anesthesiology Device Classification Panel and the Neurological Device Classification Panel recommend that electroanesthesia apparatus be classified into class III (premarket approval) because the device presents a potential unreasonable risk of illness or injury to the patient. The Panels believe that there is not sufficient information to establish a performance standard that will provide reasonable assurance of the safety and effectiveness of the device, and that there is insufficient information to show that general controls will provide such assurance. Therefore, the device should be subject to premarket approval to ensure that manufacturers satisfactorily demonstrate the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Anesthesiology Device Classification Panel based its recommendation on the insufficient number of domestic studies on human subjects. The Panel has not seen any medical data on which to judge the safety and effectiveness of the device, and believes that the technique of electroanesthesia is not considered a well-established or well-recognized clinical procedure. The Neurological Device Classification Panel noted that many factors important to the clinical application of this technique have not been sufficiently defined. The Neurological Device Classification Panel also based its recommendation on the Panel members' experience with the device, and their judgment and knowledge of the pertinent literature (Ref. 1). The National Research Council recommends that electroanesthesia be considered as a potentially useful adjunct in the maintenance of anesthesia but that electroanesthesia should be limited to investigational use until its effects, advantages, and standardization can be adequately evaluated.

5. Risks to health: (a) Electrical shock: Improper electrical grounding may allow the patient or operator to receive an electrical shock. (b) Damage to central nervous system: Excessively high electrical current or voltage could damage the central nervous system and cerebral tissues. (c) Skin burns: If the electrodes are too small and yield a high current density, skin burns may result. (d) Skin irritation: Electrode gels or pastes used to establish electrical contact between the electrode and the skin may cause skin irritation. (e) Cardiac or pulmonary interference: The position of the electrode on the head may lead to electrical interference with cardiac or pulmonary functions in the patient.

Proposed Classification

FDA agrees with the recommendation of the Anesthesiology Device Classification Panel and the Neurological Device Classification Panel and is proposing that the electroanesthesia apparatus be classified into class III (premarket approval). The agency believes that the safety and effectiveness of the device has not been established and that the device presents a potential unreasonable risk of illness or injury to the patient because of the high electrical currents necessary to induce an anesthetic state in a patient. The agency concurs with both Panels that insufficient information exists on this device either to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, or to establish a performance 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. "An Evaluation of Electroanesthesia and Electrosleep," National Research Council, NTIS, PB-241-305, 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5400, to read as follows:

§ 868.5400 Electroanesthesia apparatus.

(a) *Identification.* An electroanesthesia apparatus is a device used for the induction and maintenance of anesthesia during surgical procedures by means of an alternating or pulsed electric current that is passed through electrodes fixed to the patient's head.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 24, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33420 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1743]

Medical Devices; Classification of Ether Hooks

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ether hooks into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ether hooks:

1. Identification: An ether hook is a device that fits inside the patient's mouth and is used to deliver vaporized ether.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempted from good manufacturing practice regulations under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that ether hooks 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 Panel does not believe that this device requires performance standards to control the identified risks to health. The Panel believes that defects in the device are readily detectable before use, and, therefore, the Panel recommends that the manufacturer not be required to comply with the good manufacturing practice requirements.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Tissue damage: Sharp edges on the hook may cause tissue trauma. (b) Overexposure: if the hook is poorly designed, persons in the areas of use may be subjected to excessive environmental ether contamination. (c) Tissue reaction: If the hook materials are not biocompatible, they may cause tissue reactions.

Proposed Classification

FDA agrees with the Panel and is proposing that ether hooks be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of an ether hook be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device who does not label or otherwise represent it as sterile be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of an ether hook, even when it is not labeled or otherwise represented as sterile, must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of an ether hook must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate. A manufacturer of an ether hook that is labeled or otherwise represented as sterile is, in the manufacture of this device, subject to the GMP regulation in its entirety.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5420, to read as follows:

§ 868.5420 Ether hook.

(a) *Identification.* An ether hook is a device that fits inside the patient's mouth and is used to deliver vaporized ether.

(b) *Classification.* Class I (general controls). If the device is not labeled or otherwise represented as sterile, it is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 24, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33421 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1744]

Medical Devices; Classification of Gas-Scavenging 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 gas-scavenging apparatus into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gas-scavenging apparatus:

1. Identification: A gas-scavenging apparatus is a device used to collect excess anesthetic, analgesic, and trace gases and vapors from a breathing system, ventilator, or extracorporeal pump-oxygenator, and conduct these gases out of the personnel area by means of an exhaust system.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that gas-scavenging apparatus be classified into class II (performance standards) because the Panel believes that the design of the device must be controlled to assure that it does not cause excessive breathing resistance, which prevents the patient from receiving adequate ventilation. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel noted that a standard has been proposed by the American National Standards Institute Z-79 committee.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, gas-scavenging apparatus.

5. Risks to health: (a) Inadequate ventilation: Development of excessive negative pressure in the breathing circuit may cause high breathing resistance, resulting in inadequate ventilation of the patient. Excessive resistance or an obstruction in the scavenging system may cause an excessive pressure buildup in the breathing circuit such that the patient cannot exhale.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that gas-scavenging apparatus be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 710(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5430, to read as follows:

§ 868.5430 Gas-scavenging apparatus.

(a) *Identification.* A gas-scavenging apparatus is a device used to collect excess anesthetic, analgesic, and trace gases and vapors from a breathing system, ventilator, or extracorporeal pump-oxygenator, and conduct these gases out of the personnel area by means of an exhaust system.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33422 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1745]

Medical Devices; Classification of Portable Oxygen 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 portable oxygen generators into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of portable oxygen generators:

1. Identification: A portable oxygen generator is a device that uses either a chemical reaction or physical means (e.g., molecular sieve) to release oxygen for respiratory therapy.

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 portable oxygen generators be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that oxygen is released in sufficient quantities to support proper ventilation, that the oxygen is pure, and that there are no oxygen leaks into the environment, which increase the risk of fire and burns. The Panel believes that general controls would not provide sufficient control over these characteristics. Although portable oxygen generators are life-supporting devices, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the devices because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Fire and burns: Oxygen leaks into the environment because of faulty device design or construction could result in an explosion or fire, which may cause burns. (b) Infection: The oxygen released may contain contaminants that cause infection or allergic reaction. (c) Inadequate oxygen production: If the device does not produce enough oxygen to meet the patient's demands, hypoxia (lack of oxygen) may result.

Proposed classification

FDA agrees with the Panel and is proposing that portable oxygen generators be classified into class II. Although the device supplies supplemental oxygen that may, in an emergency, be life supporting, the agency believes that premarket approval is unnecessary because the risks to health associated with the device can be controlled by standardization and by following good manufacturing practices. The agency believes that there is sufficient information to establish a performance standard for this device. The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5440, to read as follows:

§ 868.5440 **Portable oxygen generator.**

(a) *Identification.* A portable oxygen generator is a device that uses either a chemical reaction or physical means (e.g., molecular sieve) to release oxygen for respiratory therapy.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33423 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1746]

Medical Devices; Classification of Respiratory Gas Humidifiers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying respiratory gas humidifiers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of respiratory gas humidifiers:

1. Identification: A respiratory gas humidifier is a device used to add moisture to, and sometimes warm, the

breathing gases to the patient. Cascade, gas, heated, and prefilled humidifiers are included in this generic type of device.

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 that respiratory gas humidifiers be classified into class II (performance standards) because the Panel believes that the output of the device must be controlled to assure both adequate humidification of the gases to prevent drying of the patient's airway, and that the gases are properly heated to prevent burns of the upper airway, trachea, and facial areas. The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device. The Panel also cited the standard currently being developed by the Z-79 Committee of the American National Standards Institute concerning humidifiers and nebulizers.

5. Risks to health: (a) Overhydration: Administration of gases containing a large amount of water may cause a water overload in the patient that could be hazardous, particularly to small infants. (b) Drying of airway: If the device does not properly humidify the inspired gas mixture, the dry gas may cause drying of the patient's airways. (c) Burns, hyperthermia: Excessive heating of the inspired gas mixture by the humidifier may lead to burns in the upper airway, trachea, or facial areas or to hyperthermia (a generalized elevation in body temperature). (d) Infection or allergic reaction: Bacteria and other microorganisms may multiply in the warm, moist environment of the humidifier. Inhalation of these microorganisms by the patient may result in infection or allergic reaction.

Proposed Classification

FDA agrees with the Panel and is proposing that respiratory gas humidifiers be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a performance standard for this device. The agency also believes that a performance standard is necessary because general controls alone are insufficient to control the risks to health presented by 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5450, to read as follows:

§ 868.5450 Respiratory gas humidifier.

(a) *Identification.* A respiratory gas humidifier is is a device used to add moisture to, and sometimes warm, the breathing gases to be administered to the patient. Cascade, gas, heated, and prefilled humidifiers are included in this generic type of device.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33424 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1747]

Medical Devices; Classification of Humidifiers for Home Use

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying humidifiers from home use into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of humidifiers for home use.

1. Identification: A humidifier for home use is a device used to add water vapor to inspired gases for respiratory therapy. The vapor produced by the device pervades the area surrounding the patient and is inspired during normal respiration.

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 humidifiers for home use be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the device can be adequately cleaned and disinfected to prevent contamination of the room air with microorganisms and particulate matter. The temperature of the water reservoir must be controlled to minimize

growth of microorganisms, and to assure appropriate heating and/or humidifying of inhaled gases to prevent patient burns or hyperthermia (elevation of body temperature). The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, humidifiers. The Panel noted the development of standards by the Air Conditioning and Refrigeration Institute.

5. Risks to health: (a) Infection, allergic reaction, irritation: Inadequate cleaning, disinfection and/or temperature control in the humidifier may allow the growth of microorganisms and result in infections, allergic reactions, or irritation of the patient's airway. (b) Burns, hyperthermia: If the inhaled gases are too hot, the patient may be burned or may develop hyperthermia (elevation of body temperature).

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that humidifiers for home use be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5460, to read as follows:

§ 868.5460 Humidifier for home use.

(a) *Identification.* A humidifier for home use is a device used to add water vapor to inspired gases for respiratory therapy. The vapor produced by the device pervades the area surrounding the patient and is inspired during normal respiration.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33425 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1748]

Medical Devices; Classification of Hyperbaric Chambers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying hyperbaric chambers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James. R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hyperbaric chambers:

1. Identification: A hyperbaric chamber is a device that can be pressurized to greater than atmospheric pressure. It is used to increase the environmental oxygen pressure to promote the movement of oxygen from the environment to the patient's tissue. This classification does not include those chambers used solely for topical application.

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 hyperbaric chambers be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure adequate strength of the chamber to prevent sudden decompression or explosion, to assure that the materials used will eliminate the possibility of fire, to assure that there are safety features to prevent overpressurization and prolonged exposure to pressure, and to assure that gases in the chamber do not become contaminated, causing infection. The Anesthesiology Device Classification Panel considered the Committee Report of the Undersea Medical Society on "Hyperbaric Oxygen Therapy" (Ref. 1) in evaluating the uses of hyperbaric chambers. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panels believe that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on a presentation at the August 17, 1977 Panel meeting by Drs. Shilling and Kindwall of the Undersea Medical Society, Inc., and a committee report by Dr. Kindwall (Ref. 1). The Panel also cited an existing standard: American

National Standards Institute/National Fire Protection Association 56D–1976, Hyperbaric Facilities (Ref. 2).

5. Risks to health: (a) Oxygen toxicity: Overpressurization or prolonged exposure may result in excessive tissue oxygen concentrations. (b) Cavitation of blood: Sudden decompression of the chamber may result in blood cavitation (bubble formation in the blood) in the patient. (c) Mechanical trauma: Fire or explosion of the chamber due to poor materials or design may cause burns to the patient. (d) Infection, irritation: If the chamber gas is contaminated, the patient may contract an infection.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the hyperbaric chambers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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. Kindwall, E. P., "Hyperbaric Oxygen Therapy," Committee Report, Undersea Medical Society, UMS Report Number 5–23–77.

2. American National Standards Institute/National Fire Protection Association, Hyperbaric Facilities, 56D, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 710(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5470, to read as follows:

§ 868.5470 Hyperbaric chamber.

(a) *Identification.* A hyperbaric chamber is a device that can be pressurized to greater than atmospheric pressure. It is used to increase the environmental oxygen pressure to promote the movement of oxygen from the environment to the patient's tissue. This classification does not include those chambers used solely for topical application.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33426 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1749]

Medical Devices; Classification of Hyperthermia 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 hyperthermia devices into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hyperthermia devices:

1. Identification: A hyperthermia device is a soft, liquid-filled blanket and a heat exchanger used to warm all or part of the body.

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 hyperthermia devices be classified into class II (performance standards) because the Panel believes that the temperature of the device must be controlled to avoid excessive heating of the patient. The Panel believes that the device should be constructed so that only the temperature probe intended for use with the device can be attached and that others will not fit. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, hyperthermia devices.

5. Risks to health: Excessive hyperthermia: Temperature control failure or the use of an improper temperature probe may cause excessive heating of the patient, resulting in burns, tissue damage, ventricular fibrillation (rapid, repetitive excitation of heart muscle without a coordinated contraction of the ventricle), or blood coagulation defects.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that hyperthermia devices be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health

presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5480, to read as follows:

§ 868.5480 Hyperthermia device.

(a) *Identification.* A hyperthermia device is a soft, liquid-filled blanket and a heat exchanger used to warm all or part of the body.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33427 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1750]

Medical Devices; Classification of Hypothermia 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 hypothermia devices into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hypothermia devices:

1. Identification: A hypothermia device is a liquid-filled blanket and heat exchanger used to cool all or part of the body.

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 hypothermia devices be classified into class II (performance standards) because the temperature of the device must be controlled to avoid excessive cooling of the patient. The Panel believes that the device should be constructed so that only the temperature probe intended for use with this device can be attached, and that others will not fit. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's personal knowledge of, and clinical experience with, hypothermia devices.

5. Risks to health: Excessive hypothermia: Temperature control failure or the use of an improper temperature probe may cause excessive cooling of the patient, resulting in tissue damage, ventricular fibrillation (rapid, repetitive excitation of heart muscle without a coordinated contraction of the ventricle), or blood coagulation defects.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that hypothermia devices be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believe that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5490, to read as follows:

§ 868.5490 Hypothermia device.

(a) *Identification.* A hypothermia device is a liquid-filled blanket and heat exchanger used to cool all or part of the body.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33428 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1751]

Medical Devices; Classification of Automatic Catheter Flushing 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 automatic catheter flushing devices into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of automatic catheter flushing devices:

1. Identification: An automatic catheter flushing device is used to pump fluid into an intravascular catheter to prevent clot formation.

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 automatic catheter flushing devices be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the valve mechanism adequately prevents improper infusion rates. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members; personal knowledge of, and clinical experience with, automatic catheter flushing devices.

5. Risks to health: (a) Clot formation: If the valve mechanism fails, reducing the flow rate, clots may form in the catheter and prevent infusion. (b) Overinfusion: Failure of the valve mechanism may cause an excessive flush rate, resulting in overinfusion and fluid overload to the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that automatic catheter flushing devices be classified into class II (performance standards). The agency believes that a performence standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5520, to read as follows:

§ 868.5520 Automatic catheter flushing device.

(a) *Identification.* An automatic catheter flushing device is used to pump fluid into an intravascular catheter to prevent clot formation.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33429 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1752]

Medical Devices, Classification of Flexible Laryngoscopes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying flexible laryngoscopes into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Durg Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the

development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of flexible laryngoscopes:

1. Identification: A flexible laryngoscope is a fiberoptic device used to examine and visualize a patient's upper airway and to facilitate the placement of a tracheal tube.

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 flexible laryngoscopes be classified into class II (performance standards) because the Panel believes the design of, and the materials used in, the device must be controlled to assure both that the patient's airway is not injured from sharp edges on the device and that the device can be adequately sterilized to prevent infection. The electrical design of the device also must be controlled to assure that the patient does not receive an electrical shock. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Trauma: Sharp edges on the device may cause trauma to the patient's airway. (b) Electrical shock: Improper electrical design may result in electrical shock of the patient. (c) Infection: If the device is not sterile, infection may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that flexible laryngoscopes be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5530, to read as follows:

§ 868.5530 Flexible laryngoscope.

(a) *Identification.* A flexible laryngoscope is a fiberoptic device used to examine and visualize a patient's upper airway and to facilitate placement of a tracheal tube.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33430 Filed 11-1-79; 8:45 am]
BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1753]

Medical Devices; Classification of Rigid Laryngoscopes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rigid laryngoscopes into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rigid laryngoscopes:

1. Identification: A rigid laryngoscope is a device used to examine and visualize a patient's upper airway and to facilitate placement of a tracheal tube.

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 rigid laryngoscopes be classified into Class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that no trauma occurs to the patient's airway from sharp edges, that the device can be adequately sterilized to prevent infection, and that the device's light source is reliable to prevent failure during emergency procedures. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel notes the development of a standard for laryngoscopy by the International Standards Organization Technical Committee 121.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, rigid laryngoscopes, which have been widely used for many years.

5. Risks to health: (a) Trauma: Sharp edges on the device may injure the patient's airway.

(b) Failure of light source: Sudden failure of the light source during placement of the tracheal tube may be hazardous to the patient because of increased difficulty in proper placement of the tracheal tube. (c) Infection: If the device is not sterile, infection may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that rigid laryngoscopes be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5540, to read as follows:

§ 868.5540 Rigid laryngoscope.

(a) *Identification.* A rigid laryngoscope is a device used to examine and visualize a patient's upper airway and to facilitate placement of a tracheal tube.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33431 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1754]

Medical Devices; Classification of Anesthetic Gas Masks

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying anesthetic gas masks into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposed that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of anesthetic gas masks:

1. Identification: An anesthetic gas mask is a device, usually made of conductive rubber, that is positioned over a patient's nose or mouth to direct anesthetic gases to the upper airway.

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 anesthetic gas masks be classified into class II (performance standards) because the Panel believes that the design of the device should be controlled to assure that gas delivery to the patient is adequate and that the mask is of a proper size and shape. The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, these devices and the widespread use of these devices over the past 25 years.

5. Risks to health: (a) Failure to deliver gas: Disconnection of the mask from the breathing tube may result in failure of gas delivery to the patient. (b) Inadequate delivery: Gas leakage from the mask may lead to a decrease in the volume of gas delivered to the patient. (c) Rebreathing of exhaled gases: Excessive gas volume in the device may cause the patient to rebreathe previously exhaled gas. (d) Eye injury: An improperly fitting mask may cause eye injury.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the anesthetic gas mask be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is significant experience with the device and because the risks to health associated with the device can be controlled by standardization and by following good manufacturing practices. The agency believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by 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 of Food and Drugs

proposes to amend Part 868 in Subpart F by adding new § 868.5550, to read as follows:

§ 868.5550 Anesthetic gas mask.

(a) *Identification.* An anesthetic gas mask is a device, usually made of conductive rubber, that is positioned over a patient's nose or mouth to direct anesthetic gases to the upper airway.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associated Commissioner for Regulatory Affairs.

[FR Doc. 79-33432 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1755]

Medical Devices; Classification of Gas Mask Head Straps

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying gas mask head straps into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II (performance standards). After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of gas mask head straps:

1. Identification: A gas mask head strap is a device used to hold an anesthesia gas mask in position on a patient's face.

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 gas mask head straps be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that when the device is used in an explosive atmosphere, an explosion does not occur from static electricity due to the use of non-conductive materials. The Panel also believes that a standard is necessary to prevent nerve damage which might be caused by excessive strap pressure, and to prevent dermatitis which might be caused by material that is not biocompatible or sterile. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance. The Panel noted that standards are being developed by committees of the Association of Operating Room Nurses and the National Fire Protection Association.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device. There has been widespread use of gas mask head straps for many years.

5. Risks to health: (a) Explosion: Static electricity from the use of nonconductive materials may cause an explosion if the device is used in an explosive environment. (b) Nerve damage: Excessive strap pressure may cause nerve damage if the strap is used for a long period of time. (c) Dermatitis: Adverse skin reaction may occur if the strap material is not biocompatible or sterile.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that gas mask head straps be classified into class I (general controls) with no exemptions. Because users are familiar with these simple devices and have used them successfully for many years without significant problems, the agency believes that a performance standard is unnecessary. The agency believes that general controls, including appropriate labeling regarding the conductivity or nonconductivity of the device and warnings against use of the nonconductive device in the presence of flammable anesthetic agents, are sufficient to control the risks to health presented by 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5560, to read as follows:

§ 868.5560 Gas mask head strap.

(a) *Identification.* A gas mask head strap is a device used to hold an anesthesia gas mask in position on a patient's face.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA 305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33433 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1756]

Medical Devices; Classification of Nonrebreathing Masks

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nonrebreathing masks into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nonrebreathing masks:

1. Identification: A nonrebreathing mask is a device fitting over the face that is used to supplement a patient's inspired oxygen. It uses one-way valves to prevent the patient from rebreathing exhaled gases.

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 nonrebreathing masks be classified into class II (performance standards) because the Panel believes that the design of the device should be controlled to assure that the one-way valves operate properly and that the correct gas concentration is delivered to the patient. The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that permarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, nonrebreathing masks. The Panel also cited the evaluation of disposable oxygen masks by the Emergency Care Research Institute (Ref. 1).

5. Risks to health: (a) Asphyxia: If the one-way valves do not operate properly, the patient could be asphyxiated due to lack of oxygen. (b) Hypoxia: If the mask fits the patient poorly, leakage could result, and dilution of the supplemental oxygen concentration may lead to patient hypoxia (insufficient oxygen).

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that nonrebreathing masks be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a performance standard for this device. The agency also believes that general controls alone are insufficient to control the risks to health presented by 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. "Disposable Oxygen Masks," *Health Devices*, 6(7): 157-171, 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5570, to read as follows:

§ 868.5570 Nonrebreathing mask.

(a) *Identification.* A nonrebreathing mask is a device fitting over the face that is used to supplement inspired oxygen. It utilizes one-way valves to prevent the patient from rebreathing previously exhaled gases.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33434 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1757]

Medical Devices; Classification of Oxygen Masks

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying oxygen masks into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel and the General Hospital Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These

actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel and the General Hospital Device Classification Panel, FDA advisory committees, made the following recommendation regarding the classification of oxygen masks:

1. Identification: An oxygen mask is a device placed over the patient's nose and mouth to administer oxygen.

2. Recommended classification: The Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel recommend that this device be classified into class I (general controls). The Panels recommend that there be no exemptions for this device.

3. Summary of reasons for recommendation: The Panels recommend that oxygen masks be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The Panels do not believe that this device requires performance standards to control the identified risks to health.

4. Summary of data on which the recommendation is based: The Panels based their recommendation on the Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: The Anesthesiology Device Classification Panel identified the following risks to health: (a) Delivery of inappropriate oxygen concentration: Excessive flow resistance may result in the delivery of an inappropriate oxygen concentration to the patient. (b) Eye injury: If the device is not of an appropriate size or shape to fit the patient, the patient's eye may be injured. The General Hospitl and Personal Use Device Classification Panel identified the following risks to health: (c) Infection: If the device is not sterile, infection may result. (d) Inadequate oxygen delivery: If the mask leaks excessively due to a poor fit, the appropriate amount of oxygen may not be delivered to the patient.

Proposed Classification

FDA agrees with the Panels' recommendation and is proposing that oxygen masks be classified into class I (general controls) with no exemptions. The agency 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 of Food and drugs proposes to amend Part 868 in Supbart F by adding new § 868.5580, to read as follows:

§ 8698.5580 Oxygen mask.

(a) *Identification.* An oxygen mask is a device placed over the patient's nose and mouth to administer oxygen.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33435 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1758]

Medical Devices; Classification of Scavenging Masks

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying scavenging masks into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of scavenging masks:

1. Identification: A scavenging mask is a device positioned over a patient's nose to deliver anesthetic or analgesic gases to the upper airway and to remove excess and exhaled gas. It is usually used during dentistry.

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 scavenging masks be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure adequate connector fittings, which prevent leakage of gas or accidental disconnection. In addition, the Panel believes that the size and shape of the mask must be controlled to

prevent leakage of gas from the area between the face and rim of the mask and to prevent eye injury. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, scavenging masks and related devices. These devices have been widely used for many years.

5. Risks to health: (a) Failure to deliver gas: Improper connector fittings may result in partial or complete disconnection of the gas line from the mask. (b) Decrease in volume delivered: Improper connector fittings or improper fit of the mask to the face may result in leakage of gas from these areas and delivery of insufficient gas to the patient. (c) Rebreathing: Excessive volume in the mask may result in rebreathing of exhaled gases. (d) Eye injury: Improper fit of the mask to the face may result in eye injury.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that scavenging masks be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5590, to read as follows:

§ 868.5590 Scavenging mask.

(a) *Identification.* A scavenging mask is a device positioned over a patient's nose to deliver anesthetic or analgesic gases to the upper airway and to remove excess and exhaled gas. It is usually used during dentistry.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33436 Filed 11-1-79; 8:45 am]
BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1759]

Medical Devices; Classification of Venturi Masks

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying venturi masks into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel that the device by 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 unde rthe Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of venturi masks:

1. Identification: A venturi mask is a device containing an air-mixing mechanism used to dilute 100 percent oxygen to a predetermined concentration before delivery to a patient.

2. Recommended classification: The Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel recommend that this device be classified into class II (performance standards). Both Panels recommend that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel recommend that the venturi mask be classified into class II (performance standards) because the Panels believe that the design of, and the materials used in, the device should be controlled to assure that the patient suffers no skin irritation from the the mask and that the mask delivers the prescribed oxygen concentration to the patient. The Panels believe that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panels believe that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panels based their recommendation on the Panel members' personal knowledge of, and clinical experience with, this device, as well as its widespread use and acceptance. The Anesthesiology Device Classification Panel noted that the use of venturi masks is mentioned in all standard textbooks on respiratory therapy.

5. Risks to health: The Anesthesiology Device Classification Panel and the General Hospital and Personal Use

Device Classification Panel identified the following risks to health: (a) Inappropriate oxygen delivery: If the mask becomes disconnected from the oxygen source or if the mixing orifice is not properly constructed, the amount of breathing gas delivered to the patient may be reduced. (b) Inappropriate oxygen concentration: If the air entrainment (mixing) mechanism does not function properly, the specified oxygen concentration may be in error, causing the patient to receive too little or too much oxygen. The General Hospital and Personal Use Device Classification Panel identified the following additional risk to health: (c) Adverse tissue reaction: If the mask material is incompatible with human tissue, the patient may have an adverse skin reaction.

Proposed Classification

FDA agrees with the recommendations of both Panels and is proposing that venturi masks be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a performance standard for this device. The agency also believes that general controls alone are insufficient to control the risks to health presented by 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5600, to read as follows:

§ 868.5600 Venturi mask.

(a) *Identification.* A venturi mask is a device containing an air-mixing mechanism used to dilute 100 percent oxygen to a predetermined concentration before delivery to a patient.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33437 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1760]

Medical Devices; Classification of Membrane Lungs for Long-Term Pulmonary Support

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying membrane lungs (for long-term pulmonary support) into class III (premarket approval). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to require each manufacture of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of membrane lungs for long-term pulmonary support:

1. Identification: A membrane lung is a device used to provide extracorporeal blood oxygenation for longer than 24 hours.

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 membrane lung be classified into class III (premarket approval) because the Panel believes that insufficient information exists to determine the adequacy of general controls, or to establish standards, to provide reasonable assurance of the safety and effectiveness of this device, which is both life-sustaining and life-supporting.

Therefore, the device should be subject to premarket approval to assure that manufacturers satisfactorily demonstrate the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on a presentation (May 20, 1976) by Dr. Theodor Kolobow, Chief of Cardiopulmonary Assist Devices, National Heart and Lung Institute, National Institutes of Health, Bethesda, Maryland. Dr. Kolobow discussed the need for long-term pulmonary support for critically ill patients and the advantages of extracorporeal membrane oxygenation in reducing blood trauma. However, Dr. Kolobow noted that extracorporeal membrane oxgenation is a new technique and must be used under well-controlled conditions by physicians skilled and knowledgeable in its use.

5. Risks to health: (a) Thrombocytopenia: Blood platelets important to the clotting mechanism may be trapped in the device, resulting in a tendency toward increased bleeding. (b) Hemolysis: The red blood cells may be damaged by the mechanicl features of the extracorporeal circuit, or they may be damaged if materials are used that are not biocompatible. (c) Inadequate gas exchange: If proper flow and mixing properties are not used in the extracorporeal circuit, inadequate oxygen delivery and carbon dioxide removal may result.

Proposed Classification

FDA agrees with the Panel and is proposing that membrane lungs for long-

term pulmonary support be classified into class III (premarket approval). The agency believes that insufficient information exists to determine the adequacy of general controls or to establish standards, to provide reasonable assurance of the safety and effectiveness of this life-sustaining or life-supporting device. The agency also agrees with the Panel that there are not sufficient scientific and medical data to demonstrate long-term 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5610, to read as follows:

§ 868.5610 Membrane lung for long-term pulmonary support.

(a) *Identification.* A membrane lung is a device used to provide extracorporeal blood oxygenation for longer than 24 hours.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33438 Filed 11-1-79; 8:45 am]
BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1761]

Medical Devices; Classification of Breathing Mouthpieces

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying breathing mouthpieces into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of breathing mouthpieces:

1. Identification: A breathing mouthpiece is a rigid device inserted into a patient's mouth that connects with diagnostic or therapeutic respiratory devices.

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 breathing mouthpieces be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the device does not have sharp edges that may lacerate the patient's mouth and that it can be cleaned adequately. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, breathing mouthpieces.

5. Risks to health: (a) Laceration: If the device has sharp edges, it could cut the patient's mouth. (b) Infection: If the device cannot be cleaned adequately, infection may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that breathing mouthpieces be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risk to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5620, to read as follows:

§ 868.5620 Breathing mouthpiece.

(a) *Identification.* A breathing mouthpiece is a rigid device inserted into a patient's mouth that connects with diagnostic or therapeutic respiratory devices.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33439 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

Docket No. 78N-1762

Medical Devices; Classification of Nebulizers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying nebulizers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of nebulizers:

1. Identification: A nebulizer is a device used to add particulate liquids via a spray to inspired gases that are directly delivered to the patient. Heated, ultrasonic, gas, venturi, and refillable nebulizers are included in this generic type of device.

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 nebulizers be classified into class II (performance standards) because the Panel believes that the design of the device must be controlled to assure that the device does not promote infection due to bacteria in the device, overhydrate or dry the patient's airway due to improper fluid output, or excessively heat the patient's airway due to lack of adequate temperature control. The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device. The Panel also cited the standard currently being developed by the Z-79 Committee of the American National Standards Institute concerning humidifiers and nebulizers.

5. Risks to health: (a) Overhydration: The delivery of a large amount of water to the patient may result in a water overload that could be hazardous, particularly to small infants. (b) Drying of airway: If the device does not sufficiently humidify the inspired gas mixture, the patient may breath dry gas, causing drying of the patient's airway. (c) Burns or hyperthermia (elevated body temperature): Excessive heating of the inspired gas mixture by the nebulizer may lead to burns in the upper airway, trachea, and or facial areas, or to hyperthermia. (d) Infection or allergic reaction: Bacteria and other microorganisms may multiply in the warm, moist environment of the nebulizer. Inhalation of these microorganisms by the patient may result in an infection or an allergic reaction.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that nebulizers be classified into class II (performance standards). Although the device is often used in a life support system, the agency believes that the device itself if not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a performance standard for this device. The agency also believes that general controls alone are insufficient to control the risks to health presented by 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5630, to read as follows:

§ 868.5630 Nebulizer.

(a) *Identification.* A nebulizer is a device used to add particulate liquids via a spray to inspired gases that are directly delivered to the patient. Heated, ultrasonic, gas, venturi, and refillable nebulizers are included in this generic type of device.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33440 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1763]

Medical Devices; Classification of Medicinal Nonventilatory Nebulizers (Atomizers)

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying medicinal nonventilatory

nebulizers (atomizers) into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulations 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of medicinal nonventilatory nebulizers (atomizers):

1. Identification: A medicinal nonventilatory nebulizer (atomizer) is a device used to deliver liquid medication to a patient in aerosol form.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that medicinal nonventilatory nebulizers (atomizers) 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 Panel does not believe that this device requires performance standards to control the identified risks to health. The Panel believes that the device should be exempt from the good manufacturing practice regulation because any defect in the device that is not readily detectable will not result in a device failure that could have an adverse effect on the patient.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Aspiration of components: If the device is poorly designed or assembled, the patient may aspirate pieces of the device.

Proposed classification

FDA agrees with the Panel recommendation and is proposing that medicinal nonventilatory nebulizers (atomizers) be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

FDA disagrees with the Panel's recommendation that manufacturers of medicinal nonventilatory nebulizers (atomizers) be exempt from the good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f). The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent production of medicinal nonventilatory nebulizers (atomizers) having defects that could harm users.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5640, to read as follows:

§ 868.5640 Medicinal nonventilatory nebulizer (atomizer).

(a) *Identification.* A medicinal nonventilatory nebulizer (atomizer) is a device used to deliver liquid medication to a patient in aerosol form.

(b) *Classification.* Class I (general. controls).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 33441 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1764]

Medical Devices; Classification of Esophageal Obturators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying esophageal obturators into class II (performance standards). FDA is also publishing the recommendation of the Anestheosiology 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 effectivness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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 CONTRACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following

recommendation regarding the classification of esophageal obturators:

1. Identification: An esophageal obutator is a device inserted through the patient's mouth to facilitate ventilation of the patient during emergency resuscitation by occluding (blocking) the esophagus, thereby permitting positive pressure ventilation through the trachea. The device consists of a closed-end semirigid esophagael tube that is attached to a face mask.

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 esophageal obturators be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to prevent the occurrence of esophageal or gastric trauma by assuring that the device is of the proper size and shape, and has no sharp edges.

The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device. The Panel noted that esophageal obturators are widly used in emergency medical care. The use of esophageal obturators is well accepted by the medical community, with instructional programs and literature available through the American Red Cross, the American Heart Association, and the American Medical Association.

5. Risks to health: Esophageal or gastric rutpure: If the device is not of the proper size, shape, and length, insertion into the patient could cause gastric or esophageal rupture.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that esophageal obturators be classified into class II (performance standards). Although this device is life supporting, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a performance standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

Therefore, under Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(A))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5650, to read as follows:

§ 868.5650 Esophageal obturator.

(a) *Identification.* An esophageal obturator is a device inserted through the patient's mouth to facilitate ventilation of the patient during emergency resuscitation by occluding (blocking) the esophagus, thereby permitting positive pressure ventiliation through the trachea. The device consists of a closed-end semirigid esophageal tube that is attached to a face mask.

(b) *Classification.* Class II (performance standard).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in rackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33442 Filed 11-1-79; 8:45 am]
BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1765]

Medical Devices; Classification of Portable Liquid Oxygen 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 portable liquid oxygen units into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of portable liquid oxygen units:

1. Identification: A portable liquid oxygen unit is a portable, thermally insulated container of liquid oxygen that is used for supplementation of a patient's inspired oxygen. It is sometimes accompanied by tubing and an oxygen mask.

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 portable liquid oxygen units be classified into class II (performance standards) because the Panel believes that the design of the device should be controlled to assure that the device reliably delivers oxygen to the patient and that is does not present a hazard of fire or explosion. The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and

effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on its widespread use during the past 25 years.

5. Risks to health: (a) Burns: The use of oxygen in high concentration presents a fire hazard, with the accompanying possibility of burns. (b) Inappropriate oxygen delivery: If the oxygen is not delivered reliably, the patient may receive a breathing mixture with too low or too high an oxygen concentration.

Proposed Classification

FDA agrees with the Panel and is proposing that the portable liquid oxygen units be classified into class II (performance standards). Although this device supplies supplemental oxygen that may, in an emergency, be life supporting, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a performance standard for this device. The agency also believes that general controls are insufficient to control the risks to health presented by 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5655, to read as follows:

§ 868.5655 Portable liquid oxygen unit.

(a) *Identification.* A portable liquid oxygen unit is a portable, thermally insulated container of liquid oxygen that is used for supplementation of a patient's inspired oxygen. It is sometimes accompanied by tubing and an oxygen mask.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associated Commissioner for Regulatory Affairs.

[FR Doc. 79-33443 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No.] 78N-1766

Medical Devices; Classification of Electric-Powered Percussors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electric-powered percussors into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of electric-powered percussors:

1. Identification: An electric-powered percussor is a device used to transmit vibration through a patient's chest wall to aid in freeing mucus deposits in the lung in order to improve bronchial drainage.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that electric-powered percussors be classified into class II (performance standards) because the Panel believes that the design of the device must be controlled to assure that the percussion stroke is not of such great force and/or length that it could break the ribs of the patient, and to assure that users of the device cannot pinch their fingers between the percussion ball and the body of the device. The electrical design must be controlled to assure that the patient or operator does not receive an electrical shock due to excessive leakage current. The Panel believes that general controls will not provide sufficient controls over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device, and on its widespread use.

5. Risks to health: (a) Broken ribs: Excessive force and/or length of the percussion stroke may cause broken ribs, particularly in elderly patients. (b) Trauma: Narrow clearance between the percussion ball and the body of the device may cause injury to the users' fingers. (c) Electrical shock: If the device is not designed properly, the patient or operator may receive an electrical shock.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that electric-powered percussors be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient

information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5665, to read as follows:

§ 868.5665 Electric-powered percussor.

(a) *Identification.* An electric-powered percussor is a device used to transmit vibration through a patient's chest wall to aid in freeing mucus deposits in the lung in order to improve bronchial drainage.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33444 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1767]

Medical Devices; Classification of Rebreathing 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 rebreathing devices into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rebreathing devices:

1. Identification: A rebreathing device is a device that enables the patient to rebreathe exhaled gases. It may be used in conjunction with pulmonary function testing or for increasing minute ventilation.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that rebreathing devices 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 Panel believes that the good manufacturing practice regulation will not improve the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that rebreathing devices be classified into class I. The Agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of a rebreathing device be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device who does not label or otherwise represent it as sterile be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of a rebreathing device, even when it is not labeled or otherwise represented as sterile, must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of a rebreathing device must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaing files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate. A manufacturer of a rebreathing device that is labeled or otherwise represented as sterile is, in the manufacture of this device, subject to the GMP regulation in its entirety.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5675, to read as follows:

§ 868.5675 Rebreathing device.

(a) *Identification.* A rebreathing device is a device that enables the patient to rebreathe exhaled gases. It may be used in conjunction with pulmonary function testing or for increasing minute ventilation.

(b) *Classification.* Class I (general controls). If the device is not labeled or otherwise represented as sterile, it is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 33445 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1768]

Medical Devices; Classification of Incentive Spirometers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying incentive spirometers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of incentive spirometers:

1. Identification: An incentive spirometer is a device that indicates the patient's breathing volume or flow. The device is used to provide an incentive to patients to improve their ventilation.

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 incentive spirometers be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the device does not have excessive flow resistance that would cause it to display inaccurate volume or flow data, that the device structure is of adequate strength to prevent inhalation of broken or whole components of the device, that the device can be cleaned and sterilized to prevent foreign body reaction and infection, and that the electrical design is adequate to assure that users do not receive an electrical shock. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, incentive spirometers.

5. Risks to health: (a) Inappropriate therapy: If the device does not measure the patient's inspired volume or flow accurately, the device may not accurately indicate lung condition, and thereby cause the administration of inappropriate therapy to the patient. (b) Infection: Inadequate cleaning and sterilization of the device may result in patient infection. (c) Electrical shock: If the device is not designed properly, the patient may receive an electrical shock. (d) Inhalation of foreign material: Breakage of internal parts, or in adequate cleaning of the device may result in the inhalation of foreign material.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the incentive spirometer be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5690, to read as follows:

§ 868.5690 Incentive spirometer.

(a) *Identification.* An Incentive spirometer is a device that indicates the patient's breathing volume or flow. The device is used to provide an incentive to patients to improve their ventilation.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associated Commissioner for Regulatory Affairs.

[FR Doc. 79-33446 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1769]

Medical Devices; Classification of Oxygen Tents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying oxygen tents into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of oxygen tents:

1. Identification: An oxygen tent is a non-powered device that encloses the patient's head and upper body to contain oxygen delivered to the patient.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempted from good manufacturing practice (GMP) regulations under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that oxygen tents 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 Panel does not believe that this device requires performance standards to control the identified risks to health. The Panel believes that the oxygen tent should be exempt from the good manufacturing practice regulations because all defects of the device are readily detectable before use.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Burns, asphyxiation: Because of the presence of high concentrations of oxygen, use of flammable materials in the device creates a potentially severe fire hazard. A fire could burn or asphyxiate the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that oxygen tents be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. FDA disagrees with the Panel's recommendation that manufacturers of oxygen tents be exempt from the good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)). The agency believes that compliance with this regulation is necessary to assure the quality of this device and thus its safety, effectiveness, and compliance with the adulteration and misbranding provisions of the act. Compliance with the GMP regulation will help prevent production of oxygen tents having defects that could harm users.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5700, to read as follows:

§ 868.5700 Oxygen tent.

(a) *Identification.* An oxygen tent is a non-powered device that encloses the patient's head and upper body to contain oxygen delivered to the patient.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA 305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33447 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1770]

Medical Devices; Classification of Electrically-Powered Oxygen Tents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying electrically-powered oxygen tents into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and the General Hospital and Personal Device Classification Panel, FDA advisory committees, made the following recommendation with respect to the classification of electrically-powered oxygen tents:

1. Identification: An electrically-powered oxygen tent is a device that encloses the patient's head and, via an electrically powered unit, administers inspiratory oxygen and provides control of the temperature and humidity. This generic type of device also includes the pediatric aerosol tent.

2. Recommended classification: Both the Anesthesiology Device Classification Panel and General Hospital and Personal Use Device Classification Panel recommended that the electrically-powered oxygen tent be classified into class II (performance standards). The Anesthesiology Device Classification Panel recommends that establishing a performance standard for this device be a low priority. The General Hospital Personal Use Device Classification Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: Both Panels recommend that electrically-powered oxygen tents be classified into class II (performance standards) because the Panels believe that the design of, and the materials used in, the device must be controlled to assure that the temperature and humidity are regulated, that the device has an alarm to warn of a drop in temperature which could cause hypothermia of the patient, and that electrical leakage current is minimized to prevent electrical shock and reduce the fire hazard. The Panels believe that general controls will not provide sufficient control over these characteristics. The Panels believe that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panels based their recommendation on the Panel members' personal knowledge of, and clinical experience with, electrically-powered oxygen tents. The device has been in widespread use for many years, and its fundamental principles and applications are well-accepted.

5. The Anesthesiology Device Classification Panel identified the following risks to health: (a) Burns and related injuries: Because of the presence of a high concentration of oxygen, use of flammable materials and electrical power in the device creates a potentially severe fire hazard. A design weakness or an operational malfunction could result in an explosion or fire, causing burns. (b) Electrical shock: If the device is not designed properly, the patient may receive an electrical shock. (c) Hypothermia: An inadequate temperature control or temperature alarm may result in hypothermia of the patient.

The General Hospital Personal Use Device Classification Panel identified the following risks to health: (a) Inadequate ventilation: Insufficient oxygen flow rate may result in inadequate ventilation and hypoxia. (b) Inadequate humidification: Insufficient humidification may result in drying of the patient's airway. (c) Hypothermia, hyperthermia: Failure of the temperature controls could result in hypothermia or hyperthermia.

Proposed classification

FDA agrees with the recommendation of the Anesthesiology Device Classification Panel and the General Hospital Personal Use Device Classification Panel and is proposing that the electrically-powered oxygen tent be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1050, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5710, to read as follows:

§ 868.5710 Electrically-powered oxygen tent.

(a) *Identification.* A electrically-powered oxygen tent is a device that encloses the patient's head and, via an electrically powered unit, administers inspiratory oxygen and provides control of the temperature and humidity. This generic type device also includes the pediatric aerosol tent.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33448 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1771]

Medical Devices; Classification of Bronchial Tubes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying bronchial tubes into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of bronchial tubes:

1. Identification: A bronchial tube is a device used to differentially intubate a bronchus (one of the two main branches of the trachea leading directly to the lung) in order to isolate a portion of the lung distal to the tube.

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 bronchial tubes be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device should be controlled to assure that the device permits proper ventilation of the patient, does not cause trauma to the patient's airway, does not promote infection, and is compatible with human lung tissue. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that although this device is life supporting, premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that would provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device, and its widespread use for the past 25 years.

5. Risks to health: (a) Failure to ventilate: If the bronchial tube becomes kinked, or if the cuff that isolates the portion of the lung fails, or if the bronchial tube is not of the appropriate configuration for use in a particular portion of the lung, the patient may not receive an adequate volume of breathing gas. (b) Infection: If the device is not sterile, infection may result. (c) Tissue reaction: If the bronchial tube is composed of a material that is incompatible with lung tissue, it may cause an allergic reaction. (d) Trauma: If the device is too rigid, it may cause trauma upon insertion.

Proposed Classification

FDA agrees with the Panel and is proposing that bronchial tubes be classified into class II (performance standards). Although this device is life supporting, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5720, to read as follows:

§ 868.5720 Bronchial tube.

(a) *Identification.* A bronchial tube is a device used to differentially intubate a bronchus (one of the two main branches of the trachea leading directly to the lung) in order to isolate a portion of lung distal to the tube.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33449 Filed 11-1-79; 8:45 am]
BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1772]

Medical Devices; Classification of Tracheal Tubes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying tracheal tubes into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of tracheal tubes:

1. Identification: A tracheal tube is a device inserted into a patient's trachea via the nose or mouth and used to maintain an open airway.

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 tracheal tubes be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device should be controlled to assure that the patient can be ventilated using the device, that the device is not easily occluded (blocked) by kinking or cuff problems, and that the material used in the device does not cause an allergic reaction or infection. The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device. The device has been in widespread use during the past 25 years. The Panel also cited the development of standards for tracheal tubes by a committee of the American National Standards Institute.

5. Risks to health: (a) Failure to ventilate: Blockage of the tube due to kinking, rupture or herniation of the cuff, or improper shape may prevent ventilation of the patient. (b) Infection: If the device is not sterile, infection may result. (c) Tissue reaction: If the materials used in the device are not biocompatible, they may cause tissue reactions. (d) Trauma: If the device materials are not flexible, the patient's airway may be injured during intubation.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that tracheal tubes be classified into class II (performance standards). Although the device is life supporting, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5730, to read as follows:

868.5730 Tracheal tube.

(a) *Identification.* A tracheal tube is a device inserted into a patient's trachea via the nose or mouth and used to maintain an open airway.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33450 Filed 11-1-79; 8:45 am]
BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1773]

Medical Devices; Classification of Tracheal/Bronchial Differential Ventilation Tubes

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying tracheal/bronchial differential ventilation tubes into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of tracheal/bronchial differential ventilation tubes:

1. Identification: An tracheal/bronchial differential ventilation tube is a device used to isolate the left or right lung for anesthesia and pulmonary function testing.

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 tracheal/bronchial differential ventilation tube be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the ventilation of the patient is not impaired by kinking of the tube, failure of the isolation cuff to completely seal the airway, or inappropriate shape; that the device does not injure the patient's airway because it is too rigid; and that the device is made of bio-compatible materials which cannot cause adverse tissue reaction. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that although this device is life supporting, premarket approval is not necessary to provide reasonable assurance of its safety and effectiveness because there is sufficient information available to establish a performance standard that would provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation upon the Panel members' personal knowledge of, and clinical experience with, tracheal/bronchial differential ventilation tubes. The Panel noted that the standards for tracheal tubes and cuffs and tracheal tube connectors and adaptors developed by the American National Standards Institute would in large part be applicable to tracheal/bronchial differential ventilation tubes.

5. Risks to health: (a) Failure to ventilate: If the bronchial tube becomes kinked, or if the cuff that isolates the portion of the lung fails, or if the bronchial tube is not of the appropriate configuration for use in a particular portion of the lung, the patient may not receive an adequate volume of breathing gas. (b) Infection: If the device is not sterile, infection may result. (c) Tissue reaction: If the bronchial tube is composed of a material that is incompatible with lung tissue, an allergic tissue reaction may occur. (d) Trauma: If the bronchial tube is too rigid, it may damage the patient's airway during insertion.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that tracheal/bronchial differential ventilation tubes be classified into class II (performance standards). Although this device is life supporting, the agency believes that premarket approval is unnecessary because there is sufficient information to establish to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by this 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5740, to read as follows:

§ 868.5740 Tracheal/bronchial differential ventilation tube.

(a) *Identification.* An tracheal/bronchial differential ventilation tube is a device used to isolate the left or the right lung for anesthesia and pulmonary function testing.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33451 Filed 11-1-79; 8:45 am]
BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1774]

Medical Devices; Classification of Inflatable Tracheal Tube 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 inflatable tracheal tube cuffs into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of inflatable tracheal tube cuffs:

1. Identification: An inflatable tracheal tube cuff is a device used to provide an airtight seal between the tracheal tube and the patient's trachea.

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 inflatable tracheal tube cuffs be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the cuff is permanently fixed to the tracheal tube to prevent it from falling off and obstructing the patient's airway, that the cuff is properly inflated for adequate ventilation and protection of the patient's upper airway, that the device is of the proper size and shape to prevent injury to the patient's laryngeal and tracheal walls, and that the device is biocompatible to prevent allergic tissue reaction. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that although this device is life supporting, premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, inflatable tracheal tube cuffs. Tracheal tubes have been widely used for the past 100 years. The Panel also noted the publication of a standard for tracheal tubes and cuffs by the American National Standards Institute Z-79 Committee (Ref. 1).

5. Risks to health: (a) Airway obstruction: If the cuff comes off the tracheal tube, it may become lodged in the airway and obstruct airflow. (b) Inadequate ventilation: If the cuff fails to inflate, the patient will not receive adequate ventilation through the tracheal tube, and the upper airway will not be adequately protected. (C) Tissue reaction: If the cuff is composed of a material that is not compatible with the tissues of the trachea, an allergic tissue

reaction may occur. (d) Trauma: If the cuff is not of the proper size, shape, or length, the laryngeal and/or tracheal walls may be damaged.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the inflatable tracheal tube cuff be classified into class II (performance standards). Although the device is life supporting, the agency believes that class III premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by 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. American National Standards Institute, "Tracheal Tubes and Cuffs," Z-79.1, 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5750, to read as follows:

§ 868.5750 Inflatable tracheal tube cuff.

(a) *Identification.* An inflatable tracheal tube cuff is a device used to provide an airtight seal between the tacheal tube and the patient's trachea.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33452 Filed 11-1-79; 8:45 am]
BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1775]

Medical Devices; Classification of Cuff Spreaders

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cuff spreaders into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of cuff spreaders:

1. Identification: A cuff spreader is a device used to install tracheal tube cuffs on tracheal and tracheotomy tubes.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempted from good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that cuff spreaders 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 physician can easily determine whether the device is safe and effective by examining it.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that cuff spreaders be classified into class I. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of a cuff spreader be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device who does not label or otherwise represent it as sterile be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of a cuff spreader, even when it is not labeled or otherwise represented as sterile, must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of a cuff spreader must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine

whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate. A manufacturer of a cuff spreader that is labeled or otherwise represented as sterile is, in the manufacture of this device, subject to the GMP regulation in its entirety.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5760, to read as follows:

§ 868.5760 Cuff spreader.

(a) *Identification.* A cuff spreader is a device used to install tracheal tube cuffs on tracheal and tracheotomy tubes.

(b) *Classification.* Class I (general controls). If the device is not labeled or otherwise represented as sterile, it is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33453 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1776]

Medical Devices; Classification of Tracheal Tube Fixation 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 tracheal tube fixation devices into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of tracheal tube fixation devices:

1. Identification: A tracheal tube fixation device is a device used to hold a tracheal tube in place, usually by means of straps or pinch rings.

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 tracheal tube fixation devices be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the patient is properly ventilated, the device does not cause tissue damage upon insertion, and the device is composed of biocompatible materials. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that although this device is life supporting, premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device, and its widespread use and acceptance in the medical community.

5. Risks to health: (a) Inadequate ventilation: If the device fails to hold the tracheal tube in place, the patient may be inadequately ventilated. (b) Tissue raction: If the tracheal tube holder is composed of a material that is not compatible with body tissues, an allergic tissue reaction may occur. (c) Trauma: If the fixation device is too rough or abrasive, it may cause trauma to the patient upon insertion.

Proposed Classification

FDA agrees with the Panel and is proposing that the tracheal tube fixation devices be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5770, to read as follows:

§ 868.5770 Tracheal tube fixation devices.

(a) *Identification.* A tracheal tube fixation device is a device used to hold a tracheal tube in place, usually by means of straps or pinch rings.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may

submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33454 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1777]

Medical Devices; Classification of Tube Introduction Forceps

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying tube introduction forceps into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final regulation based on this proposal become 78-1377 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8747 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of tube introduction forceps:

1. Identification: A tube introduction forcep (e.g., Magill forceps) is a right-angled device used to grasp a tracheal tube and place it in the patient's trachea

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 tube introduction forceps be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the tracheal tube is not damaged or the patient's airway injured from sharp edges on the device. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, tube introduction forceps. This device has been widely used for many years.

5. Risks to health: Trauma: Sharp edges on the device may cause trauma to the patient's airway or the tracheal tube.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that tube introduction forceps be classfied into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5780, to read as follows:

§ 868.5780 Tube introduction forceps.

(a) *Identification.* A tube introduction forcep (e.g., Magill forceps) is a right-angled device used to grasp a tracheal tube and place it in the patient's trachea.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m. Monday through Friday.

Dated: October 9, 1979

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33455 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1778]

Medical Devices; Classification of Tracheal Tube 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 tracheal tube stylets into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of tracheal tube stylets:

1. Identification: A tracheal tube stylet is a device used to make a flexible tracheal tube rigid in order to facilitate intubation.

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 tracheal tube stylets be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the patient's airway is not injured due to improper tip shape or length of the device, and to assure that the device can be sterilized to prevent infection. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, tracheal tube stylets.

5. Risks to health: (a) Trauma: Improper tip shape or length may injure the patient's airway. (b) Infection: If the device is not sterile, infection may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the tracheal tube stylets be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are sufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5790, to read as follows:

§ 868.5790 Tracheal tube stylet.

(a) *Identification.* A tracheal tube stylet is a device used to make a flexible tracheal tube rigid in order to facilitate intubation.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 33456 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1870]

Medical Devices; Classification of Airway Connectors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying airway connectors into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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 Administation, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of airway connectors:

1. Identification: An airway connector is a device used to connect a breathing gas source to a tracheal tube, tracheotomy tube, or mask.

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 airway connectors be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that leakage, disconnection, or obstruction of the connector does not occur during use. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that although this device is life supporting, premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that would provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, airway

connectors. This device is widely used and accepted. In addition, the Z-79 Committee of the American National Standards Institute has developed a standard for tracheal tube connectors and adaptors (Ref. 1).

5. Risks to health: Inadequate ventilation: Disconnection, separation, or obstruction of the connector during use may result in inadequate ventilation of the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that airway connectors be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself it not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

Reference

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. American National Standards Institute, Tracheal Tube Connectors and Adaptors, Z—79.2, 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(as))) and under authority delegated to him (21 CFR 5.12), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5810, to read as follows:

§ 868.5810 Airway connector.

(a) *Identification.* An airway connector is a device used to connect a breathing gas source to a tracheal tube, tracheotomy tube, or mask.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. to 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33457 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1781]

Medical Devices; Classification of Dental Protectors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying dental protectors into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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 Administation, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of dental protectors:

1. Identification: A dental protector is a device used to protect the patient's teeth during intubation or other manipulative procedures within the oral cavity.

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 dental protectors be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that no trauma occurs to the teeth because of the improper size, shape, length, or surface qualities of the device, and that the patient does not contact an infection because of inadequate sterilization of the device. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, dental protectors.

5. Risks to health: (a) Trauma to teeth: Improper size, shape, length, or surface qualities of the device may result in injury to the patient's teeth. (b) Infection: Improper sterilization may result in infection.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that dental protectors be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5820, to read as follows:

§ 868.5820 Dental protector.

(a) *Identification.* A dental protector is a device used to protect the patient's

teeth during intubation or other manipulative procedures within the oral cavity.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33458 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1782]

Medical Devices; Classification of Autotransfusion 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 autotransfusion apparatus into class III (premarket approval). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class III. The effect of classifying a device into class III is to require each manufacturer of the device to submit to FDA a premarket approval application at a date to be set in a future regulation. Each premarket approval application would include information concerning safety and effectiveness tests for the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of autotransfusion apparatus:

1. Identification: An autotransfusion apparatus is a device that may consist of a roller pump; nylon mesh filter, reservior, and auxilliary filter used to collect and reinfuse a patient's blood during 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 this device be classified into class III (premarket approval) because the Panel believes that the device is life sustaining and that the hazards presented by the device cannot presently be controlled by a standard. At the Anesthesiology Device Classification Panel meeting of July 16, 1977, the Panel recommended that this device be classified into class II (performance standards) because the Panel believed that the blood pumping techniques were similar to those used with cardiovascular bypass systems. The Panel at that time believed that there was sufficient information available on cardiovascular bypass systems so that standards could be written. However, on August 9, 1978, the Panel reassessed its recommendation on the autotransfusion apparatus and recommended that it be classified into class III (premarket approval) because the hazards presented by the device, particularly air emboli, cannot at this time be controlled by a standard. Therefore, the device should be subject to premarket approval to ensure that manufacturers satisfactorily demonstrate the safety and effectiveness of this device.

4. Risks to health: (a) Emboli (vascular obstruction caused by a bit of matter foreign to the blood stream, e.g., air bubbles, blood clots, etc.): Vascular obstruction from particulate matter or air bubbles may result from inadequate blood filtration or the introduction of air into the patient's circulatory system. (b) Hemolysis: Damage to red blood cells may occur from improper materials used in the apparatus (e.g., materials not biocompatible with blood) and/or the mechanical features of the extracorporeal circuit. (c) Coagulopathy: The patient may develop a blood coagulation problem from the anticoagulant therapy possibly suggested for use with the device. (d) Infection: Infection may result from inadequate sterilization of the apparatus.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the autotransfusion apparatus be classified into class III (premarket approval). The agency believes the device presents a potential unreasonable risk of illness or injury because the hazards presented by the device, particularly air emboli, cannot be controlled by a standard. The agency believes that insufficient information exists to determine that general controls would 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5830, to read as follows:

§ 868.5830 Autotransfusion apparatus.

(a) *Identification.* An autotransfusion apparatus is a device that may consist of a roller pump, nylon mesh filter, reservoir, and auxilliary filter used to collect and reinfuse a patient's blood during surgery.

(b) *Classification.* Class III (premarket approval).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33459 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1783]

Medical Devices; Classification of Blood Transfusion Microfilters

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 transfusion microfilters into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of blood transfusion microfilters:

1. Identification: A blood transfusion microfilter is a device used to remove microaggregates (small particles) from blood or blood products during transfusion.

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 blood transfusion microfilters be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the filtration surface area is adequate to prevent premature clogging and excessive flow resistance, that the effective pore size is correct to prevent passage of harmful microaggregates and pressure extrusion of trapped particles, and that the filter is compatible with blood to prevent hemolysis (destruction of red blood cells). The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel noted the development of a blood transfusion microfilter standard by a committee of the Association for the Advancement of Medical Instrumentation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, blood transfusion microfilters.

5. Risks to health: (a) Hemolysis: The use of materials that are not biocompatible with blood or improperly designed could cause hemolysis (destruction of red blood cells). (b) Embolic complications: Excessively large effective pore size may allow harmful microaggregates (particles) to enter the patient's vascular system and cause harmful alterations in brain and lung function. (c) Inadequate delivery: Inadequate filter surface area may cause excessive flow resistance or premature clogging of the filter that may result in inadequate blood delivery to the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that blood transfusion microfilters be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5840 as follows:

§ 868.5840 Blood transfusion microfilter.

(a) *Identification.* A blood transfusion microfilter is a device used to remove microaggregates (small particles) from blood or blood products during transfusion.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33460 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1784]

Medical Devices; Classification of Pressure Tubing and Accessories

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying pressure tubing and accessories into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation with respect to the classification of pressure tubing and accessories:

1. Identification: Pressure tubing and accessories are flexible or rigid devices used to deliver pressurized medical gases.

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 pressure tubing and accessories be classified into class II (performance standards) because the Panel believes that the design of the device should be controlled to prevent leakage, occlusion, or inadvertent disconnection, causing disruption of gas flow to the patient. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that although this device is life supporting, premarket approval is not necesary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device, and the widespread use of this device by medical and paramedical personnel.

5. Risks to health: Inadequate ventilation: Disconnection or occlusion of the tubing or leakage of gas from the tubing could result in inadequate ventilation of the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that pressure tubing and accessories be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5860, to read as follows:

§ 868.5860 Pressure tubing and accessories.

(a) *Identification.* Pressure tubing and accessories are flexible or rigid devices used to deliver pressurized medical gases.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33461 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1785]

Medical Devices; Classification of Nonrebreathing 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 nonrebreathing valves into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of nonrebreathing valves:

1. Identification: A nonrebreathing valve is a one-way valve that directs inspiratory gas flow to the patient and vents exhaled gasses into the atmosphere.

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 nonrebreathing valves be classified into class II (performance standards) because the Panel believes that the design of the device must be controlled to assure that the device does not increase the amount of effort necessary for breathing, or prevent adequate patient ventilation. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that although this device is life supporting, premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that would provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device. The fundamental principles and applications of this device are well accepted and have been widely used during the past 20 years.

5. Risks to health: (a) Rebreathing of breathing gas: If the valve is improperly assembled or fails to provide for one-way gas flow, the patient may rebreathe exhaled gas. (b) Inadequate ventilation: If the valve leaks, the volume of breathing gas delivered to the patient may be decreased, leading to inadequate ventilation. (c) Increased breathing effort: If a valve presents high resistence to gas flow, the patient may be forced to use unnecessary effort to breathe. (d) Occlusion: If the valve is not assembled properly, it may become occluded (blocked), preventing the flow of gas.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that nonrebreathing valves be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide rasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5870, to read as follows:

§ 868.5870 Nonrebreathing valve.

(a) *Identification.* A nonrebreathing valve is a one-way valve that directs inspiratory gas flow to the patient and vents exhaled gases into the atmosphere.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33462 Filed 11–1–79; 8:45 am]
BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N–1786]

Medical Devices; Classification of Anesthetic Vaporizers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying anesthetic vaporizers into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Room 4–65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, Md. 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of anesthetic vaporizers:

1. Identification: An anesthesia vaporizer is a device used to vaporize liquid anesthetic and deliver a controlled amount of the vapor to the patient.

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 anesthetic vaporizers be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the patient receives the proper anesthetic dose and that the device can be cleaned and sterilized to prevent contamination. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel noted the development of standards for anesthesia equipment by the committees of the American National Standard Institute and the Canadian Standards Association.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device. Anesthesia vaporizers have been widely used for more than 25 years.

5. Risks to health: (a) Overdose: Loose or sticking controls, overfilling of the vaporizer, foaming of the anesthetic agent, reversed flow, reversed connection, or inaccurate calibration

may cause an anesthetic overdose that could endanger the patient's life. (b) Infection: If the device is not sterile, infection may result. (c) Tissue reaction: If the device is not adequately cleaned, an allergic tissue reaction may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that anesthetic vaporizers be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5880, to read as follows:

§ 868.5880 Anesthetic vaporizer.

(a) *Identification.* An anesthesia vaporizer is a device used to vaporize liquid anesthetic and deliver a controlled amount of the vapor to the patient.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Room 4065, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33463 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1787]

Medical Devices; Classification of Continuous Ventilators

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 ventilators into class II (performance standards). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final regulations 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel, FDA advisory committees, made the following recommendation regarding the classification of continuous ventilators:

1. Identification: A continuous ventilator (respirator) is a device used to mechanically control or assist patient breathing. The device may deliver a predetermined percentage of oxygen in the inspired gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device.

2. Recommended classification: The Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel recommend that this device be classified into class II (performance standards). Both Panels recommend that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: Both the Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel recommend that continuous ventilators be classified into class II (performance standards) because the Panels believe the design of the device must be controlled to assure that the appropriate breathing gas is delivered to the patient at the prescribed volume, pressure, and concentration to adequately ventilate the patient. Both Panels believe that general controls will not provide sufficient control over these characteristics. Although continuous ventilators are life supporting, both Panels believe that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the devices because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panels based their recommendation on their Panel members' personal knowledge of, and clinical experience with, these devices, which have been in use for over 30 years. In addition the Z–79 Committee of the American National Standards Institute has written a standard for breathing machines for medical use (Ref. 1).

5. Risks to health: The Anesthesiology Device Classification Panel identified the following risks to health: (a) Inappropriate ventilation: Improper pressure adjustment may result in delivery to the patient's lungs of a reduced amount of air (hypoventilation), an increased amount of air (hyperventilation), and/or an improper mixture of breathing gas. The General Hospital and Personal Use Device Classification Panel identified the following risks to health: (b) Hypoxia or hyperoxia: The patient may receive too little or too much oxygen due to failure of the valves, meter connections, or gas concentration controls of the device. (c) Infection: If the device is not adequately cleaned or sterilized, the patient may contract an infection.

Proposed Classification

FDA agrees with the recommendation of both Panels and is proposing that

continuous ventilators be classified into class II (performance standards). Although this device is life supporting, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by the device.

References

1. American National Standards Institute, Breathing Machines for Medical Use, Z-79.7, 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5895 as follows:

§ 868.5840 Continuous ventilator.

(a) *Identification.* A continuous ventilator (respirator) is a device used to mechanically control or assist patient breathing. The device may deliver a predetermined percentage of oxygen in the inspired gas. Adult, pediatric, and neonatal ventilators are included in this generic type of device.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33464 Filed 11-1-79; 8:45 am]
BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1788]

Medical Devices; Classification of Noncontinuous Ventilators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying noncontinuous ventilators into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final regulations 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of noncontinuous ventilators:

1. Identification: A noncontinuous ventilator is a device used to deliver intermittently an aerosol (suspension of liquid particles in gas) to a patient's lungs and/or to augment a patient's breathing.

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 noncontinuous ventilators be classified into class II (performance standards) because the Panel believes that the design of the device must be controlled to assure that the appropriate breathing gas is delivered to the patient at the prescribed concentration, volume, and pressure. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that although this device is life supporting, premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that would provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, noncontinuous ventilators. The performance and safety of this device has been shown during 20 years of use. In addition, the Z-79 Committee of the American National Standards Institute has written a standard for breathing machines for medical use (Ref. 1).

5. Risks to health: (a) Inadequate ventilation or overdistension of lung: Uncontrolled variations in the cycling of the machine or the time allowed for inspiration or expiration may result in either the patient not receiving sufficient breathing gas or the development of excessive pressure in the lungs resulting in overdistension and rupture of lung tissue. (b) Inappropriate gas concentrations: If the air/oxygen mixing system is inaccurate, the patient may breathe a mixture too high or too low in oxygen concentration.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that noncontinuous ventilators be classified into class II. Although this device aids ventilation, it is used as adjunctive therapy and is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by 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. American National Standards Institute, Breathing Machines for Medical Use, Z-79.7, 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5905 to read as follows:

§ 868.5905 Noncontinuous ventilator.

(a) *Identification.* A noncontinuous ventilator is a device used to deliver intermittently an aerosol (suspension of liquid particles in gas) to a patient's lungs and/or to augment a patient's breathing.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 4, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33465 Filed 11-1-79; 8:45 am]
BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1789]

Medical Devices; Classification of Manual Emergency Ventilators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying manual emergency ventilators into class II (performance standards). FDA is also publishing the recommendations of both the Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and the General Hospital and Personal Use Device Panel, FDA advisory committees, made the following recommendations regarding the classification of manual emergency ventilators:

1. Identification: A manual emergency ventilator is a device, usually incorporating a bag and valve, used to provide emergency respiratory support via a face mask or a tube inserted into a patient's airway.

2. Recommended classification: Both the Anesthesiology Device Classification Panel and the General Hospital and Personal Use Device Classification Panel recommend that manual emergency ventilators be classified into class II (performance standards). The Anesthesiology Device Classification Panel recommends that establishing a performance standard for this device be a high priority. The General Hospital and Personal Use Device Classification Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: Both Panels recommend that manual emergency ventilators be classified into class II (performance standards) because the Panels believe that the design of the device should be controlled to assure that the device delivers an adequate volume of air and/or oxygen to the patient. Both Panels believe that general controls will not provide sufficient control over these characteristics. Both Panels believe that although this device is life supporting, premarket approval is unnecessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that would provide such assurance.

4. Summary of data on which the recommendation is based: Both Panels based their recommendation on their extensive personal knowledge of, and clinical experience with, manual emergency ventilators. Manual emergency ventilators have been used extensively for more than 25 years in treating critically ill patients.

5. Risks to health: Both Panels identified the following risks to health: Inadequate ventilation: Obstruction or improper operation of the valve, leaks, misassembly of the device, poor fit of the mask over the patient's face, or an inadequate volume of air/oxygen delivered to the mask may result in the patient receiving too little breathing gas at the wrong volume and/or rate. The General Hospital Device Classification Panel identified the following additional risk to health: Infection: Inability to adequately clean and sterilize the device may result in infection.

Proposed Classification

FDA agrees with both Panel recommendations and is proposing that manual emergency ventilators be classified into class II (performance standards). The agency has reviewed both Panel recommendations and has obtained additional information concerning the use of manual emergency ventilation devices. The National Academy of Sciences—National Research Council has reviewed the field of cardiopulmonary resuscitation from the standpoint of training, principles, and practice (Ref. 1). Design criteria for cardiopulmonary resuscitation equipment have emerged from their proceedings. In May 1973, the American Heart Association and the National Academy of Sciences—National Research Council cosponsored a conference on Standards for Cardiopulmonary Resuscitation and Emergency Cardiac Care. The Council recommended certain minimum criteria for manually operated devices (Ref. 2). A performance evaluation of some commercially available manually operated resuscitators has been conducted by the Emergency Care Research Institute, and certain design criteria have been suggested (Ref. 3). Although this device is life supporting, the agency believes that Class III (premarket approval) is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

The agency also believes that general controls alone are insufficient to control the risks to health presented by 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. "National Academy of Sciences—National Research Council: Cardiopulmonary Resuscitation Conference Proceedings," pp. 69–84, 124–132, 1976.

2. American Heart Association/National Academy of Sciences—National Research Council, "Standards for Cardiopulmonary Resuscitation (CPR) and Emergency Cardiac Care (ECC)," *in Journal of the American Medical Association*, 227(7), supp., 1974.

3. "Manually Operated Resuscitators," *Health Devices*, 1(1):13–17, 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 869.5915, to read as follows:

§ 868.5915 Manual emergency ventilator.

(a) *Identification.* A manual emergency ventilator is a device, usually incorporating a bag and valve, used to provide emergency respiratory support via a face mask or a tube inserted into a patient's airway.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulator Affairs.

[FR Doc. 79-33466 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1790]

Medical Devices; Classification of Powered Emergency Ventilators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying powered emergency ventilators into class II (performance standards). FDA is also publishing the recommendations of the Anesthesiology Device Classification Panel and the Dental Device Classification Panel that powered emergency ventilators be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel and the Dental Device Classification Panel, FDA advisory committees, made the following recommendation regarding the classification of powered emergency ventilators:

1. Identification: A powered emergency ventilator is a demand valve or inhalator used to provide emergency respiratory support via a facemask or a tube inserted into a patient's airway.

2. Recommended classification: The Anesthesiology Device Classification Panel and the Dental Device Classification Panel recommend that this device be classified into class II (performance standards). The Anesthesiology Device Classification Panel recommends that establishing a performance standard for this device be a high priority. The Dental Device Classification Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: Both Panels recommend that powered emergency ventilators be classified into class II (performance standards) because the Panels believe that the design of, and the materials used, in the device must be controlled to assure that the breathing gas is delivered to the patient at the prescribed concentration, volume, pressure, and rate. The Panels believe that general controls will not provide sufficient control over these characteristics. The Panels believe that although powered emergency ventilators are life supporting, premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of this device because there is sufficient information available to establish a performance standard that would provide such assurance.

4. Summary of data on which the recommendation is based: The Anesthesiology Device Classification Panel and the Dental Device Classification Panel based their recommendation on the Panel members' personal knowledge of, and clinical experience with, powered emergency ventilators. Powered emergency ventilators have been used extensively for more than 25 years in treating critically ill patients.

5. Risks to health: The Anesthesiology Device Classification Panel identified the following risks to health: (a) Inadequate ventilation: Obstruction or failure of the valves, leaks, or missassembly of the device may result in the patient receiving too little breathing gas at the wrong volume and/or rate. (b) Pneumothorax: Overpressurization may cause overdistention of the patient's lungs (pneumothorax). (c) Collapsing of airways: The use of negative pressure in the expiratory phase may cause collapse of the patient's airways. The Dental Device Classification Panel identified the following risk to health: Failure to resuscitate: Improper design of the unit may cause it to malfunction, and this could result in failure to resuscitate the patient.

Proposed Classification

FDA agrees with the recommendation of both Panels and is proposing that

powered emergency ventilators be classified into class II (performance standards). The agency has reviewed both Panels' recommendations and has obtained additional information concerning the use of powered emergency ventilators. The National Academy of Sciences—National Research Council has reviewed the field of cardiopulmonary resuscitation from the standpoints of training, principles, and practice (Ref. 1). From the Council's proceedings emerged certain design criteria for cardiopulmonary resuscitation equipment. In May 1973, the American Heart Association and the National Academy of Sciences—National Research Council co-sponsored a Conference on Standards for Cardiopulmonary Resuscitation and Emergency Cardiac Care. The Conference recommended that pressure-cycled automatic resuscitators not be used in conjunction with external cardiac compression because compression may prematurely terminate the inflation cycle of the resuscitator, resulting in inadequate patient ventilation (Ref. 2). A performance evaluation of some commercially available oxygen-powered resuscitators has been conducted by the Emergency Care Research Institute and certain design criteria have been suggested (Ref. 3). Although this device is life supporting, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by 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. "National Academy of Sciences—National Research Council: Cardiopulmonary Resuscitation Conference Proceedings," pp. 69–84, 124–132, 1976.

2. American Heart Association/National Research Council, "Standards for Cardiopulmonary Resuscitation (CPR) and Emergency Cardiac Care (ECC)," *Journal of the American Medical Association*, 227(7), Supp., 1974.

3. "Oxygen-powered Resuscitators," *Health Devices*, 3(9):207–221, 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5925 as follows:

§ 868.5925 Powered emergency ventilator.

(a) *Identification.* A powered emergency ventilator is a demand valve or inhalator used to provide emergency respiratory support via a facemask or a tube inserted into a patient's airway.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33467 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1791]

Medical Devices; Classification of External Negative Pressure Ventilators

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 negative pressure ventilators into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of external negative pressure ventilators:

1. Identification: An external, negative pressure ventilator (e.g., iron lung, cuirass) is a chamber that supports ventilation by using repetitive applications of external negative pressure over the diaphragm and upper trunk.

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 negative pressure ventilators be classified into class II (performance standards) because the Panel believes that the design of the device must be controlled to assure that there is no mechanical failure, which could cause inadequate ventilation of the patient. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that although this device is life supporting, premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device, which has been in widespread use over 50 years. Use of the device is a standard therapeutic modality for polio victims and is referenced in most texts.

5. Risks to health: Inadequate ventilation: If a mechanical failure occurs, or if an adequate air seal is not maintained, the patient may receive inadequate ventilation.

Proposed Classification

FDA agrees with the Panel and is proposing that external negative pressure ventilators be classified into class II (performance standards). Although this device is life supporting, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5935, to read as follows:

§ 868.5935 External negative pressure ventilator.

(a) *Identification.* An external, negative pressure ventilator (e.g., iron lung, cuirass) is a chamber that supports ventilation by using repetitive applications of external negative pressure over the diaphragm and upper trunk.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk document number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33468 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1793]

Medical Devices, Classification of Intermittent Mandatory Ventilation Attachments

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying intermittent mandatory ventilation attachments into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of intermittent mandatory ventilation attachments:

1. Identification: An intermittent mandatory ventilation (IMV) attachment is a device attached to a mechanical ventilator that allows spontaneous breathing by the patient while providing mechanical ventilation at a preset rate.

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 intermittent mandatory ventilation attachments be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure proper action of the valves to prevent insufficient ventilation of the patient or overdistention of the patient's lung tissues from excessive pressure. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that although this device is life supporting, classification into class III (premarket approval) is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, intermittent mandatory ventilation attachments. This device is widely accepted as a primary therapeutic modality.

5. Risks to health: (a) Inadequate ventilation: Malfunction of the one-way valves or inadequate pressure generated by the device in the patient circuit may lead to inadequate ventilation of the patient. (b) Lung damage: Excessive pressure generated by the device in the patient circuit could result in overdistension of lung tissue, which may lead to lung damage.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that intermittent mandatory ventilation (IMV) attachments be classified into class II (performance standards). The agency has reviewed the Panel recommendation and has sought additional information concerning the use of intermittent mandatory ventilation attachments. The advantages and disadvantages of IMV therapy have been reviewed in the literature (Refs. 1 and 2). An IMV attachment is essentially a timer that cycles a ventilator to deliver a breath to the patient at a preset rate. As such, many IMV devices have been homemade, increasing the possibility of improper assembly. As an increasing number of manufacturers incorporate IMV circuits into their ventilators, this problem should decrease (Ref. 1). Yestingsmeier and Miller evaluated an IMV attachment not incorporated into a ventilator, for its dependability and accuracy, and

determined it to be acceptable (Ref. 3). Modifications of IMV circuits called intermittent demand ventilation (IDV) and synchronized intermittent mandatory ventilation (SIMV) have been produced. The purpose of these circuits is to associate IMV with a more normal physiology. Shapiro et al. reported favorably on IDV as a therapeutic technique (Ref. 4).

Although this device is life supporting, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by 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. Kirby, R. R., D. Desautels, J. H. Modell, and R. A. Smith, "Mechanical Ventilation," *in* "Respiratory Care: A Guide to Clinical Practice," Edited by Burton, G. G., G. M. Gee, J. E. Hodgkin, and J. B. Lippincott, Philadelphia, 1977.

2. Egan, D. F., "Fundamentals of Respiratory Therapy," C. V. Mosby, St. Louis, pp. 428–432, 1977.

3. Yestingsmeier, J., and W. F. Miller, "Evaluation of IMV Controller for Accuracy, Dependability, and Adaptability," *Respiratory Care*, 21(2):145–147, 1976.

4. Shapiro, B. A., R. A. Harrison, J. R. Walton, and R. Davison, "Intermittent Demand Ventilation (IDV): A New Technique for Supporting Ventilation in Critically Ill Patients," *Respiratory Care*, 21(6):521–525, 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5955, to read as follows:

§ 868.5955 Intermittent mandatory ventilation attachment.

(a) *Identification.* An intermittent mandatory ventilation (IMV) attachment is a device attached to a mechanical ventilator that allows spontaneous breathing by the patient while providing mechanical ventilation at a preset rate.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before (January 2, 1980) submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33469 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1794]

Medical Devices; Classification of Positive End Expiratory Pressure Breathing Attachments

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying positive and expiratory pressure (PEEP) attachments into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of positive and expiratory pressure (PEEP) breathing attachments:

1. Identification: A positive end expiratory pressure (PEEP) breathing attachment is a device attached to a ventilator that is used to elevate pressure in a patient's lungs above atmospheric pressure at the end of exhalation.

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 PEEP breathing attachments be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that the device does not cause excess pressure to develop in the patient's lungs, and that the device develops adequate pressure to prevent patient hypoxia (lack of oxygen). The Panel believes that general controls will not provide sufficient control over these characteristics. Although this device is life supporting, the Panel believes that premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that will provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's personal knowledge of, and clinical experience with, the device. The device is currently in widespread use.

5. Risks to health: (a) Excessive pressure: If the device creates excessive pressure in the patient circuit, overdistension of the lung with barotrauma (rupture of lung tissue), pneumothorax (air in the lung cavity), and/or a reduction in cardiac output (blood flow) may result. (b) Hypoxia: Inadequate gas pressure in the patient circuit may result in patient hypoxia (lack of oxygen).

Proposed Classification

FDA agrees with the Panel and is proposing that positive and expiratory pressure (PEEP) breathing attachments

be classified into class II (performance standards). Although this device is life supporting, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to contrtol the risks to health presented by 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5965, to read as follows:

§ 868.5965 Positive end expiratory pressure breathing attachment.

(a) *Identification.* A positive end expiratory pressure (PEEP) breathing attachment is a device attached to a ventilator that is used to elevate pressure in a patient's lungs above atmospheric pressure at the end of exhalation.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–33470 Filed 11–1–79; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 868

[Docket No. 78N–1795]

Medical Devices; Classification of Ventilator 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 ventilator tubing into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of ventilator tubing:

1. Identification: Ventilator tubing is a device used as a conduit for gases between the ventilator and the patient during mechanical ventilation of a patient.

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 ventilator tubing be classified into class II (performance standards) because the Panel believes that the design of the device must be controlled to prevent leakage through the tubing or disconnection of the tubing from other components in the breathing system. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that although this device is life supporting, premarket approval is not necessary to provide reasonable assurance of the safety and effectiveness of the device because there is sufficient information available to establish a performance standard that would provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, ventilator tubing. The Panel also cited the ongoing development of a standard for breathing tubes by the Z–79 Committee of the American National Standards Institute.

5. Risk to health: Inadequate ventilation: If the breathing tube components do not fit together properly, gas leakage or complete disconnection may occur, leading to inadequate ventilation of the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that ventilator tubing be classified into class II (performance standards). Although this device is often used in a life support system, the agency believes that the device itself is not directly life supporting. Therefore, the agency believes that premarket approval is unnecessary because there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that general controls alone are insufficient to control the risks to health presented by 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5975 as follows:

§ 868.5975 Ventilator tubing.

(a) *Identification.* Ventilator tubing is a device used as a conduit for gases between the ventilator and the patient during mechanical ventilation of a patient.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between

9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33471 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1796]

Medical Devices; Classification of Tee Drains (Water Traps)

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying tee drains (water traps) into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of tee drains (water traps):

1. Identification: A tee drain (water trap) is a device that traps and drains water that collects in ventilator tubing during respiratory therapy, thereby preventing an increase in breathing resistance.

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 tee drain (water trap) be classified into class II (performance standards) because the Panel believes that the design of, and the materials used in, the device must be controlled to assure that standard connector fittings are used to prevent gas leakage. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard to provide such assurance.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' knowledge of, and clinical experience with, this device.

5. Risks to health: (a) Inadequate ventilation: Improper size of the connector fittings or inadequate sealing of components may allow gas leakage from the device, leading to inadequate patient ventilation. (b) Inadequate drainage: Improper positioning of the water trap above the patient's airway may cause inadequate drainage of the breathing circuit.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that tee drains (water traps) be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart F by adding new § 868.5995, to read as follows:

§ 868.5995 Tee drain (water trap).

(a) *Identification.* A tee drain (water trap) is a device that traps and drains water that collects in ventilator tubing during respiratory therapy, thereby preventing an increase in breathing resistance.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33472 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1797]

Medical Devices; Classification of Anesthetic Cabinets, Tables, or Trays

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying anesthetic cabinets, tables, or trays into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class II (performance standards). The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of anesthetic cabinets, tables, or trays:

1. Identification: An anesthetic cabinet, table, or tray is a device used to store anesthetic equipment and drugs. The device is usually constructed to eliminate build-up of static electrical charges.

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 anesthetic cabinets, tables, or trays be classified into class II because it believes that the designs and materials used in the devices must be controlled to assure that the devices are constructed to reduce the risk of explosion caused by the build-up of static electrical charges. The design and materials should also be controlled to assure that the devices are stable and do not cause injury by falling on patients or users. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard. The Panel noted that appropriate sections of the conductivity standards of the National Fire Protection Association and Underwriters Laboratories may be relevant to these devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices.

5. Risks to health: (a) Burns, related injuries: If there is inadequate electrical conductivity throughout the device, burns and related injuries may occur from an explosion due to build-up of static electrical charges in the presence of flammable gases.

(b) Trauma: Poor stability may allow the device to fall on someone, causing injury.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that anesthetic cabinets, tables, or trays be classified into class I (general controls) with no exemptions. Because users are familiar with these simple devices and have used them successfully for many years without significant problems, the agency believes that a performance standard is unnecessary. The agency believes that general controls, including appropriate labeling regarding the conductivity or nonconductivity of the device and warnings against use of the nonconductive device in the presence of flammable anesthetic agents, are sufficient to control the risks to health presented by 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 of Food and Drugs proposes to amend Part 868 in Subpart G by adding new § 868.6100, to read as follows:

§ 868.6100 Anesthetic cabinet, table, or tray.

(a) *Identification.* An anesthetic cabinet, table, or tray is a device used to store anesthetic equipment and drugs. The device is usually constructed to eliminate build-up of static electrical charges.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33473 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1798]

Medical Devices; Classification of Cardiopulmonary Emergency Carts

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 emergency carts into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Devise Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-340), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cardiopulmonary emergency carts:

1. Identification: A cardiopulmonary emergency cart is a device used to store and transport resuscitation supplies. The device is related to the delivery of

proper emergency treatment, but it does not include any equipment used in cardiopulmonary resuscitation.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel recommends that cardiopulmonary emergency carts 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 Panel recommends that manufacturers not be required to comply with the good manufacturing practice requirements because any defect in the device will not result in a device failure having an adverse effect on the patient.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that cardiopulmonary emergency carts be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of a cardiopulmonary emergency cart be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act (21 U.S.C. 360j(f)), FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of a cardiopulmonary emergency cart must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of a cardiopulmonary emergency cart must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart G by adding new § 868.6175, to read as follows:

§ 868.6175 Cardiopulmonary emergency cart.

(a) *Identification.* A cardiopulmonary emergency cart is a device used to store and transport resuscitation supplies. The device is related to the delivery of proper emergency treatment, but it does not include any equipment used in cardiopulmonary resuscitation.

(b) *Classification.* Class I (*general controls*). The device is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.180, with respect to complaint files.

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33474 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1799]

Medical Devices; Classification of Nose 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 nose clips into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of nose clips:

1. Identification: A nose clip is a device used to close the external nares (nostrils) during diagnostic or therapeutic procedures.

2. Recommended classification: Class I (general controls). The Panel recommends that the device be exempt from the good manufacturing practice (GMP) regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)).

3. Summary of reasons for recommendation: The Panel

recommends that nose clips 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 Panel recommends that manufacturers not be required to comply with the good manufacturing practice requirements. The device presents no risks to health, and the integrity of the device can easily be determined by examination.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that nose clips be classified into class I (general controls) because the agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of a nose clip be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act, FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of a nose clip must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of a nose clip must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 868 in Subpart G by adding new § 868.6225, to read as follows:

§ 868.6225 Nose clip.

(a) *Identification.* A nose clip is a device used to close the external nares (nostrils) during diagnostic or therapeutic procedures.

(b) *Classification.* Class I (general controls). The device is exempt from the good manufacturing practice regulation in Part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulator Affairs.

[FR Doc. 79-33475 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

[21 CFR Part 868]

[Docket No. 78N-1800]

Medical Devices; Classification of Portable Air 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 portable air compressors into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of portable air compressors:

1. Identification: A portable air compressor is a device used to provide compressed air for medical use, e.g., to drive ventilators and other respiratory equipment.

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 portable air compressors be classified into class II (performance standards) because the Panel believes that the design and materials used in the device must be controlled to assure that the device reliably delivers adequate pressure to drive patient ventilators and other respiratory equipment, and that the delivered air is free of contaminants. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a 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. The Panel noted that standards for air compressors have been developed by the Compressed Gas Association (CGA) and National Fire

Protection Association (NFPA) committee.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Inadequate ventilation (breathing): Lack of adequate pressure may cause inadequate ventilation of the patient. (b) Inhalation of foreign substances: If the delivered air is not pure, the patient may inhale foreign substances such as bacteria and oil.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that portable air compressors be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart G by adding new § 868.6250, to read as follows:

§ 868.6250 Portable air compressor.

(a) *Identification.* A portable air compressor is a device used to provide compressed air for medical use, e.g., to drive ventilators and other respiratory equipment.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33478 Filed 11-1-79; 8:45 am]
BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1801]

Medical Devices; Classification of Gas Cylinders

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying gas cylinders into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gas cylinders:

1. Identification: A gas cylinder is a device used as a container for pressurized medical gas. This identification applies only to gas containers that are empty, i.e., to containers that are not filled with gas by the manufacturer or distributor. A cylinder is considered empty when the pressure level is one-tenth (1/10) of the labeled filling pressure at 21° C (70° F).

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 a gas cylinder be classified into class II (performance standards) because the Panel believes that the design and materials used in the device must be controlled to assure that the cylinder is strong enough so that it does not rupture under use conditions. The Panel also believes that cylinders should be color coded according to the system accepted by most manufacturers in the United States (e.g., green for oxygen; gray for carbon dioxide; blue for nitrous oxide; orange for cyclopropane; red for ethylene; brown for helium; black for nitrogen; and yellow is for air) and should incorporate the pin-index safety system to reduce the possibility of delivering the wrong gas to the patient. In addition, the Panel believes that the cylinder should be clean and sterile to assure that the patient is protected from breathing contaminants that may cause airway infection and irritation. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel believes that the current Department of Transportation regulation for transport of medical gases in Title 49 of the Code of Federal Regulations provides an adequate and effective standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, gas cylinders.

5. Risks to health: (a) Trauma: If the cylinder is not strong enough it may rupture and cause injury to the patient and damage to other equipment, and may also endanger the patient's life due to lack of an inhaled gas source. (b) Infection and irritation of airway: Contaminants in the cylinder may result in infection or irritation of the patient's airway. (c) Wrong gas delivered to patient: Lack of the proper color code or a pin-index safety system may result in the wrong gas being delivered to the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that gas cylinders be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart G by adding new § 868.6275, to read as follows:

§ 868.6275 Gas cylinder.

(a) *Identification.* A gas cylinder is a device used as a container for pressurized medical gas. This identification applies only to gas containers that are empty, i.e., to containers that are not filled with gas by the manufacturer or distributor. A cylinder is considered empty when the pressure level is one-tenth (1/10) of the labeled filling pressure at 21° C (70° F).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33477 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 868

[Docket No. 78N-1802]

Medical Devices; Classification of Gas Cylinder 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 gas cylinder holders into class II (performance standards).

FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gas cylinder holders:

1. Identification: A gas cylinder holder is a device used to hold a gas cylinder in place.

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 gas cylinder holders be classified into class II (performance standards) because the Panel believes that the design and materials used in the device must be controlled to assure adequate strength and stability to prevent damage caused by falling gas cylinders. The Panel believes that general controls will not provide sufficient control over this characteristic. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: Damage and trauma: If the cylinder holder is not sufficiently strong or stable, the cylinder may fall and cause damage to equipment and injury to users.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that gas cylinder holders be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart G by adding new § 868.6285, to read as follows:

§ 868.6285 Gas cylinder holder.

(a) *Identification.* A gas cylinder holder is a device used to hold a gas cylinder in place.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments

may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33478 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1805]

Medical Devices; Classification of Calibration Gases

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying calibration gases into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of calibration gases:

1. Identification: A calibration gas is a device consisting of a container of gas of known concentration used to calibrate gas concentration measurement devices.

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 gas cylinder holders be classified into class II (performance standards) because the Panel believes that the design and materials used in the device must be controlled to assure adequate strength and stability to prevent damage caused by falling gas cylinders. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: Inappropriate therapy: Inaccurate gas concentration data may result in the incorrect calibration of concentration measurement devices, thereby causing inappropriate therapy.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that calibration gases be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart G by adding new § 868.6400, to read as follows:

§ 868.6400 Calibration gas.

(a) *Identification.* A calibration gas is a device consisting of a container of gas of known concentration used to calibrate gas concentration measurement devices.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33479 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1806]

Medical Devices; Classification of Anesthesia Stools

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying anesthesia stools into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of anesthesia stools:

1. Identification: An anesthesia stool is a device used as a stool for the anesthesiologist in the operating room.

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 anesthesia stools be classified into class II (performance standards) because the Panel believes that the design and materials used in the device must be controlled to assure good electrical conductivity from the anesthesiologist to the floor to prevent explosion hazards from build-up of static electrical charges and to assure that the stool is stable at all seat heights. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel noted the development of a conductivity standard by the National Fire Protection Association.

4. Summary of data on which the recommendation is based: The Panel based it recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Burns, related injuries: Poor electrical conductivity from the operator to the floor may lead to an explosion due to a build-up of static electrical charges in the presence of flammable gas, causing burns and related injuries to nearby personnel. (b) Trauma: If the stool is unstable, the user may fall and be injured.

Proposed Classification

FDA disagrees with the Panel recommendation and is proposing that anesthesia stools be classified into class I (general controls) with no exemptions. Because users are familiar with these simple devices and have used them successfully for many years without significant problems, the agency believes that a performance standard is unnecessary. The agency believes that general controls, including appropriate labeling regarding the conductivity or nonconductivity of the device and warnings against use of the nonconductive device in the presence of flammable anesthetic agents, are sufficient to control the risks to health presented by 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 of Food and Drugs proposes to amend Part 868 in Subpart G by adding new § 868.6700, to read as follows:

§ 868.6700 Anesthesia stool.

(a) *Identification.* An anesthesia stool is a device used as a stool for the anesthesiologist in the operating room.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33480 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1810]

Medical Devices; Classification of Tracheobronchial Suction 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 tracheobronchial suction catheters into class I (general controls). FDA is also publishing the recommendation of the Anesthesiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments. FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by January 2, 1980. FDA proposes that the final 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 Adminstration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of tracheobronchial suction catheters:

1. Identification: A tracheobronchial suction catheter is a device used to aspirate liquids or semisolids from a patient's upper airway.

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 tracheobronchial suction catheters be classified into class I (general controls) because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Trauma: Poor design (e.g., improper size, shape, or excessive rigidity) of the device may cause trauma to the patient's airway tissues. (b) Infection: If the device is not sterile, infection may result.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the tracheobronchial suction catheters be classified into class I (general controls) with no exemptions. The agency 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 of Food and Drugs proposes to amend Part 868 in Subpart G by adding new § 868.6810, to read as follows:

§ 868.6810 Tracheobronchial suction catheter.

(a) *Identification.* A tracheobronchial suction catheter is a device used to aspirate liquids or semisolids from a patient's upper airway.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before (January 2, 1980,) submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33481 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1807]

Medical Devices; Classification of Patient Position Supports

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 position supports into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK–430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of patient position supports:

1. Identification: A patient position support is a device used to maintain the position of an anesthetized patient during 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 patient position supports be classified into class II (performance standards) because the Panel believes that the design and materials used in the device must be controlled to assure proper padding and positioning of supports to prevent soft tissue, joint, and peripheral nerve injury in unconscious, anesthetized patients; and to assure conductivity of electricity from the patient to the floor to prevent explosion hazards from build-up of static electrical charges in the presence of flammable gases. The Panel noted that the literature contains many reports of nerve, soft tissue, and joint injury from improperly designed, padded, or placed positioning supports. The Panel believes that general controls will not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel noted the development of standards for conductivity by the National Fire Protection Association.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device and their knowledge of the relevant literature.

5. Risks to health: (a) Tissue injury: Improper padding and positioning of supports may cause soft tissue, joint, and peripheral nerve damage to unconscious, anesthetized patients. (b) Burns and related injuries: Poor conductivity of electricity from the patient to the floor may lead to burns and related injuries from explosions caused by build-up of static electrical charges in the presence of a flammable gas.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that patient position supports be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart G by adding new § 868.6820, to read as follows:

§ 868.6820 Patient position support.

(a) *Identification.* A patient position support is a device used to maintain the position of an anesthetized patient during surgery.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers

Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33482 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

[Docket No. 78N-1808]

Medical Devices; Classification of Medical Gas Yoke Assemblies

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 gas yoke assemblies into class II (performance standards). FDA is also publishing the recommendation of 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 January 2, 1980. FDA proposes that the final 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: James R. Veale, Bureau of Medical Devices (HFK-430), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Anesthesiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of medical gas yoke assemblies:

1. Identification: A medical gas yoke assembly is a device used to connect medical gas cylinders to regulators and/or needle valves to supply gases for anesthesia or respiratory therapy. The device may include a gas filter.

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 gas yoke assemblies be classified into class II (performance standards) because the Panel believes that the design, materials, and construction of the device must be controlled to assure that a proper connection is made between the gas cylinder and other devices to prevent fire and burns due to leakage of flammable gases. In addition, the Panel believes that the device should incorporate a system, such as a pin-index safety system, to prevent delivery of an inappropriate gas to the patient, and that the yoke filter should operate effectively to prevent contamination of the breathing system or infection of the patient. The Panel believes that general controls would not provide sufficient control over these characteristics. The Panel believes that a standard would provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel noted the development of standards for this device by the committees of the Compressed Gas Association, Inc., the British Standards Institute, and the Norges Standardiseringsforbund.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: (a) Burns and related injuries: Leakage of flammable gases due to poor connections may cause burns or related injuries to users. (b) Inappropriate therapy: Lack of a pin-index safety system may result in the delivery of an inappropriate gas to the patient. (c) Contamination or infection: An ineffective yoke filter may result in contamination of the breathing system or infection of the patient.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that medical gas yoke assemblies be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a standard for this 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 of Food and Drugs proposes to amend Part 868 in Subpart G by adding new § 868.6985, to read as follows:

§ 868.6985 Medical gas yoke assembly.

(a) *Identification.* A medical gas yoke assembly is a device used to connect medical gas cylinders to regulators and/or needle valves to supply gases for anesthesia or respiratory therapy. The device may include a gas filter.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before January 2, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 9, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-33483 Filed 11-1-79; 8:45 am]

BILLING CODE 4110-03-M

federal register

Friday
November 2, 1979

Part IV

Department of Labor

Employment Standards Administration

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

DEPARTMENT OF LABOR

Employment Standards Administration, Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination 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 on construction projects of the character and in the 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 the 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. 14949, 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 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates (37 FR 21138) and of Secretary 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, Wage & Hour Division, Office of Government Contract Wage Standards, Division of Construction 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 Determination Decision.

New General Wage Determination Decisions

Maryland.—MD79-3048.
West Virginia.—WV79-3044.

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.

*Connecticut:	
*CT79-2010	Apr. 6, 1979.
CT79-2011	Apr. 6, 1979.
Florida:	
FL79-1064	Apr. 13, 1979.
Hawaii:	
HI78-5130	Nov. 24, 1978.
Idaho:	
ID79-5112	May 25, 1979.
Kentucky:	
KY79-1018	Feb. 2, 1979.
Maine:	
ME79-2042	May 4, 1979.
Oklahoma:	
OK79-4023	Feb. 2, 1979.
OK79-4076	Aug. 17, 1979.
Pennsylvania:	
PA79-3007	Apr. 6, 1979.
PA78-3043	May 12, 1978.
PA78-3071	Oct. 6, 1978.
Texas:	
TX79-4068	July 6, 1979.

Supersedeas Decisions 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.

Indiana:	
IN77-2021, IN77-2022, IN77-2023 (IN79-2083)	Feb. 8, 1977.
IN77-2099 (IN79-2084)	May 27, 1977.
New Mexico:	
NM79-4022 (NM79-4104)	Feb. 2, 1979.
NM79-4079 (NM79-4103)	Sept. 7, 1979.
Utah:	
UT78-5128 (UT79-5135)	Oct. 6, 1979.

Cancellation of General Wage Determination Decision

The general wage decision listed below is cancelled. Agencies with construction projects pending to which the cancelled decision would have been applicable should utilize the project

determination procedure by submitting Form SF-308. See Regulations Part 1 (29 CFR), Section 1.5. Contracts for which bids have been opened shall not be affected by this notice. Also, consistent with 29 CFR 1.7(b)(2), the incorporation of the cancelled decision in contract specifications, the opening of bids for which is within ten (10) days of this notice, need not be affected. IN77-2026—Orange County, Indiana—Residential Construction.

Signed at Washington, D.C. this 26th day of October 1979.

C. Lamar Johnson,

Deputy Administrator, Wage and Hour Division.

BILLING CODE 4510-27-M

NEW DECISION

STATE: MARYLAND COUNTY: HARFORD
DECISION NO : MD79-3048 DATE: Date of Publication
DESCRIPTION OF WORK: Building Construction Projects (does not include single family homes and apartments up to and including 4 stories)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Bricklayers	$11 18	70	50		07
Carpenters	7 08				
Cement Masons	10 00	60	55		04
Electricians:					
Zone 1 - From Zero Milestone at Baltimore City Hall to 25 miles	11 30	.80	3% + 1 20		½%
Zone 2 - Beyond 25 miles from Zero Milestone at Baltimore City Hall	11 55	80	3% + 1 20		½%
Ironworkers	8.35				
Laborers:					
Laborers	5 52				
Mason Tenders	5 51				
Lathers	8 00				
Painters	7 30				
Plasterers	8 00				
Plumbers	8 64				
Roofers	9 00	.60	45		
Sheet Metal Workers	7 79				
Soft Floor Layers	7 20				
Sprinkler Fitters	12 96	.75	1 05		08
Truck Drivers	5 00				
Power Equipment Operators:					
Bulldozer	6 50				
Roller	5 50				
Scraper-Pan	5 13				

Welders - receive rate prescribed for craft performing operation to which welding is incidental

"Unlisted classifications needed for work not included within the scope of the classification listed may be added after award only as provided in the labor standards contract clauses (29 CFR, 5 5(a)(ii))

NEW DECISION

STATE: WEST VIRGINIA COUNTIES: BERKELEY, JEFFERSON AND MORGAN
DECISION NO : WV79-3044 DATE: DATE OF PUBLICATION
DESCRIPTION OF WORK: Building Construction Projects (does not include single family homes and apartments up to and including 4 stories)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
BRICKLAYERS	$ 8.00				
CARPENTERS	6 17				
CEMENT MASONS	6 04				
ELECTRICIANS	6.65				
GLAZIERS	7.00				
IRONWORKERS	5.50				
LABORERS	4 43				
PAINTERS	5.05				
PLASTERERS	5.75				
PLUMBERS & PIPEFITTERS	6.50				
ROOFERS	5.50				
SHEET METAL WORKERS	5 18				
TILE SETTERS	5 90				
TRUCK DRIVERS	4.89				
POWER EQUIPMENT OPERATORS:					
Backhoe	5.68				
Bulldozer	5.58				
Crane	6.91				
Front End Loader	5 48				

Unlisted classifications needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards contract clauses (29 CFR, 5 5(a)(ii))

MODIFICATIONS P. 1

DECISION NO. CT79-2010 -
MOD. #6
(44 FR 20913 - April 6, 1979)
Fairfield, Litchfield & Windham Cos., Connecticut

Change:

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
LABORERS (Heavy and Highway Construction):					
Laborers	$ 8.35	.60	.80		.10
Acetylene Burners; Asphalt Raker; Chain Saw Operator; Concrete & Power Buggy Operators; Concrete Saw Operators; Fence & Guard Rail Erectors; Form Setters; Hand Operated Concrete Vibratory Compactor Operators; Mason Tenders; Pipelayers; Pneumatic Gas & Electric Drill Operators; Powdermen & Wagon Drill Operators	8.60	.60	.80		.10
Air Track Operators; Block Paver; Curb Setters	8.85	.60	.80		.10
Blasters	9.10	.60	.80		.10

MODIFICATIONS P. 2

DECISION NO. CT79-2010 -
MOD. #6 Cont'd

Heavy and Highway Construction

POWER EQUIPMENT OPERATORS:	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
CLASS 1	$ 12 18	1.05	.95	a	15
CLASS 2	12 01	1 05	.95	a	15
CLASS 3	11 65	1 05	.95	a	15
CLASS 4	11 44	1.05	.95	a	15
CLASS 5	11 27	1 05	95	a	15
CLASS 6	11.06	1 05	.95	a	.15
CLASS 7	10 83	1 05	.95	a	.15
CLASS 8	9.85	1 05	.95	a	.15
CLASS 9	9.97	1 05	95	a	.15
CLASS 10	10.36	1.05	.95	a	.15
CLASS 11	10.75	1.05	.95	a	.15
CLASS 12	9 46	1.05	.95	a	.15
CLASS 13	10 29	1.05	.95	a	.15

Crane with 150' boom - $.25 extra
Crane with 200' boom - $.50 extra

CLASS 1 - Erecting and Handling Structural Steel; Front End Loader (7 cy or over)
CLASS 2 - Piledriver; Power Shovel and Crane; Dragline; Gradall; Trenching Machine; Lighter Derrick Paver (Concrete); Derrick (Stiff Leg and Guy); Steel Pile Sheeting; Koehring Loader (Skooper) Master Mechanic
CLASS 3 - Drill (Joy Heavy Weight Champion or equivalent); Side Boom, Loader (Euclid), Mucking Machine; Pumpcrete; Rock and Earth Boring Machine; Post Hole Digger; Well Digger; & Hammer (Vibratory); Central Mix; Combination Hoe & Loader (over ½ Yd)
CLASS 4 - Asphalt Spreader
CLASS 5 - Front End Loader (3yds. or over); Grader; Power Stone Spreader; Combination Hoe and Loader
CLASS 6 - Asphalt Roller; Bulldozer; Carryall; Maintenance Engineer; Concrete Mixer (5 Bags and over); Welder
CLASS 7 - Front End Loader (under 3 yds.); Roller; Power Chipper; Fork Lift; Finishing Machine; Asphalt Plant; Power Pavement Breaker; Dinky Machine
CLASS 8 - Compressor; Pump
CLASS 9 - Firemen (High Pressure)
CLASS 10 - Well Point system
CLASS 11 - Compressor Battery
CLASS 12 - Oiler
Class 13 - Batch Plant; Bulk Cement Plant

MODIFICATIONS P 3

DECISION NO. CT79-2010 - MOD. #6 (Cont'd)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
POWER EQUIPMENT OPERATORS: Survey Crew					
Chief of Party	$ 10.35	1 05	95	a	15
Ass't Chief to Party	9 60	1 05	95	a	15
Instrument Man	8 85	1 05	95	a	15
Rodman & Chainman	6 58	1.05	.95	a	.15
TRUCK DRIVERS (Building, Heavy and Highway Construction)					
CLASS 1	8.26	70	80	a	
CLASS 2	8.36	.70	.80	a	
CLASS 3	8.46	.70	80	a	
CLASS 4	8 41	.70	80	a	
CLASS 5	8 51	70	80	a	
CLASS 6	8 65	.70	80	a	

CLASS 1 - Two Axle Trucks; Helpers
CLASS 2 - Three Axle Trucks; Two Axle Ready Mix
CLASS 3 - Four Axle Trucks; Heavy Duty Trailer-up to 40 Tons
CLASS 4 - Three Axle Ready-Mix
CLASS 5 - Four Axle Ready-Mix; Specialized Earth Moving Equipment other than Conventional Type on-the-road Trucks and Semi-Trailer (including Euclids)
CLASS 6 - Heavy Duty Trailer-40 Tons and over

PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independnece Day; D-Labor Day; E-Thanksgiving Day & F-Christmas Day

FOOTNOTE:
a. 7 Paid Holiday: A through F and Good Friday

MODIFICATIONS P. 4

DECISION NO. CT79-2011 - MOD. #6
(44 FR 20921 - April 6, 1979)
Hartford, Middlesex, New Haven, New London & Tolland Counties, Connecticut

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Change:					
LABORERS (Heavy and Highway Construction):					
Laborers	$ 8.35	.60	80		.10
Acetylene Burners; Asphalt Raker; Chain Saw Operator; Concrete & Power Buggy Operators; Concrete Saw Operators; Fence & Guard Rail Erectors; Form Setters; Hand Operated Concrete Vibratory Compactor Operators; Mason Tenders; Pipelayers; Pneumatic Gas & Electric Drill Operators; Powdermen & Wagon Drill Operators	8.60	.60	80		.10
Air Track Operators; Block Paver; Curb Setters	8 85	.60	80		10
Blasters	9 10	60	80		.10

MODIFICATIONS P. 5

DECISION NO. CT79-2011 - MOD. #6 Cont'd

Heavy and Highway Construction	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
POWER EQUIPMENT OPERATORS:					
CLASS 1	$ 12 18	1 05	.95	a	.15
CLASS 2	12.01	1.05	.95	a	.15
CLASS 3	11.65	1 05	.95	a	.15
CLASS 4	11.44	1 05	.95	a	.15
CLASS 5	11.27	1.05	.95	a	.15
CLASS 6	11.06	1.05	.95	a	.15
CLASS 7	10.83	1.05	.95	a	.15
CLASS 8	9.85	1 05	.95	a	.15
CLASS 9	9.97	1.05	.95	a	.15
CLASS 10	10 36	1.05	.95	a	.15
CLASS 11	10.75	1.05	.95	a	.15
CLASS 12	9.46	1.05	.95	a	.15
CLASS 13	10.29	1.05	.95	a	.15
Crane with 150' boom - $.25 extra					
Crane with 200' boom - $.50 extra					

CLASS 1 - Erecting and Handling Structural Steel; Front End Loader (7 cy. or over)
CLASS 2 - Piledriver; Power Shovel and Crane; Dragline; Gradall; Trenching Machine; Lighter Derrick Paver (Concrete); Derrick (Stiff Leg and Guy); Steel Pile Sheeting; Koehring Loader (Skooper; Master Mechanic
CLASS 3 - Drill (Joy Heavy Weight Champion or equivalent); Side Boom, Loader (Euclid), Mucking Machine; Pumpcrete; Rock and Earth Boring Machine; Post Hole Digger; Well Digger; & Hammer (Vibratory); Central Mix; Combination Hoe & Loader (over ½ Yd)
CLASS 4 - Asphalt Spreader
CLASS 5 - Front End Loader (3yds. or over); Grader; Power Stone Spreader; Combination Hoe and Loader
CLASS 6 - Asphalt Roller; Bulldozer; Carryall; Maintenance Engineer; Concrete Mixer (5 Bags and over); Welder
CLASS 7 - Front End Loader (under 3 yds.); Roller; Power Chipper; Fork Lift; Finishing Machine; Asphalt Plant; Power Pavement Breaker; Dinky Machine
CLASS 8 - Compressor; Pump
CLASS 9 - Firemen (High Pressure)
CLASS 10 - Well Point system
CLASS 11 - Compressor Battery
CLASS 12 - Oiler
Class 13 - Batch Plant; Bulk Cement Plant

MODIFICATIONS P. 6

DECISION NO. CT79-2011 - MOD. #6 (Cont'd)

POWER EQUIPMENT OPERATORS: Survey Crew	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr.
Chief of Party	$ 10.35	1.05	.95	a	.15
Ass't Chief to Party	9.60	1.05	.95	a	.15
Instrument Man	8 85	1.05	.95	a	.15
Rodman & Chainman	6.58	1.05	.95	a	.15
TRUCK DRIVERS (Building, Heavy and Highway Construction)					
CLASS 1	8.26	.70	.80	a	
CLASS 2	8.36	.70	.80	a	
CLASS 3	8.46	.70	.80	a	
CLASS 4	8.41	.70	.80	a	
CLASS 5	8.51	.70	.80	a	
CLASS 6	8.65	.70	.80	a	

CLASS 1 - Two Axle Trucks; Helpers
CLASS 2 - Three Axle Trucks; Two Axle Ready Mix
CLASS 3 - Four Axle Trucks; Heavy Duty Trailer-up to 40 Tons
CLASS 4 - Three Axle Ready-Mix
CLASS 5 - Four Axle Ready-Mix; Specialized Earth Moving Equipment other than Conventional Type on-the-road Trucks and Semi-Trailer (including Euclids)
CLASS 6 - Heavy Duty Trailer-40 Tons and over

PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independnece Day; D-Labor Day; E-Thanksgiving Day & F-Christmas Day

FOOTNOTE:
a. 7 Paid Holiday: A through F and Good Friday

DECISION #FL79-1064 - Mod. #4
(44 FR 22308 - April 13, 1979)
Orange County, Florida

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Change:					
Asbestos Workers	$11.43	.55	.45		.06
Bricklayers:					
Bricklayers	9.20	.50	.40		.04
Stonemasons	9.20	.50	.40		.04
Marble Masons	9.20	.50	.40		.04
Plasterers	9.20	.50	.40		.04
Cement Masons	9.20	.50	.40		.04
Carpenters	9.68	.50	.65		.07
Ironworkers:					
Structural & Ornamental	10.28	.65	.90	.65	.05
Reinforcing	10.28	.65	.90	.65	.05
Millwrights	11.27	.60	.70		.10

DECISION #HI78-5130-Mod. #4
(43 FR 55143-November 24, 1978)
Statewide, Hawaii

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Change:					
Boilermakers	$12 68	.65	$1 00		
Carpenters:					
Carpenters; Hardwood Floorlayers; Patent Scaffold Erectors; Pneumatic Nailers; Shinglers	10 75	1 34	1 85	1.00	.06
Power Saw Operator (2 HP and over)	10.90	1.34	1 85	1 00	06
Millwrights	11 00	1 34	1.85	1.00	.06
Dredging:					
Hydraulic Suction Dredges; Clamshell Dredges; Boat Operators; Derricks:					
Group 1	12 14	1 25	2 55	.90	10
Group 2	11 53	1 25	2 55	.90	.10
Group 3	11.08	1.25	2 55	90	.10
Group 4	9 80	1.25	2.55	90	10
Group 5	9 53	1.25	2 55	90	10
Group 6	9 36	1 25	2 55	.90	10
Group 7	11 89	1 25	2.55	90	.10
Group 8	10 76	1 25	2 55	90	10
Group 9	11 59	1 25	2 55	.90	10
Group 10	8 88	1 25	2 55	90	10
Drywall Applicator	10 85	1 34	1 85	1 00	.06
Glaziers	10 50	1 20	1 07	.97	.20
Laborers:					
Group 1-h	7 60	.99	.65	.55	
Power Equipment Operators: (Except Piledriving and Steel Erection):					
Group 1	9.25	1.25	2.55	.90	.10
Group 2	9.36	1 25	2.55	90	10
Group 3	9.53	1 25	2 55	.90	.10
Group 4	9.80	1.25	2.55	.90	.10
Group 5	10 11	1 25	2 55	90	10
Group 6	10 76	1 25	2 55	90	.10
Group 7	11 08	1.25	2.55	.90	10
Group 8	11.19	1.25	2.55	.90	.10

MODIFICATIONS P. 9

DECISION NO. HI78-5130 (Cont'd)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Group 9	$11.30	$1.25	$2.55	.90	.10
Group 9-A	11.53	1.25	2.55	.90	.10
Group 10	11.59	1.25	2 55	.90	.10
Group 10-A	11.74	1 25	2.55	.90	.10
Group 11	11.89	1.25	2 55	.90	.10
Group 12	12.25	1.25	2.55	.90	.10
Roofers	11.95	1.10	1.25	.50	.15
Sheet Metal Workers	12.92	1.61	2 86		41
Soft Floor Layers	11.80	.70	1.25	.55	.24
Sprinkler Fitters	13.75	.75	1.05		.08
Truck Drivers:					
Flatbed	9.53	1.25	1.30		
Dump, 8 yds. and under; Water Truck (up to and including 2000 gallons)	9.80	1.25	1.30		
Water Truck (over 2000 gallons)	10.11	1.25	1.30		
Tandem, Semi-trailer or Semi-dump	10.76	1.25	1.30		
Slip-in or pup	11.08	1.25	1.30		
End Dumps, unlicensed (Euclid, Mack, Caterpillar or similar):					
Tractor Trailer (hauling equipment)	11.19	1.25	1.30		

MODIFICATIONS P. 10

DECISION #ID79-5112-Mod. #3
(44 FR 30570 - May 25, 1979)
Statewide, Idaho

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Change:					
Asbestos Workers:					
Benewah, Bonner, Boundary, Clearwater, Idaho County (north half), Kootenai, Latah, Lewis, Nez Perce and Shoshone Counties	$14.64	.72	$1.30		.04
Remaining Counties and Idaho County (south half)	12.61	.77	1.37		
Boilermakers:					
Benewah, Bonner, Boundary, Clearwater, Idaho, Kootenai, Latah, Lewis, Nez Perce and Shoshone Counties	13.61	1.175	1 25	1 00	.04
Remaining Counties	13 41	1.175	1.25	1 00	.04
Bricklayers;					
Stonemasons:					
Benewah, Bonner, Boundary, Kootenai and Shoshone Cos.	14.00		1.00		
Clearwater, Idaho, Latah, Lewis and Nez Perce Counties	13.11	.80	1.00		.05
Cement Masons:					
Benewah, Bonner, Boundary, Clearwater, Idaho County (north of 46th Parallel), Kootenai, Latah, Lewis, Nez Perce and Shoshone Counties:					
Zone 1:					
Cement Masons	11.33	.90	1.25		.10

DECISION NO. ID79-5112 (Cont'd)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Gunnite; Power Machine; Power Troweling Machine; Power Magnesite or Other material with oxichloride base	$11 48	90	$1 25		10
Power Tools	11.78	.90	1 25		.10
Zone 2:					
Cement Masons	12 03	.90	1.25		.10
Gunnite; Power Machine; Power Troweling Machine; Power Magnesite or other material with oxichloride base	12 18	90	1.25		.10
Power Tools	12.48	.90	1 25		.10
Zone 3:					
Cement Masons	12 28	.90	1.25		.10
Gunnite; Power Machine; Power Troweling Machine; Power Magnesite or other material with oxichloride base	12 43	90	1.25		10
Power Tools	12.73	90	1 25		.10
Zone 4:					
Cement Masons	12 73	.90	1.25		.10
Gunnite; Power Machine; Power Troweling Machine; Power Magnesite or other material with oxichloride base	12 88	90	1 25		.10
Power Tools	13 18	90	1 25		.10
Zone 5:					
Cement Masons	13 23	90	1.25		.10
Gunnite; Power Machine; Power Troweling Machine; Power Magnesite or other material with oxichloride base	13 38	.90	1 25		.10

DECISION NO. ID79-5112 (Cont'd)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Power Tools	$13.68	.90	$1.25		.10
Glaziers:					
Ada, Adams, Boise, Canyon, Elmore, Gem, Gooding County (western part of County from a line running north and south through the eastern limits of the City of Bliss), Idaho County (southern part of County from a line running east and west through the north limits of Elk City), Owyhee, Payette, Valley and Washington Counties	11 51	.42	.30		.12
Marble Setters:					
Clearwater, Idaho, Latah, Lewis and Nez Perce Counties	13.11	80	1 00		.05
Benewah, Bonner, Boundary, Kootenai and Shoshone Counties	14 00		1.00		
Plasterers:					
Benewah, Bonner, Boundary, Clearwater, Idaho, Kootenai, Latah, Lewis, Nez Perce and Shoshone Counties	11.18	.90	1.25		
Plumbers:					
Remaining Counties and Idaho County (south of the 46th Parallel)	12 92	.94	1.60		.10

MODIFICATIONS P 13

DECISION NO. ID79-5112 (Cont'd)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Roofers:					
Benewah, Bonner, Boundary, Clearwater, Idaho County (north of the 46th Parallel) Kootenai, Latah, Lewis, Nez Perce and Shoshone Counties	$11.19	.75	$1.25		.02
Sheet Metal Workers:					
Benewah, Bonner, Boundary, Clearwater, Kootenai, Latah, Lewis, Nez Perce and Shoshone Counties	15.13	3%+.68	1.14		.14
Sprinkler Fitters	13.79	.75	1.05		.08
Terrazzo Workers and Tile Setters:					
Benewah, Bonner, Boundary, Kootenai and Shoshone Cos	14.00		1.00		

MODIFICATIONS P 14

DECISION #KY79-1018 - Mod. #2
(44 FR 6866 - February 2, 1979)
Fayette County, Kentucky

CHANGE:

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Bricklayers & Stone masons	$11.90	.45	.50		
Carpenters & Soft floor layers	11.40	.55	.30		
Cement masons	12.20				
Electricians	13.35	.45	3% + .50		.0025
Elevator Constructors:					
Mechanics	12.57	1.045	.69	a + b	.03
Helpers	8.80	1.045	.69	a + b	.03
Probationary helpers	6.285				
Glaziers	13.25				
Ironworkers	12.00	1.40	1.45		.06
Laborers:					
Group I	8.40	.35	.47		
Group II	8.80	.35	.47		
Group III	9.00	.35	.47		
Group IV	9.10	.35	.47		
Group V	9.60	.35	.47		
Group VI	9.90	.35	.47		
Lathers	11.65		.10		
Line Construction:					
Linemen & equipment operators	13.85	.60	3%		¼ of 1%
Cable splicers	14.10	.60	3%		¼ of 1%
Groundmen - truck drivers	11.08	.60	3%		¼ of 1%
Groundmen	10.39	.60	3%		¼ of 1%
Marble, Tile, & Terrazzo Workers	10.85	.45	.50		.01
Millwrights & Piledrivermen	11.90	.55	.30		
Painters:					
Brush, drywall finishers, & paperhangers	9.90	.45			
Steeple jack work, window jack work, work in enclosed bldg. over 35' in height above permanent working floor area, & steamcleaning	10.30	.45			
Sandblasting & spray	10.55	.45			
Plumbers & Pipefitters	12.50	.65	.85		.05
Power Equipment Operators:					
Class A	11.60	.50	.80		.05
Class B	8.86	.50	.80		.05
Class C	8.09	.50	.80		.05
Roofers	9.40	.65			
Sheet metal workers	12.88	1.563	1.47		.16
Sprinkler fitters	13.33	.75	1.05		.08

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
DECISION NO. ME79-2042 - MOD. #2 (44 FR 26434 - May 4, 1979) Cumberland County, Maine					
Change:					
Electricians	$10.00	65	3%+ 75		.02

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
DECISION NO. OK79-4023 - Mod.#4 (44 FR 6881 - February 2, 1979) Comanche County, Oklahoma					
CHANGE:					
LABORERS:					
Group I	$6 80	25	40		
Group II	7 05	25	40		
Group III	7 55	25	40		
Painters:					
Brush-roller	8.90		.25	70	05
Brush-roller (structural-steel)	9 15		25	70	05
Spray	9 55		25	70	05
Swing stage, bosun chair work	9 15		.25	.70	.05
Taping & bedding	9 20		25	70	05
Sandblasting	9 25		25	70	05
Sheet metal workers	12 20	60	.88		.05
Sprinkler fitters	12.79	75	1.05		.08
DECISION NO. OK79-4073 - Mod. #2 (44 FR 45863 - August 3, 1979) Garfield County, Oklahoma					
CHANGE:					
CEMENT MASONS	8 50				
LABORERS:					
GROUP I	6 65	.25	40		
GROUP II	6 90	25	40		
GROUP III	7 50	25	40		
SHEET METAL WORKERS	12 20	60	88		05
SPRINKLER FITTERS	12.79	.75	1 05		05

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr
DECISION NO. OK79-4076 - Mod. #2 (44 FR 48585 - August 17, 1979) Latimer, LeFlore, Haskell, Sequoyah & Pushmataha Counties, Oklahoma					
CHANGE:					
LABORERS (Haskell, LeFlore and Sequoyah Counties):					
Area I	$7.35	.25	.40		
Area II	7 65	25	40		
Area III	7 85	.25	.40		
Area IV	7.85	25	40		
LABORERS (Latimer & Pushmataha Counties):					
Area I	6 95	25	.40		
Area II	7 25	25	40		
Area III	7 45	.25	40		
Area IV	7 45	.25	40		
SPRINKLER FITTERS	12.79	.75	1.05		.08

DECISION NO. PA79-3007 - MOD. #5 (44 FR 20932 - April 6, 1979) Clinton, Centre, Huntingdon, Fulton & Mifflin Counties, Pennsylvania	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
CHANGE:					
ASBESTOS WORKERS:					
Zone 1	$11 875	80	60		01
Zone 2	11 61	1.12	90		01
IRONWORKERS:					
Zone 1	11 925	.975	1 47		.04
LATHERS:					
Zone 1	11 54		30		01
MILLWRIGHTS	11 20	6%	6%	25%	½%
PILEDRIVERMEN	12 98	5.5%	10%		50%
PLUMBERS & STEAMFITTERS:					
Zone 2	12 07	78	1 13	.75	.24
ROOFERS:					
Zone 3					
Composition roofers	13.51	.77	1 50		16

DECISION NO. PA78-3037 - MOD. #5 (43 FR 17239 - April 21, 1978) Blair County, Pennsylvania					
CHANGE:					
IRONWORKERS:					
Structural	11.925	.975	1.47		.04
PLUMBERS & STEAMFITTERS	12.07	.78	1.13		.24
ROOFERS	13.51	.77	1.50		.16

DECISION NO. PA78-3043 - MOD. #7 (43 FR 20707 - May 12, 1978) Elk, Forest, McKean and Warren Counties, Pennsylvania	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
CHANGE:					
BRICKLAYERS & STONEMASONS:					
Zone 2	$12 20	.75	95		05
ELECTRICIANS:					
Zone 1 - Elk, Forest and McKean Counties	11 25	60	3%+ 40		1%
Zone 2 - Warren County	13.25	.72	3%+ 68		½ of 1%
GLAZIERS					
Zone 2	11 54	.90	1.50		.25
IRONWORKERS					
Zone 1 - Forest and Warren Cos	13 00	1 86	1.01		.15
Zone 2 - Elk & McKean Counties	11 925	975	1.47		04
LABORERS:					
Common laborer, carpenter tender, scaffold builder for masons, window cleaner, form stripper and mover, scaffold and runways, building materials handlers (loading and unloading), concrete pitman, puddler, mason tender	10.00	9%	7%		
Mechanical tamper (power) powered wheelbarrows and buggies and worklifts, sweepers and similar, mortar mixer, ball bottom man on furnaces and stacks, jackhammer man, concrete buster, wagon drill helper, concrete saw operator,					

DECISION NO. PA78-3043 - (CONT"D)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
CHANGE:					
LABORERS: (CONT'D)					
blaster's helper drill runner's helper (includes drill mounted truck, track or similar) sheeters and shores, vibrator operators, power tamper torch, carryable pumps, chain saw operator, pipe layers, all material conveyors and elevators, signal man, walk behind fork lift or similar, whacker, sand blaster, maintenance man, west brick buggies or similar scaffold builder for plasterers regardless of height, hod carrier, plasterer tender, form cleaning machine operator, plasterer applicating and/or pump machine operator, paving breaker, asphalt raker, lancer, berfix cutting tool, gunnite potman, blacksmith, tool dresser (cable tools)	10.25	9%	7%		
Blasters, wagon drill operator, drill runner, gunnite nozzle man, grout machine operator, walk behind power roller and tamper, welder driller (cable tools)	10 80	9%	7%		

DECISION NO. PA78-3043 - (CONT'D)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr.
CHANGE:					
MILLWRIGHTS					
Zone 1 - Elk and Forest Counties	12.20	6%	6%	25%	½%
PAINTERS:					
Zone 4 - Remainder of McKean County Brush & Roller	10 50				
Spray	11.65				
PILEDRIVERMEN	12.98	5 5%	10%		50%
PLUMBERS & STEAMFITTERS:					
Zone 1 - Elk County	12 07	78	1 13	75	24
Zone 2 - Forest County	12 60	90	1 30		.10
Zone 3 - McKean & Warren Counties:					
Contracts under $500 00	9 54	68	.55		04
Contracts over $500 00	13 21	68	.55		04
ROOFERS					
Zone 1 - Elk and Forest Counties	13 51	.77	1 50		.16

MODIFICATIONS P. 21

DECISION NO. PA78-3071 - MOD. #3 (43 FR 46477 - October 6, 1978) Erie County, Pennsylvania	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr
CHANGE:					
BRICKLAYERS	$13 20	80	40		02
CEMENT MASONS	12 735	60			015
ELECTRICIANS	13 25	72	3%+ 68		½ of 1%
MARBLE SETTERS, TERRAZZO WORKERS & TILE SETTERS	11 55	80	60		02
PLASTERERS	11.96	60			.015
OMIT:					
LABORERS:					
Group 1	8.84	.80	.60		.01
Group II	8 95	80	60		.01
Group III	9 05	80	60		01
Group IV	9.11	.80	.60		.01
Group V	9 16	.80	.60		.01
Group VI	9.26	.80	.60		.01
Group VII	9.32	.80	.60		.01

LABOR CLASSIFICATIONS

Group I - Building & common, carpenter tender, heaters & salamanders, power sweepers, power vacuum sweepers, pumps including 1-½", signal man concrete bucket, wrecking & demolition, window washing

Group II - Bricklayer & mason tenders, electric operated conveyor, electric operated hoist, fork lift up to 9 ft., plumber & sewer laborers, scaffold builders, float grinder & sander

Group III - Burners, concrete saw operator, hod carriers, mortar mixers, plasterer tenders powered wheel-barrows & buggies

Group IV - Dual vibrator roller (walk behind type) Berfix cutting tool, blasters helpers, drill operator helper, jackhammer & air tool operators, mechanical tampers & air tampers, vibrator - air or otherwise

Group V - Mixing mortar for more than 3 masons by hand

Group VI - Blasters, drill operators, gunite nozzle man & machine man

Group VII - Pasterer mixing machine & pump

MODIFICATIONS P.22

DECISION NO. PA78-3071 - (CONT'D)	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
ADD:					
LABORERS:					
Common Laborers	9 91	9%	9%		3%
Mason tenders	10 11	9%	9%		3%

DECISION NO. TX79-4068 - MOD. #1 (44 FR 39895 - July 6, 1979) Bastrop, Blanco, Caldwell, Fayette, Hays, Lee, Llano, Travis & Williamson Cos, Texas	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
ADD:					
Soft floor layers	$ 4.88				

SUPERSEDEAS DECISION

STATE: INDIANA COUNTIES: *See Below
DECISION NO IN79-2083 DATE: Date of Publication
Supersedes Decision Nos. IN77-2021 dated February 18, 1977 in 42 FR 10196; IN77-2022 dated February 18, 1977 in 42 FR 10197; and IN77-2023 dated February 18, 1977 in 42 FR 10197
DESCRIPTION OF WORK: Residential Construction Projects Consisting of single family homes and apartments up to and including 4 stories.

*Daviess, DuBois, Gibson, & Knox

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
AIR CONDITIONING & HEATING MECHANICS	$ 6 25				
BRICKLAYERS:					
DuBois County	6.50				
Remaining Counties	12.65	.60	1 00		.04
CARPENTERS	6.23				
CEMENT MASONS	7.75				
ELECTRICIANS:					
DuBois County	4.75				
Remaining Counties	6.76	.50	38		½8
DRYWALL FINISHERS	7.25				
LABORERS	5 15				
PAINTERS, Brush	5 48				
PLUMBERS	6.00				
SHEET METAL WORKERS	6 00				
POWER EQUIPMENT OPERATORS:					
Backhoes	8.98				
Bulldozers	7.00				

Unlisted classifications needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards contract clauses (29 CFR, 5.5 (a) (1) (ii)).

SUPERSEDEAS DECISION

STATE: INDIANA COUNTIES: *See Below
DECISION NO : IN79-2084 DATE: Date of Publication
Supersedes Decision No IN77-2099, dated May 27, 1977 in 42 FR 27554
DESCRIPTION OF WORK: Residential Construction Projects Consisting of single family homes and apartments up to and including 4 stories

*Boone, Clinton, Montgomery, & Tippecanoe

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
AIR CONDITIONING & HEATING MECHANICS	$ 6.36				
BRICKLAYERS	6 25				
CARPENTERS	6 00				
CEMENT MASONS	7 60				
DRYWALL FINISHERS	7 00				
DRYWALL HANGERS	7 00				
ELECTRICIANS	6 67				
INSULATION INSTALLERS	6 50				
LABORERS	4 70				
PAINTERS, Brush	5 81				
PLUMBERS	6 50				
ROOFERS	5 85				
SHEET METAL WORKERS	6 89				
TRUCK DRIVERS	6.85				
POWER EQUIPMENT OPERATORS:					
Backhoes	7 62				
Bulldozers	10.30				
Graders	10 30				

Unlisted classifications needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards contract clauses (29 CFR, 5.5 (a) (1) (ii)).

SUPERSEDEAS DECISION

STATE: New Mexico COUNTY: Statewide
DECISION NO.: NM79-4103 DATE: Date of Publication
Supersedeas Decision No. NM79-4079 dated September 7, 1979 in 44 FR 52557

DESCRIPTION OF WORK: BUILDING AND HEAVY PROJECTS (also including RESIDENTIAL PROJECT in Santa Fe, Bernalillo, Rio Arriba, Taos, Sandoval and Valencia Counties).

BUILDING & HEAVY CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
ASBESTOS WORKERS:					
(Statewide, except Union, Lea, Harding, Curry, Roosevelt and Quay Cos.)	13.26	.50	1.37a		.06
Union, Harding, Lea, Roosevelt, Curry and Quay Cos.	10.00	.65	.55		.07
BOILERMAKERS	11.75	1.175	1.25	.75	
BRICKLAYERS-STONEMASONS:					
Zone I-A	11.31	.77	.50		.10
Zone I-B	12.56	.77	.50		.10
Zone I-C	13.56	.77	.50		.10
Zone II	11.41	.77	.50		.10
Zone III	12.41	.77	.50		.10
Zone IV	11.51	.77	.40		.10
Zone V	12.51	.77	.40		.10
Zone VI	10.81	.77	.40		.10
Zone VII	11.61	.77	.40		.10
Zone VIII	12.24	.77	.30		.10
Zone IX	10.99	.77	.30		.10

BRICKLAYERS' ZONE DEFINITIONS

ZONE I - Union, Harding, Santa Fe, Valencia, Torrence, Taos, Socorro, Mora, McKinley, Colfax, Catron, San Miguel, San Juan, Sandoval, Rio Arriba, Bernalillo and Los Alamos Counties
From basing point of Albuquerque Main Post Office:
Zone I-A - 0 to 25 road miles
Zone I-B - 25 to 50 road miles
Zone I-C - Over 50 road miles
ZONE II - Curry and Roosevelt Counties
ZONE III - DeBaca, Guadalupe and Quay Counties
ZONE IV - Chaves County
ZONE V - Lincoln County
ZONE VI - Lee and Eddy Counties
ZONE VII - Otero Counties
ZONE VIII - Luna and Grant Counties, communities of Silver City, Bayard, Central, Hurley and new town site of Tyrone; Hidalgo and Sierra Counties
ZONE IX - Dona Ana County

DECISION NO. NM79-4103. Page 2

BUILDING & HEAVY CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
CARPENTERS:					
Dwelling houses & apartments not to exceed two stories in height:					
Zone I-A	7.50	1.10	1.20	.65	.20
Zone I-B	8.75	1.10	1 20	.65	.20
Zone I-C	9.50	1.10	1.20	.65	.20
General Building, Heavy & Residential Construction (Dwelling houses and apartments over two stories in height):					
Zone 2-A	11.40	1.10	1.20		.20
Zone 2-B	12.90	1.10	1.20		.20
Zone 2-C	13.65	1.10	1.20		.20

CARPENTERS' ZONE DEFINITIONS

CARPENTER (STATEWIDE) - From nearest basing points of the following cities of Towns: Alamogordo, Albuquerque, Artesia, Bayard, Belen, Carlsbad, Clovis, Deming, Espanola, Eunice, Farmington, Gallup, Grants, Hobbs, Las Cruces, Las Vegas, Lordsburg, Lovington, Portales, Raton, Roswell, Ruidoso, Santa Fe, Santa Rosa, Silver City, Socorro, Taos, and Tucumcari:
ZONE I - Dwelling houses & apartments not to exceed two stories in height:
Zone I-A - 0 - 15 road miles from nearest basing point
Zone I-B - 15 to 35 road miles from nearest basing point
Zone I-C - Over 35 road miles from nearest basing poing
ZONE II - General Building & Heavy Construction & Residential Construction (Dwelling houses & apartments over two stories in height:
Zone 2-A - 0 - 15 road miles from nearest basing point
Zone 2-B - 15 to 35 road miles from nearest basing point
Zone 2-C - Over 35 road miles from nearest basing point

CARPENTERS - San Juan County Only					
Zone I	11.40	1.10	1.20		.20
Zone II	13.65	1.10	1.20		.20
Zone III	13.65	1.10	1.20		.20

SAN JUAN COUNTY ZONE DEFINITIONS FOR CARPENTERS

ZONE I - Within 15 road miles of the City of Farmington
ZONE II - More than 15 miles, but less than 35 miles from Farmington
ZONE III - 35 miles or more from the City of Farmington

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr.
CEMENT MASON:					
Area I	9.77	.77	.60		.20
Area II:					
Zone 1	9.77	.77	.60		.20
Zone 2	10.75	.77	.60		.20
Zone 3	10.97	.77	.60		.20
Cement masons (Residential)	6.00	.77	.60		.20
Cement masons (Heavy)	9.77	.77	.60		.20
CEMENT MASONS:					
Composition & Machine Oprs.					
Area I	10.02	.77	.60		.20
Area II:					
Zone 1	10.02	.77	.60		.20
Zone 2	10.97	.77	.60		.20
Zone 3	11.22	.77	.60		.20

CEMENT MASONS AREA DEFINITIONS

AREA I - Statewide except Farmington, San Juan County

AREA II - Farmington, San Juan County
Zone I - 0 - 15 miles from Farmington City Hall
Zone II - 15-35 miles from Farmington City Hall
Zone III - 35 miles and over from Farmington City Hall

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ELECTRICIANS:					
Zone I					
1-A	12.15	.60	3%+.70		½%
1-B	13.00	.60	3%+.70		½%
1-C	13.73	.60	3%+.70		½%
1-D	14.58	.60	3%+.70		½%
Zone II	13.73	.60	3%+.70		½%
Zone III					
3-A	9.60	.30	3%		1/10%
3-B	11.05	.30	3%		1/10%
Zone IV					
4-A	11.75	.60	3%		.01
4-B	12.10	.60	3%		.01
4-C	12.25	.60	3%		.01
4-D	12.50	.60	3%		.01

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
CABLE SPLICERS:					
Zone I					
1-A	13.37	.60	3%+.70		½%
1-B	14.22	.60	3%+.70		½%
1-C	14.95	.60	3%+.70		½%
1-D	15.80	.60	3%+.70		½%
Zone II	14.95	.60	3%+.70		½%
Zone III					
3-A	9.85	.30	3%		1/10%
3-B	11.30	.30	3%		1/10%
Zone IV					
4-A	12.10	.60	3%		.01
4-B	12.45	.60	3%		.01
4-C	12.60	.60	3%		.01
4-D	12.85	.60	3%		.01

ELECTRICIANS-CABLE SPLICERS ZONE DEFINITIONS

ZONE I
Area 1 - Bernalillo, Santa Fe, Torrance, DeBaca, Guadalupe, Quay, San Miguel, Mora, Harding, Union, Colfax, Taos, Rio Arriba, Grant, Sandoval, Valencia, Socorro, Catron, McKinley, Sierra, San Juan, Chaves, Curry, Lincoln and Roosevelt Counties
Area 1-A - From nearest basing point cities, towns and mileage from main post office in the following towns:
Albuquerque - 15 miles from main post office
Santa Fe - 15 miles from main post office
Las Vegas - 8 miles from main post office
Farmington - 8 miles from main post office
Raton - 6 miles from main post office
Tucumari - 6 miles from main post office
Azteg - 6 miles from main post office
Roswell - 12 miles from main post office
Ruidoso - 12 miles from main post office
Portales - 12 miles from main post office
Carrizozo - 12 miles from main post office
Clovis - 12 miles from main post office
Gallup - 10 miles from main post office
*Pojoaque - 2 miles from main post office
*All areas adjacent to Pojoaque that are over two (2) miles distant from the main post office in that town will be zoned out of Santa Fe.

ZONE I CONTD:
Area 1-B - extending up to 20 miles beyond Area 1-A

Area 1-C - extending up to 30 miles from Area 1-A

Area 1-D - anything beyond 30 miles from Area 1-A
ZONE II - Los Alamos County
ZONE III - Dona Ana, Otero, Luna, Hidalgo Counties
Zone 3-A - Within 10 miles radius from the post office in Las Cruces and within a 5 mile radius from the post office in Alamogordo.
Zone 3-B - Dona Ana, Otero, Luna, and Hidalgo Counties (except that area specified in Zone 3-A)
ZONE IV - Eddy and Lea Counties - the following zones shall be designated from the main post office in Artesia, Carlsbad, Hobbs and Lovington:
Zone 4-A - 0 -12 miles from main post office
Zone 4-B - 12 - 22 miles from main post office
Zone 4-C - 22 - 40 miles beyond main post office
Zone 4-D - 40 miles and beyond main post office

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
ELEVATOR CONSTRUCTORS:					
Bernalillo, Catron, Colfax, Curry, DeBaca, Guadalupe, Harding, Lincoln, Los Alamos, McKinley, Mora, Quay, Rio Arriba, Roosevelt, Sandoval, San Juan, San Miguel, Santa Fe, Socorro, Taos, Torrance, Union and Valencia Cos.:					
Elevator constructors	11.50	.545	.35	4%+b+c	.02
Elevator constructors helpers	70%JR	.545	.35	4%+b+c	.02
Elevator constructors, prob.	50%JR				
Chaves, Hidalgo, Dona Ana, Eddy, Grant, Lea, Luna, Otera and Sierra Cos.:					
Elevator constructors	8.68	.895	.69	4%+b+c	.035
Elevator constructors helper	70%JR	.895	.69	4%+b+c	.035
Elevator constructors, prob.	50%JR				
GLAZIERS	9.79	.70	.30		.04

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
IRONWORKERS:					
ZONE I	11.80	.75	1.25		.18
ZONE II					
Area 1	11 80	.75	1.25		.18
Area 2	13.05	.75	1.25		.18
Area 3	13 80	.75	1.25		.18
Area 4	14.05	.75	1.25		.18
ZONE III	11 05	.55	1.40		.15
ZONE IV	12.05	.55	1.40		.15

IRONWORKERS ZONE DEFINITIONS

ZONE I - Bernalillo, Catron, Colfax, DeBaca, Guadalupe, Lincoln, Los Alamos, McKinley, Mora, Rio Arriba, Sandoval, Santa Fe, Socorro, Taos, Torrance, and Valencia Counties
ZONE II - Farmington, San Juan County
Area 1 - Shall extend a distance of 6 road miles inclusive beyond the City Hall
Area 2 - Shall extend a distance of 8 road miles inclusive beyond the outer perimeter of area 1
Area 3 - Shall extend a distance of 10 road miles inclusive beyond the outer limits of area 2
Area 4 - Shall extend a distance of 27 road miles inclusive beyond the outer limits of area 3
Other areas not within Area 1, 2, 3, and 4 shall revert to the $15.00 oer day subsistence rate.
ZONE III - Dona Ana, county with the exception of that portion of the county that lies within the White Sands Missile Range; Chaves County, Eddy County except that Potash Basin and defined as the area 10 road miles on Highway 62 and Highway 180, east of Carlsbad.
ZONE IV - Curry, Harding, Quay, Union, Hidalgo, Grant, Lea, Luna, Otero and Sierra Counties; also Potash Basin, White Sands and McGregor Missile Ranges.

LABORERS: BUILDING					
Group I	7.61	.63	.77		.10
Group II	7.91	.63	.77		.10
Group III	7.91	.63	.77		.10
Group IV	8.21	.63	.77		.10
Group V	8.36	.63	.77		.10

BUILDING LABORERS CLASSIFICATION DEFINITIONS

GROUP I - Unskilled; building and common laborers, carpenter tenders, concrete workers, chainmen - stakedrivers, concrete buggy operators
GROUP II - Semi-skilled; air and power tool operator, asphalt rakers, demolition, gunite, rebound men, fog machine operator, power buggy operators, rodmen; sand blasterers (pot men), window washers, wagon, core and diamond drillers tenders; outside scaler, grade setter
GROUP III - Wagon core, diamond drillers
GROUP IV - Concrete burner, cement mason tenders, hod carriers, mortar mixers, plaster spreader operators, plaster tenders, gunite nozzlemen, pipelayers, pumpcrete nozzlemen
GROUP V - Powdermen and blasterers

LABORERS (HEAVY CONSTRUCTION & SITE PREPARATION & DIRT WORK)

ZONE I - Statewide including 15 miles from Farmington Hall
ZONE II - 15 to 35 miles from Farmington Hall
ZONE III - 35 miles and over from Farmington Hall

LABORERS (HEAVY CONSTRUCTION & SITE PREPARATION & DIRT WORK)	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
ZONE I					
Group 1	7.61	.63	.77		.10
Group 2	7.91	.63	.77		.10
Group 3	8.01	.63	.77		.10
Group 4	8.21	.63	.77		.10
Group 5	8.36	.63	.77		.10
ZONE II					
Group 1	8.11	.63	.77		.10
Group 2	8.41	.63	.77		.10
Group 3	8.51	.63	.77		.10
Group 4	8.71	.63	.77		.10
Group 5	8.86	.63	.77		.10
ZONE III					
Group 1	8.61	.63	.77		.10
Group 2	8.91	.63	.77		.10
Group 3	9.01	.63	.77		.10
Group 4	9.21	.63	.77		.10
Group 5	9.36	.63	.77		.10

LABORERS (HEAVY CONSTRUCTION, SITE PREPARATION AND DIRT WORK) CLASSIFICATION DEFINITIONS

GROUP I - Unskilled - Construction and general laborers, carpenter tenders, concrete workers, stakedrivers, concrete buggy operators
GROUP II - Semi-skilled - Air and power tool operators, asphalt rakers, cutting torch operators, demolition, gunite rebound men, rod and chainmen, grade setters, power buggy operators, sand blasters (pot men), nozzlemen, wagon core and diamond drillers' tenders, outside scalers, fog machine operators
GROUP III - Wagon core, diamond drillers
GROUP IV - Miscellaneous - concrete burner, cement mason tenders, hod carriers, mortar mixers, plaster spreader operators, plaster tenders, gunite nozzlemen, pipelayers, pumpcrete nozzleman
GROUP V - Powdermen and blasters

LABORERS RESIDENTIAL CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Group I	5.02	.63	.77		.10
Group II	5.32	.63	.77		.10
Group III	5.42	.63	.77		.10
Group IV	5.62	.63	.77		.10

RESIDENTIAL LABORERS' CLASSIFICATION DEFINITIONS

GROUP I - Unskilled - Building and common laborers, carpenter tenders, concrete workers, chainmen - stakedrivers, concrete buggy operators, hand
GROUP II - Semi-skilled - air and power tool operator, asphalt rakers, demolition, gunnite rebound men, fog machine operator, power buggy operator, rodmen, sand blasterers (pot men), window washers, wagon, core and diamond drillers, tender outside
GROUP III - Wagon core, diamond drillers
GROUP IV - Concrete burner, cement mason tenders, hod carriers, mortar mixers, plaster spreader operators, plaster tenders, gunnite nozzlemen, pipelayer, pumpcrete nozzlemen

LATHERS:	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Zone I	11.64	.77			.06
Zone II	12.56	.77			.01
Zone III	8.98	.77			.01

LATHERS ZONE DEFINITIONS

ZONE I - Catron, Grant, Bernalillo, Roosevelt, Union, Sandoval, San Juan, Socorro, Torrance and Valencia Counties
ZONE II - Colfax, Los Alamos, Mora, Rio Arriba, San Miguel, Santa Fe and Taos Counties
ZONE III - Dona Ana and Otero Counties

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
LEAD BURNERS					
Zone I	13.25	.68	1.42		.16
Zone II	13.75	.68	1.42		.16
Zone III	15.00	.68	1.42		.16
Zone IV	13.88	.68	1.42		.16

LEAD BURNERS BASING POINT & AREA DEFINITIONS

BASING POINT CITIES OR TOWNS:
Albuquerque, Alamorgordo, Anthony, Artesia, Belen, Carlsbad, Clovis, Deming, Espanola, Farmington, Gallup, Grants, Hobbs, Las Cruces, Las Vegas, Lovington, Portales, Raton, Socorro, Roswell, Ruidoso, Santa Fe, Silver City, Santa Rosa, Taos, Tucumcari and Truth of Consequence
Zone I - Shall include a distance of seven road miles inclusive beyond the city or town limits
Zone II - Shall extend a distance of 4 road miles inclusive beyond the outer perimeter of area I.
Zone III- Shall apply to all areas not within 1 or 2, or not within the specific areas.
Zone IV (SPECIFIC AREA) - Los Alamos, White Rock, South Mesa, McGregor Range, White Sands Missile Range, and/or Proving Grounds

COMMERCIAL LINE WORK

Bernalillo, Colfax, Catron, Chaves, Curry, DeBaca, Grant, Guadalupe, Harding, Lincoln, Los Alamos, McKinley, Mora, Quay, Rio Arriba, Roosevelt, Sandoval, San Juan, San Miguel, Santa Fe, Sierra, Socorro, Taos, Torrance, Union, Valencia and White Sands Missile Range and that portion of Fort Bliss in New Mexico

ZONE I
Cities and Towns Basing Points - Miles from Main Post Offices

Albuquerque - 15 miles
Santa Fe - 10 miles
Las Vegas - 8 miles
Farmington - 6 miles
Raton - 6 miles
Tucumcari - 6 miles
Aztec - 6 miles
Roswell - 12 miles
Ruidoso - 12 miles
Portales - 12 miles
Carrisoso - 12 miles
Clovis - 12 miles
Gallup - 12 miles
*Pojoaque - 2 miles

COMMERCIAL LINE WORK CONTD:

*All areas adjacent to Pojoaque that are over two miles distant from the main post office in that town will be zoned out of Santa Fe.

ZONE II - Extending up to 20 miles beyond zone 1

ZONE III - Extending up to 30 miles beyond zone 1

ZONE IV - Anything beyond 30 miles from zone 1

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
COMMERCIAL LINE WORK					
ZONE I					
Linemen - technicians	12.15	.60	3%+.70		½%
Cable splicers	13.37	.60	3%+.70		½%
Equipment Operator (includes helicopter op.)	11.54	.60	3%+.70		½%
Equipment Operator (includes Helicopter mechanic)	10.57	.60	3%+.70		½%
Powderman	10.57	.60	3%+.70		½%
Groundman & Jackhammer Oprs.	8.63	.60	3%+.70		½%
ZONE II					
Linemen - technicians	13.00	.60	3%+.70		½%
Cable splicers	14.22	.60	3%+.70		½%
Equipment Opr. (includes helicopter op.)	12.39	.60	3%+.70		½%
Equipment Opr. (includes Helicopter mechanic)	11.42	.60	3%+.70		½%
Powderman	11.42	.60	3%+.70		½%
Groundman & Jackhammer Oprs.	9.48	.60	3%+.70		½%
ZONE III					
Linemen - technicians	13.73	.60	3%+.70		½%
Cable splicers	14.95	.60	3%+.70		½%
Equipment Opr. (includes helicopter op.)	13.73	.60	3%+.70		½%
Equipment Opr. (includes helicopter mechanic)	12.15	.60	3%+.70		½%
Powderman	12.15	.60	3%+.70		½%
Groundman & Jackhammer Oprs.	10.21	.60	3%+.70		½%
ZONE IV					
Linemen - technicians	14.58	.60	3%+.70		½%
Cable splicers	15.80	.60	3%+.70		½%
Equipment Opr. (includes helicopter op.)	13.97	.60	3%+.70		½%
Equipment Opr. (includes helicopter mechanic)	13.00	.60	3%+.70		½%
Powderman		.60	3%+.70		½%
Groundman & Jackhammer Oprs.	11.06	.60	3%+.70		½%

Las Alamos County - Use ZONE III rates.

COMMERCIAL LINE WORK
Applies to switching stations and substations adjacent to power plants in Zone 1 and zone 2 in Luna, Dona Ana, Otero and Hidalgo Counties, exclusive of White Sands Missile Range and that portion of Fort Bliss in New Mexico.

ZONE I
The area within 25 miles radius from the downtown Post Office of El Paso, Texas. Fort Bliss and Biggs Field; the area within a five mile radius of any city, town or municipality within which an employer establishes or maintains his place of business; the area within ten mile radius from the post office in Las Cruces, New Mexico, and within a five mile radius from the post office in Alamogordo, New Mexico.

ZONE II
All other areas of the jurisdiction except those specified in zone 1

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
ZONE I					
Linemen - technicians	9.60	.30	3%		½%
Cable splicers	9.85	.30	3%		½%
Equipment opr. (includes helicopter opr.)	9.12	.30	3%		½%
Equipment opr. (includes helicopter mechanic)	8.40	.30	3%		½%
Powderman	8.40	.30	3%		½%
Groundman & Jackhammer Oprs.	6.82	.30	3%		½%
ZONE II					
Linemen - technicians	11.05	.30	3%		½%
Cable splicers	11.30	.30	3%		½%
Equipment Opr. (includes helicopter opr.)	10.50	.30	3%		½%
Equipment Opr. (includes helicopter mechanic)	9.67	.30	3%		½%
Powderman	9.67	.30	3%		½%
Groundman & Jackhammer Oprs.	7.85	.30	3%		½%

COMMERCIAL LINE WORK
Applies to switching stations adjacent to power plants in Eddy and Lea Counties; the following zones listed shall be designated from main Post Office of Artesia, Carlsbad, Hobbs & Lovington.
Zone A - 0 - 12 miles
Zone B - 12 - 22 miles
Zone C - 22 to 40 miles
Zone D - 40 miles and beyond

COMMERCIAL LINE WORK CONTD:	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
ZONE A					
Linemen - technician	$11.75	.60	3%		½%
Cable splicers	12.10	.60	3%		½%
Equipment Opr. (includes helicopter opr.)	11.16	.60	3%		½%
Equipment Opr. (includes helicopter mechanic)	10.28	.60	3%		½%
Powderman	10.28	.60	3%		½%
Groundman & Jackhammer Oprs	8.34	.60	3%		½%
ZONE B					
Linemen - technician	12.10	.60	3%		½%
Cable splicers	12.45	.60	3%		½%
Equipment opr. (includes helicopter opr)	11.51	.60	3%		½%
Equipment opr. (includes helicopter mechanic)	10.63	.60	3%		½%
Powderman	10.63	.60	3%		½%
Groundman & Jackhammer Oprs.	8.69	.60	3%		½%
ZONE C					
Linemen - technician	12.25	.60	3%		½%
Cable splicers	12.60	.60	3%		½%
Equipment opr. (includes helicopter opr)	11.66	.60	3%		½%
Equipment opr. (includes helicopter mechanic)	10.78	.60	3%		½%
Powderman	10.78	.60	3%		½%
Groundman & Jackhammer Oprs.	8.84	.60	3%		½%
ZONE D					
Linemen - technician	12.50	.60	3%		½%
Cable splicers	12.85	.60	3%		½%
Equipment opr. (includes helicopter opr)	11.91	.60	3%		½%
Equipment opr. (includes helicopter mechanic)	11.13	.60	3%		½%
Powderman	11.13	.60	3%		½%
Groundman & Jackhammer Oprs.	9.09	.60	3%		½%

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
MARBLE, TILE & TERRAZZO WORKERS	9.80	.77			
MARBLE, TILE & TERRAZZO FINISHERS	8.09	.77			
MILLWRIGHTS & PILEDRIVERMEN:					
Zone 1	12.15	1.10	1.20		.20
Zone 2	13.65	1.10	1.20		.20
Zone 3	14.40	1.10	1.20		.20

MILLWRIGHTS & PILEDRIVERMEN ZONE DEFINITIONS

BASING POINT - FROM ALBUQUERQUE CITY LIMITS:
Zone 1 - 0 to 15 road miles from basing point
Zone 2 - 15 to 35 road miles from basing point
Zone 3 - Over 35 road miles from basing point

PAINTERS: ZONE I					
Class 1-A	9.47	.70	.40		.05
Class 1-B	9.97	.70	.40		.05
Class 1-C	9.72	.70	.40		.05
Class 1-D	10.05	.70	.40		.05
Class 1-E	9.80	.70	.40		.05
ZONE II:					
Class 2-A	8.60	.70	.40		.05
Class 2-B	8.82	.70	.40		.05
Class 2-C	9.25	.70	.40		.05
Class 2-D	8.70	.70	.40		.05
Class 2-E	9.35	.70	.40		.05
Class 2-F	8.60	.70	.40		.05
Class 2-G	9.10	.70	.40		.05
ZONE II (RESIDENTIAL)					
Brush & rollers	8.60	.70	.40		.05
Spray & sandblast	9.25	.70	.40		.05
Paperhangers	8.82	.70	.40		.05
Vinyl hangers	8.70	.70	.40		.05
ZONE III					
Class 3-A	8.23	.68			.02
Class 3-B	8.65	.68			.02
Class 3-C	8.375	.68			.02
Class 3-D	9.08	.68			.02

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
PAINTERS' CONTD:					
ZONE IV					
Class 4-A	7.12	.35	.20		.05
Class 4-B	7.62	.35	.20		.05
Class 4-C	7.37	.35	.20		.05
Class 4-D	7.22	.35	.20		.05
Class 4-E	7.70	.35	.20		.05
Class 4-F	7.45	.35	.20		.05

PAINTERS' ZONE AND CLASSIFICATION DEFINITIONS

ZONE I - San Juan, McKinley, Bernalillo, Torrance, Guadalupe, Quay, Catron, Socorro, Lincoln, DeBaca, Roosevelt, Chaves, Valencia, Sierra, Grant, Hidalgo, Curry, Lea and Eddy Counties, New Mexico.
- Class A - Painters, roller and hand textures
- Class B - Painters, spray, sandblasting, painter on steel bridges, tanks towers, pipe and structural
- Class C - Paperhanger
- Class D - Drywall finisher, ames tool operator
- Class E - Hand finisher machine texture

ZONE II - Colfax, Hardin, Los Alamos, Mora, Sandoval, San Miguel, Rio Arriba, Taos, Union and Santa Fe Counties
- Class A - Painters and roller
- Class B - Paperhangers
- Class C - Spray, sandblast, steel, special coating applicator
- Class D - Vinyl hangers
- Class E - Drywall finisher tool and machine texture
- Class F - Hand texture
- Class G - Hand finisher

ZONE III - Luna, Otero and Dona Ana Counties
- Class A - Brush, paperhangers
- Class B - Spray, sandblasting, swing stage, stripping machine
- Class C - Ames tool and steel brush after erection
- Class D - Radio towers, water tanks smoke stake 70 - 100 ft.

ZONE IV - Residential Construction in Santa Fe, Sandoval, Rio Arriba & Taos Counties
- Class A - Brush and roller
- Class B - Spray, parking lot stripping
- Class C - Paperhangers
- Class D - Vinyl hangers
- Class E - Drywall finishers - ames tool op., machine texture
- Class F - Drywall finishers - hand finisher

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr.
PLASTERERS:					
Statewide, except Otero, Grant, Sierra, Dona Ana, & Hidalgo Counties	11.01	.77	.60		.06
Otero, Grant, Sierra, Dona Ana, Luna and Hidalgo Counties	8.48	.77	.25		.01
PLUMBERS-PIPEFITTERS:					
Area I	12 75	.68	1 42		.16
Area II	13 25	.68	1.42		.16
Area III	14 50	.68	1.42		.16
Specific area	13 38	.68	1.42		.16
Residential	8.05	.68	.25		.16

PLUMBERS - PIPEFITTERS' ZONES DEFINITIONS

BASING POINT CITIES OR TOWNS:
Albuquerque, Alamogordo, Anthony, Artesia, Belen, Carlsbad, Clovis, Deming, Espanola, Farmington, Gallup, Grants, Hobbs, Las Cruces, Las Vegas, Lordsburg, Lovington, Portales, Raton, Roswell, Ruidoso, Santa Fe, Silver City, Santa Rosa, Taos, Tucumcari, Truth of Consequence and Socorro, New Mexico

Area I - Shall include a distance of seven road miles inclusive beyond the city or town limits.

Area II - Shall extend a distance of four road miles inclusive beyond the outer perimeter of area I.

Area III - Shall apply to all areas not within areas 1 or 2, or not within the specific area.

Specific Area - Los Alamos, White Rock, South Mesa, McGregor Range, White Sands Missile Range and/or Proving Grounds, Atlas Missile Complex Sites in Chaves and Lincoln Counties, and the Oro Grande Range Camp and Dona Ana and Otero Counties

POWER EQUIPMENT OPERATORS AREA DEFINITIONS:
AREA I - Farmington, San Juan County
Zone I - 0 - 15 miles from Farmington City Hall
Zone II - 15 - 35 miles from Farmington City Hall
Zone III - 35-50 miles from Farmington City Hall
AREA II - Statewide, except San Juan County

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
POWER EQUIPMENT OPERATORS					
AREA I (RESIDENTIAL & BUILDING CONSTRUCTION)					
ZONE I					
Group 1	$ 8 88	.70	.60		.15
Group 2	9 92	.70	.60		.15
Group 3	10 00	.70	.60		.15
Group 4	10.06	.70	.60		.15
Group 5	10.12	.70	.60		.15
Group 6	10 22	.70	.60		.15
Group 7	10 32	.70	.60		.15
Group 8	11.40	.70	.60		.15
ZONE II					
Group 1	10 63	.70	.60		.15
Group 2	11 67	.70	.60		.15
Group 3	11 75	.70	.60		.15
Group 4	11.81	.70	.60		.15
Group 5	11 87	.70	.60		.15
Group 6	11 97	.70	.60		.15
Group 7	12 07	.70	.60		.15
Group 8	13.15	.70	.60		.15
ZONE III					
Group 1	11.13	.70	.60		.15
Group 2	12 17	.70	.60		.15
Group 3	12.25	.70	.60		.15
Group 4	12.31	.70	.60		.15
Group 5	12 37	.70	.60		.15
Group 6	12.47	.70	.60		.15
Group 7	12.57	.70	.60		.15
Group 8	13.65	.70	.60		.15
AREA II (RESIDENTIAL & GENERAL BUILDING CONSTRUCTION)					
Group 1	8 88	.70	.60		.15
Group 2	9.92	.70	.60		.15
Group 3	10.00	.70	.60		.15
Group 4	10 06	.70	.60		.15
Group 5	10 12	.70	.60		.15
Group 6	10 22	.70	.60		.15
Group 7	10.32	.70	.60		.15
Group 8	11 40	.70	.60		.15

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HEAVY CONSTRUCTION (POWER EQUIPMENT OPERATORS AREA DEFINITIONS)

AREA I - Statewide, except San Juan County
Basing points for zone pay shall be determined from the Center of the following cities - Albuquerque, Carlsbad, Gallup, Raton & Las Cruces
Zone I - 0 - 50 miles
Zone II - Over 50 miles
AREA II - Farmington, San Juan County
Zone I - 0 - 15 miles from Farmington City Hall
Zone II - 15 to 35 miles from Farmington City Hall
Zone III - Over 35 miles from Farmington City Hall

HEAVY CONSTRUCTION (AREA I):	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
GROUP I					
Zone 1	$ 8.83	.75	.60		.15
Zone 2	10.08	.75	.60		.15
GROUP II					
Zone 1	9.87	.75	.60		.15
Zone 2	11.12	.75	.60		.15
GROUP III					
Zone 1	9.95	.75	.60		.15
Zone 2	11.20	.75	.60		.15
GROUP IV					
Zone 1	10.01	.75	.60		.15
Zone 2	11.26	.75	.60		.15
GROUP V					
Zone 1	10.07	.75	.60		.15
Zone 2	11.32	.75	.60		.15
GROUP VI					
Zone 1	10.17	.75	.60		.15
Zone 2	11.52	.75	.60		.15
GROUP VII					
Zone 1	10.27	.75	.60		.15
Zone 2	11.52	.75	.60		.15
GROUP VIII					
Zone 1	11.35	.75	.60		.15
Zone 2	12.60	.75	.60		.15
(HEAVY CONSTRUCTION) POWER EQUIPMENT OPERATORS HEAVY CONSTRUCTION (AREA II)					
GROUP I					
Zone 1	8.83	.75	.60		.15
Zone 2	10.08	.75	.60		.15
Zone 3	10.58	.75	.60		.15
GROUP II					
Zone 1	9.87	.75	.60		.15
Zone 2	11.12	.75	.60		.15
Zone 3	11.62	.75	.60		.15
GROUP III					
Zone 1	9.95	.75	.60		.15
Zone 2	11.20	.75	.60		.15
Zone 3	11.70	.75	.60		.15

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HEAVY CONSTRUCTION AREA II CONTD:	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
GROUP IV					
Zone 1	$10.01	.75	.60		.15
Zone 2	11.26	.75	.60		.15
Zone 3	11.76	.75	.60		.15
GROUP V					
Zone 1	10.07	.75	.60		.15
Zone 2	11.32	.75	.60		.15
Zone 3	11.82	.75	.60		.15
GROUP VI					
Zone 1	10.17	.75	.60		.15
Zone 2	11.42	.75	.60		.15
Zone 3	11.92	.75	.60		.15
GROUP VII					
Zone 1	10.27	.75	.60		.15
Zone 2	11.52	.75	.60		.15
Zone 3	12.02	.75	.60		.15
GROUP VIII					
Zone 1	11.35	.75	.60		.15
Zone 2	12.60	.75	.60		.15
Zone 3	13.10	.75	.60		.15

POWER EQUIPMENT OPERATORS AREA DEFINITIONS
AREA I - Farmington, San Juan County
Zone I - 0 - 15 miles from Farmington City Hall
Zone II - 15-35 miles from Farmington City Hall
Zone III - 35-50 miles from Farmington City Hall
AREA II - Statewide, except San Juan County

AREA I (SITE PREPARATION & DIRT WORK)	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr
ZONE I					
Group 1	8.88	.75	.60		.15
Group 2	9.92	.75	.60		.15
Group 3	10.00	.75	.60		.15
Group 4	10.06	.75	.60		.15
Group 5	10.12	.75	.60		.15
Group 6	10.22	.75	.60		.15
Group 7	10.32	.75	.60		.15
Group 8	11.40	.75	.60		.15

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
AREA I (SITE PREPARATION & DIRT WORK CONTD:)					
ZONE II					
Group 1	$10.63	.75	.60		.15
Group 2	11 67	.75	.60		.15
Group 3	11.75	.75	.60		.15
Group 4	11.81	.75	.60		.15
Group 5	11.87	.75	.60		.15
Group 6	11 97	.75	.60		.15
Group 7	12 07	.75	.60		.15
Group 8	13.15	.75	.60		.15
ZONE III					
Group 1	11.13	.75	.60		.15
Group 2	12.17	.75	.60		.15
Group 3	12 25	.75	.60		.15
Group 4	12.31	.75	.60		.15
Group 5	12.37	.75	.60		.15
Group 6	12 47	.75	.60		.15
Group 7	12.57	.75	.60		.15
Group 8	13.65	.75	.60		.15
AREA II (SITE PREPARATION & DIRT WORK)					
Group 1	8.88	.75	.60		.15
Group 2	9 92	.75	.60		.15
Group 3	10.00	.75	.60		.15
Group 4	10.06	.75	.60		.15
Group 5	10 12	.75	.60		.15
Group 6	10.22	.75	.60		.15
Group 7	10.32	.75	.60		.15
Group 8	11 40	.75	.60		.15

POWER EQUIPMENT OPERATORS CLASSIFICATION DEFINITIONS
BUILDING, RESIDENTIAL, HEAVY CONSTRUCTION & SITE PREPARATION & DIRT WORK

GROUP I - Fireman, oiler, screedman, scale operator such as bin-a batch, rubber tired farm type tractor, tractors under 50 HP without attachments, breakman, concrete paving curing machine (bridge-type), helper; (mechanic, welder, grease truck)

GROUP II - Rollers, sheepsfoot or pneumatic self propelled w/o dozer, concrete conveyor, service truck operator (head oiler), air compressor (300 CFM & over), pumps (6" and over), screening plants, concrete mixers (under 1 CY), concrete saw or grinder-span type, 1 drum hoist, air tugger, elevating belt type loaders, forklift, lumber stacker, tractor farm type (under 50 HP with attachments) motorman and industrial locomotive operator, winch truck, front end loaders, (under 2 CY), power plants which generate over 15 KW, welding machines

POWER EQUIPMENT OPERATORS CLASSIFICATION DEFINITIONS CONTD:
BUILDING, RESIDENTIAL, HEAVY CONSTRUCTION & SITE PREPARATION & DIRT WORK

GROUP III - Bituminous distributors, boilers, retort and hot oil heaters, concrete mixers (1 CY and over), concrete paver-single drum, drilling equipment, motor grades (rough), shaft and tunnel equipment; (refrigeration, slusher, jumbo forms), trenching machines (all types), pump crete and gunite machines, slipform paver, mechanical bullfloats, concrete slab spreading machine, concrete slab finishing machine, asphalt plants, bituminous finishing machines, crushing plants

GROUP IV - Front end loaders (2 thru 10 CY), rollers steel wheeled-all types, bulldozers, scrapers (motor or towed), elevating graders, concrete batching plants, self-propelled rollers -- equipped with dozer, twin-bowl scrapers and quad 8 or 9 pushers (35¢ over basic rate, three bowl scraper (60¢ over basic rate)

GROUP V - Hydraulic cranes-with less than 50 feet of boom (20 tons and under), concrete paver-double drum, cat cranes, hysters, side and swingboom cats, 2 drum hoists, auto fine grader

GROUP VI - Mucking machines - all types, motor grader (finish) mechanic - welder

GROUP VII - Steam engineers, loader (front end over 10 CY), concrete pump (snorkel type)

GROUP VIII - All shovel type equipment: cranes, draglines, backhoes, derricks, guy & stiff leg, pipemobile (No. 2 operator), piledriver, hydraulic cranes (20 tons & over), mine hoist, belt loader ("C.M.I." Type), booms & jibs 150 ft. through 199 ft. - 25¢ per hour above base pay. 200 ft. and over - 50¢ per hour above base pay. Shovel (wheel type), boring machine (tunnel or shaft mole), pipe mobile

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
ROOFERS (BLDG. CONST)	9.10	.50			
ROOFERS (RESIDENTIAL CONST)	7.90	.50			
SHEET METAL WORKERS:					
Zone 1	10.87	.53	1.00		.12
Zone 2	9.62	38+.51	.385		.04
Zone 3	8.35	.20			.05
Zone 4	11.87	.53	1.00		.12

SHEET METAL WORKERS ZONE DEFINITIONS

Zone 1 - Bernalillo, Catron, Chaves, Colfax, Curry, DeBaca, Guadalupe, Harding, Lincoln, McKinley, Mora, Quay, Rio Arriba, Roosevelt, Sandoval, San Miguel, Santa Fe, Socorro, Union, Taos, Torrance, Valencia, San Juan Counties, Kirtland Air Force Base.

Zone 2 - Dona Ana, Eddy, Grant, Hidalgo, Lea, Luna, Sierra and Otero Counties

Zone 3 - Holloman Air Force Base, White Sands and McGregor Ranges

Zone 4 - Los Alamos County

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
SPRINKLER FITTERS	12.91	.75	1.05		.08
SOFT FLOOR LAYERS:					
Zone 1	8.50	.38	.10		.02
Zone 2	9.20	.70	.50		.04

SOFT FLOOR LAYERS' ZONE DEFINITIONS

Zone 1 - Dona Ana, Luna and Otero Counties
Zone 2 - Statewide (excluding Dona Ana, Lune and Otero Counties

SOUND INSTALLERS:					
SOUNDMAN					
Zone 1	10.35	.60	3%		½%
Zone 2	11.64	.60	3%		½%
Zone 3	14.23	.60	3%		½%
TECHNICIANS					
Zone 1	8.28	.60	3%		½%
Zone 2	9.57	.60	3%		½%
Zone 3	12.16	.60	3%		½%
SOUND INSTALLERS					
Zone 1	6.73	.60	3%		½%
Zone 2	8.02	.60	3%		½%
Zone 3	10.61	.60	3%		½%

SOUND INSTALLERS ZONE DEFINITIONS

ZONE I - Thirty mile radius of main post office in Albuquerque
ZONE II - Remainder of Valencia, Sandoval, Santa Fe, Torrance, and Socorro Counties, the hourly rates of pay shall be increased to twelve and one-half (12½) percent of journeyman rate of pay for Zone I.
ZONE III - Chaves, Curry, Roosevelt, Lincoln, Guadalupe, DeBaca, Quay, San Miguel, Mora, Harding, Union, Colfax, Taos, Rio Arriba, Catron, Sierra, Grant, Los Alamos, San Juan, McKinley Counties, the hourly rates of pay shall be increased by thirty-seven and one-half (37.5) percent of the journeyman rate of pay for Zone I.

TRUCK DRIVERS ZONE PAY BASING POINTS AND DEFINITIONS LISTED BELOW FOR BUILDING AND HEAVY CONSTRUCTION.

BASING POINTS ARE AS FOLLOWS:
Alamogordo, Albuquerque, Artesia, Bayard, Belen, Carlsbad, Clovis, Deming, Espanola, Eunice, Farmington, Gallup, Grants, Hobbs, La Cruces, Las Vegas, Lordsburg, Los Alamos, Lovington, Portales, Raton, Roswell, Ruidoso, Santa Fe, Santa Rosa, Silver City, Socorro, Taos, Tucumcari

ZONE I - Shall be jobs or projects within 15 road miles from the starting points listed above.
ZONE II - Shall be jobs or projects which are more than fifteen road miles, but less than thirty-five road miles from base points.
ZONE III - Shall be those jobs or projects which are thirty-five road miles or more from the base points.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
BUILDING CONSTRUCTION:					
TRUCK DRIVERS (ZONE I)					
Group 1	$ 7.76	.77	.77		
Group 2	7.88	.77	.77		
Group 3	7.96	.77	.77		
Group 4	8.08	.77	.77		
Group 5	8.13	.77	.77		
Group 6	8.23	.77	.77		
Group 7	8.33	.77	.77		
Group 8	8.47	.77	.77		
Group 9	8.62	.77	.77		
TRUCK DRIVERS (ZONE II)					
Group 1	9.01	.77	.77		
Group 2	9.13	.77	.77		
Group 3	9.21	.77	.77		
Group 4	9.33	.77	.77		
Group 5	9.38	.77	.77		
Group 6	9.48	.77	.77		
Group 7	9.58	.77	.77		
Group 8	9.72	.77	.77		
Group 9	9.87	.77	.77		
TRUCK DRIVERS (ZONE III)					
Group 1	9.51	.77	.77		
Group 2	9.63	.77	.77		
Group 3	9.71	.77	.77		
Group 4	9.83	.77	.77		
Group 5	9.88	.77	.77		
Group 6	9.98	.77	.77		
Group 7	10.08	.77	.77		
Group 8	10.22	.77	.77		
Group 9	10.37	.77	.77		

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
RESIDENTIAL CONSTRUCTION:					
TRUCK DRIVERS					
Group 1	$7 46	.77	.77		
Group 2	7 58	.77	.77		
Group 3	7.66	.77	.77		
Group 4	7 78	.77	.77		
Group 5	7.83	.77	.77		
Group 6	7.93	.77	.77		
Group 7	8.03	.77	.77		
Group 8	8.17	.77	.77		
Group 9	8.32	.77	.77		
HEAVY CONSTRUCTION:					
TRUCK DRIVERS (ZONE I)					
Group 1	7.91	.77	.77		
Group 2	8 03	.77	.77		
Group 3	8.11	.77	.77		
Group 4	8.23	.77	.77		
Group 5	8.28	.77	.77		
Group 6	8.38	.77	.77		
Group 7	8.48	.77	.77		
Group 8	8.62	.77	.77		
Group 9	8.77	.77	.77		
TRUCK DRIVERS (ZONE II)					
Group 1	9 16	.77	.77		
Group 2	9.28	.77	.77		
Group 3	9.36	.77	.77		
Group 4	9 48	.77	.77		
Group 5	9.53	.77	.77		
Group 6	9.63	.77	.77		
Group 7	9.73	.77	.77		
Group 8	9 87	.77	.77		
Group 9	10.02	.77	.77		
TRUCK DRIVERS (ZONE III)					
Group 1	9.41	.77	.77		
Group 2	9.53	.77	.77		
Group 3	9 61	.77	.77		
Group 4	9.73	.77	.77		
Group 5	9.78	.77	.77		
Group 6	9.88	.77	.77		
Group 7	9.98	.77	.77		
Group 8	10.12	.77	.77		
Group 9	10.27	.77	.77		

TRUCK DRIVERS CLASSIFICATION DEFINITIONS (BUILDING, RESIDENTIAL CONSTRUCTION)

GROUP I - Pickup 3/4 ton and under, service station, including lubrication, light tire repair and washer, swamper or riding helper, 2 or 4 up

GROUP II- Bus or taxi driver, dump or batch truck under 8 C.Y.W.L.C.: flat bed (bobtail) 2 ton and under; mechanic and welder helper; fork lift under 5 tons MRC.

GROUP III - Dump trucks (including all highway and off highway) 8 up to 16 C.Y.W.L.C.; water, fuel or oil trucks less than 3,000 gal., flat bed (bobtail) over 2 tons

GROUP IV - Distributor driver; heavy tire repairman; lumber carrier driver; young buggy or similar equipment, transit mix or agitator 2 or 3 axle bobtail driver (flat-bed or van single axle); forklifts 5 ton and over MRC: field equipment servicemen

GROUP V - Dumpsters and dumpcrete driver; water, fuel or oil truck 3,000 to 6,000 gal; lowboys and light equipment driver; euclid type tank wagon under 6,000 gal.

GROUP VI - Vacuum truck; dump trucks (including all highway and off-highway 16 up to 22 C.Y.W.L.C.

GROUP VII - Transit mix or agitator semi or 4 axle equipment driver; flaherty truck type spreader box driver; slurry truck driver; bulk cement driver; semi-doubles; 4 axle bobtail; winch truck and "A" frame; dump truck (including all highway and off-highway) 22 CY up to 35 C.Y.W.L.C.: head field equipment servicement

GROUP VIII - Euclid diesel power turnarocker; terra coba-DW20-LeTourneau Pulls and similar diesel powered equipment when used to haul materials and assigned to a teamster-lowboy heavy equipment driver; water, fuel or oil trucks 6,000 gal. and over including tank wagon drivers, semi-trailer driver (flat-bed or van tandems); light equipment mechanic; dump trucks (including all highway and off-highway) 35 C.Y.W L.C. and over; truck and trailer or semi-trailer (flatbed); eject all

GROUP IX - Lowboy (heavy equipment double gooseneck); heavy equipment mechanic; welder (body and fender men)

HEAVY CONSTRUCTION TRUCK DRIVERS CLASSIFICATION DEFINITIONS

GROUP I - Pickup 3/4 to and under, service station, lubrication, light tire repair or washer, swamper or riding helper, teamster 2 or 4 up

GROUP II - Bus or taxi driver, dump or batch truck, under 8 C.Y.W.L.C. flatbed (bobtail) 2 ton and under, warehouseman including material checker, cardex man, expeditor, mechanic and welder helper, forklift under 5 ton M.R.C.

GROUP III - Dump trucks (including all highway & off-highway) 8 up to 16 C.Y.W.L.C., water,fuel or oil trucks less than 3,000 gals., flatbed (bobtail) over 2 tons

GROUP IV - Distributor driver, heavy tire repair, lumber carrier driver, yound buggy or similar equipment, transit mix or agitator 2 or 3 axle bobtail equipment, scissor truck, bulk cement bobtail 2 or 3 axles, semi-trailer flatbed or van single axle, forklift 5 ton and over M.R.C., field equipment servicemen

GROUP V - Dumpster and dumpcrete driver, water, fuel or oil truck, 3,000 to 6,000 gals., capacity, lowboy, light equipment driver, euclid type tank wagon under 6,000 gallons

GROUP VI - Vacuum truck, dump trucks (including all highway & off-highway) 16 up to 22 C.Y.W.L.C.

GROUP VII - Transit mix or agitator semi or 4 axle equipment driver, flaherty truck type spreader box driver, slurry truck driver, bulk cement driver, semi-doubles, 4 axle bobtail, winch truck & "A" frame, dump trucks (including all highway and off-highway) 22 C.Y. up to 35 C.Y.W.L.C. head field equipment servicemen

GROUP VIII - Euclid diesel powered turnarocker, terra cobra, DW 10, DW 20, LeTourneau pulls and similar diesel powered equipment when used to haul materials and assigned to a teamster, lowboy heavy equipment driver, water, fuel or oil truck 6,000 gallons and over (including tank wagon drivers), semi-trailer driver (flatbed or van tandems) light equipment mechanic, dump trucks (including all highway and off-highway) 35 C.Y.W.L.C. and over, truck and trailer or semi-trailer (flatbed), ejectall

GROUP IX - Lowboy (heavy equipment, double gooseneck), heavy equipment mechanic, welder (body and fender man)

PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day; G-Friday after Thanksgiving

FOOTNOTES:
a - Includes $.07 contribution to the Occupational Health Fund
b - 1st 6 months - none; 6 months to 5 years, 6%; over 5 years, 8% of basic hourly rate.
c - Holidays A through G

WELDERS - receive rate prescribed for craft performing operation to which welding is incidental.

"Unlisted classifications needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards contract clauses (29 CFR, 5,5 (a)(ii)."

SUPERSEDEAS DECISION

STATE: NEW MEXICO COUNTY: STATEWIDE
DECISION NO. NM79-4104 DATE: Date of Publication
Supersedes Decision No. NM79-4022 dated February 2, 1979 in 44 FR 6877
DESCRIPTION OF WORK: Sewer & Water & Highway Projects

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
CARPENTERS	$6.32	10	20	.10	.04
CEMENT MASONS	5 76	.26			
IRONWORKERS:					
Reinforcing	5.58	25	.25		
Structural	7 99	.50	.75		.04
LABORERS:					
GROUP I	3.51	20	.15		
GROUP II	3.81	20	15		
Group III	3 81	20	.15		
Group IV	4.21	.20	.15		

LABORERS CLASSIFICATION DEFINITIONS

GROUP I
Common laborer; carpenter tender; concrete buggy operator (hand); concrete workers
GROUP II
Wagon, air track, drill and diamond drillers' tender (outside)
GROUP III
Air and power tool man; asphalt raker; batching plant scaleman; tenders (to cement masons and plasters); chain sawman; concrete touchup-man; concrete saw man; curbing machine; asphalt or cement; cutting torchman; metal form setter-road; grade setter; hod carrier; mortar mixer and mason tender; powderman; scaler; vibrator compactor (hand type); vibrator-man (hand -type); concrete power buggyman, wagon; air track drill and diamond drillers (outside)
GROUP IV
Gunite pumpcreteman & nozzleman; multiplate setter; pipelayer; Manhole builder; Powderman-blaster-make up

PAINTERS:					
Brush	4 57	.10	.20	.10	.04
Spray	6 13	.11	.07	.01	01

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
POWER EQUIPMENT OPERATORS:					
Group I	$5.69	.15	.10		.01
Group II	5.89	.15	.10		01
Group III	6.47	15	10		.01
Group IV	6.49	.15	.10		.01
Group V	6.49	.15	10		.01
Group VI	6.64	.15	.10		.01
Group VII	6.69	.15	.10		.01
Group VIII	6.84	.15	.10		.01
Group IX	7.34	.15	10		.01
Group X	8.14	.15	.10		.01

POWER EQUIPMENT OPERATORS CLASSIFICATION DEFINITIONS

GROUP I - Concrete paving curing machine
GROUP II - Belt type conveyors (material & concrete); broom (self-propelled); fork lift; grease truck operator; head oiler; hydro lift; tractor (under 50 drawbar HP with or without attachment); Industrial locomotive brake-man; front end loader (2 CY or less); fireman; oiler screedman; roller (pull type); mulching machine ; roller (self-propelled)
GROUP III - Concrete paving form grader; concrete paving gang vibrator; concrete paving joint or saw machine; concrete paving sub grader; tractor with backhoe attachment; subgrade or base finisher; power plant (electric\general or welding machine)
GROUP IV -Bulldozer (including self-propelled roller, with dozer attachment); batch or continous mix plant (concrete soil-cement, or asphalt); roller (steel wheel); front end loader (2 CY thru 10 CY); scraper operator; motor grader
GROUP V - Asphalt distributor; asphalt paving or laydown machine; asphalt retort heater; mixer, heavy duty, asphalt or soil cement; trenching; clam type shaftmucker; backhoe, clamshell, dragline, gradall, shovel (under 3/4 cy); elevating grader or belt loader; cranes (crawler or mobile) under 20 ton; air compressor (300 CFM & over); crushing screening and washing plants; drilling machine (cable core or rotary); mixer, concrete (1 cy and less); pump (6" intake or over); winch truck; hoist (1 drum); industrial locomotive motorman; lumber stacker; tractor (50 drawbar HP or over)

POWER EQUIPMENT OPERATORS CLASSIFICATION DEFINITION (CONT'D)

GROUP VI - Concrete paver mixer; host (2 drum and over); side-boom; traveling crane; piledriver; backhoe, clamshell, dragline, gradall, shovel (3/4 cy to 3 cy); cranes (crawler or mobile) 20 ton to 40 ton; front end loader (over 10 cy); mixer, concrete (over 1 cy); mechanic and/or welder)

GROUP VII - Concrete slip-form paving machine; concrete paving finishing machine; concrete paving longitudinal float; gunite machine; refrigerator; jumbo former drilling stage; slusher; concrete paving spreader; pumpcrete machine; grout pump operator

GROUP VIII - Mine hoist; bulldozer (multiple units); scraper (multiple units); mucking machine; backhoe, clamshell, dragline, gradall, shovel (over 3 cy); cranes (crawler or mobile) over 40 tons

GROUP IX--Belt loader (CMI types) overator; derrick, cableway

GROUP X - Pipemobile operator; mole operator

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
TRUCK DRIVERS:					
Distributor (asphalt)	$4.65	.26			
Dump or batch truck:					
Under 8 cy	4.25	.26			
8 cy and under 16 cy	4.45	.26			
Diesel-powered transport	4.85	.26			
Flatbed, 1-1/2 ton	4.25	.26			
Flatbed, over 1-1/2 ton	4.45	.26			
Lowboy, heavy equipment	4.85	.26			
Lowboy, light equipment	4.65	.26			
Off-highway hauler	4.65	.26			
Pick-up truck 3/4 ton or under	4.25	.26			
Tank Truck:					
3,001 gal. to 6,000 gal.	4.45	.26			
6,001 gal and over	4.65	.26			
Trailer or semi-trailer dump	4.65	.26			
Transit mix	4.65	.26			
Warehousemen	4.25	.26			

LINE CONSTRUCTION AREA & ZONE DEFINITIONS

Bernalillo, Colfax, Catron, Chaves, Curry, DeBaca, Grant, Guadalupe, Harding, Lincoln, Los Alamos, McKinley, Mora, Quay, Rio Arriba, Roosevelt, Sandoval, San Juan, San Miguel, Santa Fe, Sierra, Socorro, Taos, Torrance, Union, Valencia and White Sands Missile Range and that portion of Fort Bliss in New Mexico

LINE CONSTRUCTION AREA AND ZONE DEFINITIONS (CONT'D)

ZONE I - Cities and Towns Basing Points - Miles from Main Post Offices

Albuquerque - 15 miles
Santa Fe - 10 miles
Las Vegas - 8 miles
Farmington - 6 miles
Raton - 6 miles
Tucumcari - 6 miles
Aztec - 6 miles
Roswell - 12 miles
Ruidoso - 12 miles
Portales - 12 miles
Carrisoso - 12 miles
Clovis - 12 miles
Gallup - 12 miles
*Pojoaque - 2 miles

*All areas adjacent to Pojoaque that are over two miles distant from the main post office in that town will be zoned out of Santa Fe.

ZONE II - Extending up to 20 miles beyond zone 1

ZONE III - Extending up to 30 miles beyond zone 1

ZONE IV - Anything beyond 30 miles from zone 1

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr
LINE CONSTRUCTION:					
ZONE I					
Linemen - Technicians	$12.15	.60	3%+.70		1/2%
Cable splicers	13.37	.60	3%+.70		1/2%
Equipment Operator (includes Helicopter op.)	11.54	.60	3%+.70		1/2%
Equipment mechanic (includes Helicopter mechanic	10.57	.60	3%+.70		1/2%
Powderman	10.57	.60	3%+.70		1/2%
Groundman & Jackhammer Oprs	8.63	.60	3%+.70		1/2%
ZONE II					
Linemen - Technicians	13.00	.60	3%+.70		1/2%
Cable splicers	14.22	.60	3%+.70		1/2%
Equipment operator (includes Helicopter op.)	12.39	.60	3%+.70		1/2%
Equipment operator (includes Helicopter mechanic	11.42	.60	3%+.70		1/2%
Powderman	11.42	.60	3%+.70		1/2%
Groundman & Jackhammer oprs	9.48	.60	3%+.70		1/2%

LINE CONSTRUCTION (CONT'D)	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
ZONE III					
Linemen - Technicians	$13.73	.60	3%+.70		1/2%
Cable splicers	14 95	.60	3%+.70		1/2%
Equipment Operator (includes Helicopter opr)	13.73	.60	3%+.70		1/2%
Equipment mechanic (includes Helicopter mechanic	12.15	.60	3%+ 70		1/2%
Powderman	12.15	.60	3%+.70		1/2%
Groundman & Jackhammer op	10.21	.60	3%+.70		1/2%
ZONE IV					
Linemen - Technician	14.58	.60	3%+.70		1/2%
Cable splicers	15.80	.60	3%+ 70		1/2%
Equipment operator (includes Helicopter opr)	13.97	.60	3%+.70		1/2%
Equipment mechanic (includes Helicopter mechanic	13 00	.60	3%+.70		1/2%
Powderman	13.00	.60	3%+.70		1/2%
Groundman & Jackhammer op.	11.06	.60	3%+.70		1/2%
Los Alamos County-Use Zone III Rates.					

LINE CONSTRUCTION AREA & ZONE DEFINITION

Applies to switching stations and substations adjacent to power plants in zone 1 and zone 2 in Luna, Dona Ana, Otero and Hidalgo Counties, exclusive of White Sands Missile Range and that portion of Fort Bliss in New Mexico.

ZONE I - The area within 25 miles radius from the downtown Post Office of El Paso, Texa. Fort Bliss and Biggs Field; the area within a five mile radius of any city, town or municipality within which an employer establishes or maintains his place of business; the area with a ten mile radius from the post office in Las Cruces, New Mexico, and within a five mile radius from the post office in Alamogordo, New Mexico.

ZON

ZONE II

All other areas of the jurisdiction except those specified in zone 1

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
ZONE I					
Linemen - technicians	$ 9.60	.30	3%		1/2%
Cable splicers	9.85	.30	3%		1/2%
Equipment operator (includes Helicopter op.)	9 12	.30	3%		1/2%
Equipment mechanic (includes helicopter mechanic)	8.40	.30	3%		1/2%
Powderman	8.40	.30	3%		1/2%
Groundman & Jackhammer op.	6 82	.30	3%		1/2%
ZONE II					
Linemen - technicians	11.05	.30	3%		1/2%
Cable splicers	11.30	.30	3%		1/2%
Equipment operator (includes Helicopter op.)	10.50	.30	3%		1/2%
Equipment operator (includes Helicopter mechanic)	9.67	.30	3%		1/2%
Powderman	9.67	.30	3%		1/2%
Groundman & Jackhammer op	7.85	.30	3%		1/2%

LINE CONSTRUCTION AREA AND ZONE DEFINITION

Applies to switching stations adjacent to power plants in Eddy and Lea Counties; the following zones listed shall be designated from main Post Office of Artesia, Carlsbad, Hobbs and Lovington.

ZONE A - 0 - 12 miles
ZONE B - 12 - 22 miles
ZONE C - 22 - 40 miles
ZONE D - 40 miles and beyond

LINE CONSTRUCTION					
ZONE A					
Linemen-technician	11.75	.60	3%		1/2%
Cable splicers	12.10	60	3%		1/2%
Equipment op. (includes Helicopter operator)	11.16	.60	3%		1/2%
Equipment mechanic (includes helicopter mechanic and Powderman	10 28	60	3%		1/2%
Groundman & Jackhammer op	8.34	.60	3%		1/2%

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
LINE CONSTRUCTION (cont'd)					
ZONE B					
Linemen-technician	$12.10	60	3%		1/2%
Cable splicers	12 45	.60	3%		1/2%
Equipment op (includes helicopter operator)	11 51	60	3%		1/2%
Equipment mechanic (includes helicopter mechanic & Powderman	10 63	.60	3%		1/2%
Groundman & jackhammer op	8 69	.60	3%		1/2%
ZONE C					
Linemen-technician	12.25	.60	3%		1/2%
Cable splicers	12.60	60	3%		1/2%
Equipment op. (includes helicopter operator)	11.66	.60	3%		1/2%
Equipment mechnaic (includes helicopter mechanic & Powderman	10.78	.60	3%		1/2%
Groundman & Jackhammer op	8.84	.60	3%		1/2%
ZONE D					
Linemen-technician	12.50	.60	3%		1/2%
Cable splicers	12.85	.60	3%		1/2%
Equipment op. (includes helicopter operator)	11.91	.60	3%		1/2%
Equipment mechanic (includes helicopter mechanic & Powderman	11.13	.60	3%		1/2%
LINE CONSTRUCTION-UTILITY LINE WORK FOR ELECTRIC AND TELEPHONE UTILITIES REA CO-OPS, RAILROADS AND MUNICIPALITIES:					
Linemen-technician	11.40	.60	3%+.70		1/2%
Cable splicers	12.21	.60	3%+.70		1/2%
Equipment op. (includes helicopter operator)	10.84	.60	3%+.70		1/2%
Equipment mechanic (includes helicopter mechanic) & Powderman	9.94	.60	3%+.70		1/2%
Groundman & Jackhammerman operator	8.15	.60	3%+.70		1/2%

"Unlisted classifications needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(ii)."

SUPERSEDEAS DECISION

STATE: Utah COUNTIES: Statewide
DECISION NUMBER: UT79-5135 DATE: Date of Publication
Supersedes Decision No. UT78-5128 dated October 6, 1978, in 43 FR 46480
DESCRIPTION OF WORK: Building Projects (does not include single family homes and apartments up to and including 4 stories), heavy and highway projects.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr
ASBESTOS WORKERS	$12.61	.77	$1.37		
BOILERMAKERS	13.41	1.175	1.25	1.00	.04
BRICKLAYERS	12.00	.60	.62		.10
CARPENTERS:					
Building Construction:					
Carpenters	11.25	.55	.65		.03
Saw Operators; Carpenters handling creosote materials	11.50	.55	.65		.03
Millwrights	12.10	.55	.65		.03
Piledrivermen	13.83	.55	.65		.03
Heavy and Highway Construction:					
Zone 1: Area 0 to 40 road miles from the following Cities: Brigham City, Cedar City, Kanab, Logan, Moab, Monticello, Ogden, Price, Provo, Richfield, St. George, Salt Lake City, Vernal:					
Carpenters	11.25	.55	.65		.03
Saw operators; Carpenters handling creosote materials	11.50	.55	.65		.03
Millwrights	12.10	.55	.65		.03
Piledrivermen	13.83	.55	.65		.03
Zone 2: Area 40 to 60 road miles from the Cities listed in Zone 1:					
Carpenters	12.25	.55	.65		.03
Saw operators; Carpenters handling creosote materials	12.50	.55	.65		.03
Millwrights	12.10	.55	.65		.03
Piledrivermen	13.83	.55	.65		.03

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
CARPENTERS: (Cont'd)					
Zone 3: Area over 60 road miles from the Cities listed in Zone 1:					
Carpenters	$13.25	.55	.65		.03
Saw Operators; Carpenters handling creosote materials	13.50	.55	.65		.03
Millwrights	12.10	.55	.65		.03
Piledrivermen	13.83	.55	.65		.03
CEMENT MASONS:					
Building Construction:					
Cement Masons	9.99	.55	.65		
Machine Operator; Mastic Floor Materials	10.17	.55	.65		
Swing Scaffold; Swing Stage	10.29	.55	.65		
Heavy and Highway Construction:					
Zone 1: Area 0 to 40 road miles from the following Cities: Brigham City, Cedar City, Kanab, Logan, Moab, Monticello, Ogden, Price, Provo, Richfield, St. George, Salt Lake City, Vernal:					
Cement Masons	9.99	.55	.65		
Machine Operator; Mastic Floor Materials	10.12	.55	.65		
Swing Scaffold, Swing Stage	10.24	.55	.65		
Zone 2: Area 40-60 road miles from the Cities listed in Zone 1:					
Cement Masons	10.99	.55	.65		
Machine Operator; Mastic Floor Materials	11.12	.55	.65		
Swing Scaffold; Swing Stage	11.24	.55	.65		

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
CEMENT MASONS: (Cont'd)					
Zone 3: Area over 60 road miles from the Cities listed in Zone 1:					
Cement Masons	$11.99	.55	.65		
Machine Operator; Mastic Floor Materials	12.12	.55	.65		
Swing Scaffold; Swing Stage	12.24	.55	.65		
DRYWALL INSTALLERS:					
Taping, finishing and texturing (hand or machine)	11.64	.51	.30		.03
ELECTRICIANS:					
North section of Utah - Box Elder, Cache, Davis County (north of 41st Parallel), Morgan, Rich, Weber Counties:					
Zone 1: That area 10 miles on either side of Interstate Hwy. #15, commencing on the south at the 41st Parallel in Davis County, continuing north to Highway #91 - Interstate 15 junction south of Brigham City; at this point go east and north through Logan and continue north to the 42nd Parallel in Cache County on Hwy. #91:					
Electricians; Technicians	12.50	.75	3%+.75		8/10%
Cable Splicers	12.75	.75	3%+.75		8/10%

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
ELECTRICIANS: (Cont'd)					
Zone 2: That area not included in Zone 1 that lies east of 112°20' longitude in Box Elder County and that area lying west of 111°35', north of the 41st Parallel and south of the 40th Parallel in Cache, Morgan, Weber Counties:					
Electricians;					
Technicians	$13.00	.75	3%+.75		8/10%
Cable Splicers	13.25	.75	3%+.75		8/10%
Zone 3: That area lying east of 111°35' longitude and north of the 41st Parallel in Cache, Morgan, Rich, Weber Counties; also the area in Box Elder Co. lying west of 112°20' longitude and north and east of Utah Hwy. #83:					
Electricians;					
Technicians	13.50	.75	3%+.75		8/10%
Cable Splicers	13.75	.75	3%+.75		8/10%
Zone 3-A: That area from a point 2 miles north of Center Street in Smithfield to the Utah-Idaho State Line and 10 miles east and west from Highway #91:					
Electricians;					
Technicians	13.50	.75	3%+.75		8/10%
Cable Splicers	13.75	.75	3%+.75		8/10%

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
ELECTRICIANS: (Cont'd)					
North Section of Utah (Cont'd):					
Zone 4: All other area west of Zones 3 and 3-A in Box Elder County:					
Electricians;					
Technicians	$15.75	.75	3%+.75		8/10%
Cable Splicers	16.00	.75	3%+.75		8/10%
In Zones 2, 3, and 3-A, on any job or project not exceeding $200,000 electrical, labor and material including, Zone 1 rates shall apply.					
South section of Utah (Remaining Counties):					
Zone 1: Davis County (south of 41st Parallel); Salt Lake County; Tooele County (northeast corner beginning at a point where the township line between Township 3 south and Township 4 south, Salt Lake Base Meridian, intersects the east boundary line of Tooele County and thence west along said township line to the southwest corner of Section 32, Township 3 south, Range 4 west, Salt Lake Base Meridian, thence north to the northwest corner of Section 17 of Township 3 south, Range 4 west, thence west to longitude 112.5°, thence north along the line of longitude 112.5° to the north line of Tooele County); Utah County (north of 40th Parallel):					

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr.
ELECTRICIANS: (cont'd)					
South Section of Utah (Remaining Cos.) (Cont'd):					
Area A: Ten miles either direction (east or west) from Interstate Hwy. #15, bounded on the north by the 41st Parallel and on the south by the 40th Parallel:					
Electricians;					
Technicians	$12.50	.75	3%+.75		8/10%
Cable Splicers	13.00	.75	3%+.75		8/10%
Area B: The balance of Zone 1 that lies in Davis Salt Lake, Utah Counties:					
Electricians;					
Technicians	13.25	.75	3%+.75		8/10%
Cable Splicers	13.75	.75	3%+.75		8/10%
Area C: That portion of the remainder of Zone 1 that lies in Tooele Co.:					
Electricians;					
Technicians	14.00	.75	3%+.75		8/10%
Cable Splicers	14.50	.75	3%+.75		8/10%
Zone 2: Remainder of Cos. and all portions of Cos. not included in Zone 1 of the south section of Utah:					
Electricians; Technicians	16.00	.75	3%+.75		8/10%
Cable Splicers	16.50	.75	3%+.75		8/10%
ELEVATOR CONSTRUCTORS	11.02	.895	.69	a	.03
ELEVATOR CONSTRUCTORS' HELPERS	7.71	.895	.69	a	.03
ELEVATOR CONSTRUCTORS' HELPERS (PROB.)	5.51				

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
GLAZIERS:					
Iron and Washington Cos.	$14.17	.65	.40		.05
Remaining Counties	9.51	.51	.40	b+1.12	
IRONWORKERS:					
Fence Erectors; Ornamental; Reinforcing; Structural	12.00	.75	1.35		.05
LATHERS	10.32	.55	.50		.01
LINE CONSTRUCTION WORKERS:					
Groundman	8.94	.45	3%		1/4%
Line Equipment Serviceman	10.65	.45	3%		1/4%
Line Equipment Mechanic:					
Base Shop	10.65	.45	3%		1/4%
Right-of-way	11.37	.45	3%		1/4%
Line Equipment Operators	10.82	.45	3%		1/4%
Linemen	12.00	.45	3%		1/4%
Cable Splicers	13.20	.45	3%		1/4%
MARBLE SETTERS	11.57	.50	.45	.60	.02
MASON TENDERS	8.72	.40	.35		
PAINTERS:					
Box Elder, Cache, Rich Counties; and the following Counties north of an east-west line from the north boundary of Farmington: Davis, Morgan, Summit, Tooele and Weber Counties					
Brush; Roller	10.22	.51	.50		.05
Spray; Sandblast; Steeplejack; Brush, steel and bridge; Brush (swing stage)	10.47	.51	.50		.05
Spray (swing stage); Sandblaster (swing stage); Spray, steel and bridge	10.67	.51	.50		.05
Remaining part of State:					
Brush; Roller	10.70	.51	.30		.02
Brush (swing stage); Brush (steel and bridge); Spray, Sandblaster; Steeplejack	11.00	.51	.30		.02

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
PAINTERS: (Cont'd)					
Spray (swing stage); Spray (steel and bridge); Sandblaster (swing stage)	$11.25	.51	.30		.02
Wallcovering Hanger	10.95	.51	.30		.02
PLASTERERS' TENDERS	8.80	.40	.35		
PLASTERERS	10.40	.55	.65		.01
PLUMBERS; Pipefitters	12.20	.81	1.10		.06
REFRIGERATION and AIR CONDITIONING	12.20	.81	1.10		.06
ROOFERS	10.94	.57	.35		.05
SHEET METAL WORKERS	12.30	.75	.88		.12
SOFT FLOOR LAYERS	9.98	.51	.27		
SPRINKLER FITTERS	12.29	.75	1.05		.08
TERRAZZO WORKERS and TILE LAYERS	11.57	.50	.45	.60	.02
WELDER: Receive rate prescribed for craft performing operation to which Welding is incidental.					

FOOTNOTES:

a. Employer contributes 8% of basic hourly rate for 5 years' service and 6% of basic hourly rate for 6 months' to 5 years' service as Vacation Pay Credit. 7 Paid Holidays: A through G.

b. Employees who have been employed for a period of 1 year shall have 3 weeks' vacation with pay. Should a holiday listed below occur within an employee's vacation period he shall be allotted an additional day's vacation. 8 Paid Holidays: A through F and President's Day and Pioneer Day.

PAID HOLIDAYS:
A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day; G-Friday after Thanksgiving

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
LABORERS Building Construction					
Group 1	$7.77	.50	.35		.04
Group 2	7.90	.50	.35		.04
Group 3	8.02	.50	.35		.04
Group 4	8.27	.50	.35		.04
Group 5	8.77	.50	.35		.04

LABORERS
Building Construction

Group 1: General Laborer

Group 2: Asphalt Raker; Sandblast Pot Tender; Gunite Nozzleman; Concrete Pump (Head Hoseman); Signalman and Dumpman on concrete construction

Group 3: Work of all types using cutting torch; Operators of gasoline, electric or pneumatic tools (e.g., Compressor, Compactors, Jackhammer, Vibrator, Concrete Saw, Chain Saw and Concrete Cutting Torch); Pipelayer; Laser Instrument Operator; Refinery Tank and Vessel Cleaner; Sandblaster

Group 4: Air Track and similar Drills

Group 5: Powderman

Unlisted classifications needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

LABORERS* Heavy and Highway Construction	Basic Hourly Rates	Basic Hourly Rates	Fringe Benefits Payments			
			H & W	Pensions	Vacation	Education and/or Appr Tr
	AREA 1	AREA 2				
Group 1	$ 8.02	$9.52	.50	.35	.25	.04
Group 2	8.15	9 65	.50	.35	.25	.04
Group 3	8.27	9.77	.50	.35	.25	.04
Group 4	8.52	10.02	.50	.35	.25	.04
Group 5	9.02	10.52	.50	.35	.25	.04
Tunnel and Shaft Work						
Group 1	8.17	9.67	.50	.35	.25	.04
Group 2	8.27	9.77	.50	.35	.25	.04
Group 3	8.47	9.97	.50	.35	.25	.04
Group 4	8.92	10.42	.50	.35	.25	.04

*SEE AREA DEFINITION following TRUCK DRIVERS' Classifications.

LABORERS
Heavy and Highway Construction

Group 1: General Laborers

Group 2: Asphalt Raker; Sandblast Pot Tender; Gunite Nozzleman; Concrete Pump Head Hoseman; Signalman and Dumpman on concrete construction

Groip 3: Work of all types using cutting torch; Operators of gasoline, electric or pneumatic tools (e.g., Compressor, Compactors, Jackhammer, Vibrator, Concrete Saw, Chain Saw and Concrete Cutting Torch); Pipelayer; Laser Instrument Operator; Refinery Tank and Vessel Cleaner; Sandblaster

Group 4: Air Tank and similar Drills

Group 5: Powderman

Tunnel and Shaft Work

Group 1: Underground Laborers

Group 2: Brakeman; Chucktender; Dumpman; Powderman Tender; Puddler; Nipper; Tapman; Vibrator; Screedmen

Group 3: Cutting Machine Operator; Drill Doctor; Finisher; Gunite Gunman; Miner; Powder Makeup Man; Spader and Tugger; Steelman; Gunite Groundman; Gunite Nozzleman; Gunite Rodman; Concrete Head Hoseman

Group 4: Shifter

Unlisted classifications needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards contract clauses (29 CFR, 5.5 (a)(1)(ii)).

POWER EQUIPMENT OPERATORS: Building Construction	Basic Hourly Rates	Basic Hourly Rates	Fringe Benefits Payments			
			H & W	Pensions	Vacation	Education and/or Appr Tr.
	AREA 1	AREA 2				
Group 1	$ 8.06	$9.06	.90	$1.565	.75	.05
Group 2	8.45	9.45	.90	1.565	.75	.05
Group 3	8.65	9.65	.90	1.565	.75	.05
Group 4	8.76	9.76	.90	1.565	.75	.05
Group 5	8.76	9.76	.90	1.565	.75	.05
Group 6	9.27	10.27	.90	1.565	.75	.05
Group 7	9.44	10.44	.90	1.565	.75	.05
Group 7-A	9.56	10.56	.90	1.565	.75	.05
Group 8	9.89	10.89	.90	1.565	.75	.05
Group 8-A	9.96	10.96	.90	1.565	.75	.05
Group 9	10.12	11.12	.90	1.565	.75	.05
Group 10	10.30	11.30	.90	1.565	.75	.05
Group 11	10.79	11.79	.90	1.565	.75	.05
Group 11-A	11.75	12.75	.90	1.565	.75	.05
Group 11-B	12.24	13.24	.90	1.565	.75	.05
Group 12	12.52	13.52	.90	1.565	.75	.05

*SEE AREA DEFINITIONS - following TRUCK DRIVERS' Classifications.

POWER EQUIPMENT OPERATORS
Building Construction

Group 1: Assistant to Engineer; Elevator Operator; Hydraulic Monitor; Material Loader or Conveyor Operator

Group 2: Air Compressor Operator; Concrete Mixer Operator (skip-type); Concrete Pump or Pumpcrete Gun Operator; Generator Operator (100 KW or over); Mixer Box Operator or similar (concrete or asphalt plant continuous mix); Pump Operator; Truck Crane Oiler

Group 3: Front End Loader (up to and including 1 cu. yd. struck M.R.C.); Hoist Operator - 1 drum; Slip Form Pumps

Group 4: Heavy Duty Repairman and Welder

Group 5: Air Compressor Operator (2 or more compressors); Signalman; Small Rubber-tired Tractor; Small self-propelled pneumatic Rollers; Towermobile Operator; Welding Machine (2 or more); Concrete Conveyor, building site

Group 6: A-Frame Truck and Tugger Hoist; Fork Lift (construction jobsite); Kolman Loader and similar; Loader Operator (over 1 cu. yd. to and including 2 cu. yds. struck M.R.C.); McGinnis Internal Full Slab Vibrator (on airports, highways, canals and warehouses); Mixermobile Operator; Ross Carrier or similar type; Small rubber-tired tractor (with attachments, including Backhoe); Small rubber-tired Trenching Machine; Small Tractor with Boom; Gradesetter

Group 7: Bridge Crane; Concrete Mixer Operator (paving or batch plant); Drilling Machine Operator (well or diamond); Dual Drum Mixers; Hoist Operator - 2 drums; Lull High-lift (40 ft. or similar); Roller Operator or self-propelled Compactors; Tractor Operator (Sheep's Foot and compacting equipment); Trenching Machine; Concrete Conveyor or Concrete Pump, Truck or equipment mounted (boom length to apply); Self-propelled Compactor with or without Dozer

Group 7-A: Tractor Operator (Bulldozer or tractor-drawn Scraper or drag-type Shovel or boom attachment, up to and including D-7 or similar)

POWER EQUIPMENT OPERATORS (Cont'd)
Building Construction

Group 8: Chicago Boom (including Stiff Leg and Sheer Pole); Concrete Batch Plant (multiple units); Loader Operator (over 2 cu. yds. up to and including 5 cu. yds. struck M.R.C.); Self-propelled Boom type Lifting Device (center mount) (10 ton capacity or less M.R.C.)

Group 8-A: Heavy Duty Repairman or Welder; Tractor Operator (Bulldozer or tractor-drawn Scraper or drag-type Shovel or Boom attachment, larger than D-7 or similar)

Group 9: Motor Patrol

Group 10: Loader Operator (over 5 cu. yds. up to and including 12 cu. yds. struck M.R.C.); Universal Equipment Operator (Shovel, Backhoe, Dragline, Derrick, Derrick Barge, Clamshell, Crane, Grade-all, etc.) (up to and including 5 cu. yds. struck M.R.C.); Self-propelled Boom type Lifting Device (center mount); Tower Crane (Linden type or similar designs and capacity)

Group 11: Remote Controlled (over 12 cu. yds. struck M.R.C. up to 18 cu. yds. M.R.C.)

Group 11-A: Loader Operator (over 12 cu. yds. struck M.R.C. up to 18 cu. yds. M.R.C.)

Group 11-B: Operator of Helicopter (when used in erection work)

Group 12: Cranes over 125 tons

Unlisted classification needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards contract clauses (29 CFR, 5.5(a)(1)(ii)).

POWER EQUIPMENT OPERATORS* Heavy and Highway Construction	Basic Hourly Rates AREA 1	Basic Hourly Rates AREA 2	Fringe Benefits Payments H & W	Pensions	Vacation	Education and/or Appr Tr
Group 1	$10.26	$11.76	$1.28	$1.90	$1.00	.14
Group 2	10.61	12.11	1.28	1.90	1.00	.14
Group 3	10.79	12.29	1.28	1.90	1.00	.14
Group 4	10.90	12.40	1.28	1.90	1.00	.14
Group 5	11.36	12.86	1.28	1.90	1.00	.14
Group 6	11.51	13.01	1.28	1.90	1.00	.14
Group 6-A	11.62	13.12	1.28	1.90	1.00	.14
Group 7	11.92	13.42	1.28	1.90	1.00	.14
Group 7-A	11.98	13.48	1.28	1.90	1.00	.14
Group 8	12.04	13.54	1.28	1.90	1.00	.14
Group 9	12.20	13.70	1.28	1.90	1.00	.14
Group 10	12.64	14.14	1.28	1.90	1.00	.14
Group 10-A	13.60	15.10	1.28	1.90	1.00	.14
Group 10-B	14.05	15.55	1.28	1.90	1.00	.14
Group 11	14.21	15.71	1.28	1.90	1.00	.14

*SEE AREA DEFINITION - following TRUCK DRIVERS' Classifications.

Underground and Shaft Work:
Underground Work: Employees working underground shall receive $.30 per hour in addition to their straight-time hourly wage rate.
Shaft Work: Employees working within Shafts, Stopes and Raises shall receive $.50 per hour in addition to their straight-time hourly rates.

POWER EQUIPMENT OPERATORS
Heavy and Highway Construction

Group 1: Assistant to Engineer; Brakeman - Locomotive; Elevator Operator; Fireman; Asphalt Plant Fireman; Hydraulic Monitor; Material Loader or Conveyor Operator; Partsman - field; Repairman Tender - field; Chainman; Rodman

Group 2: Boxman, asphalt plant; Air Compressor Operator; Concrete Mixer Operator (skip type); Concrete Pump or Pumpcrete Gun Operator; Engineer, Dinky Operator; Generator Operator (100 KW or over); Mixer Box Operator or similar (concrete or asphalt plant continuous mix); Pump Operator; Screedman; Self-propelled, automatically applied concrete curing machine (on streets, highways, airports and canals); Truck Crane Oiler (Assistant to Engineer)

Group 3: Ballast Jack Tamper; Ballast Regulator; Ballast Tamper - multiple purpose; Front End Loader (up to and including 1 cu. yd. struck M.R.C.); Hoist Operator - 1 drum; Line Master; Slip Form Pumps

Group 4: Batch Operator (asphalt plant); Air Compressor Operator (2 or more compressors); Concrete Conveyor, building site; Lube and Service Engineer (mobile and grease rack); Motorman; Pavement Breaker Operator (Emsco and similar type); Shuttlecar; Signalman; Slurry Seal Machine or similar; Small rubber-tired Tractor; Small self-propelled pneumatic Rollers; Towermobile Operator; Welding Machine (2 or more)

Group 5: A-Frame Truck and Tugger Hoist; Concrete Saws (self-propelled unit on streets, highways, airports and canals); Engineer - Locomotive; Forklift (construction jobsite); Gradesetter; Kolman Loader (and similar); McGinnis Internal Full Slab Vibrator (on airports, highways, canals and warehouses); Mixermobile Operator; Pipe Bending Machine Operator; Pipe Cleaning Machine; Pipe Wrapping Machine; Power Jumbo Operator (setting slip forms, etc., in tunnels); Road Mixing Machine Operator; Ross Carrier or similar type; Small rubber-tired Trenching Machine; Small rubber-tired tractor (with attachments, including Backhoe); Small Tractor with boom; Surface Heater (self-propelled); Loader Operator (over 1 cu. yd. up to and including 2 cu. yds. struck m.R.C.)

POWER EQUIPMENT OPERATORS (Cont'd)
Heavy and Highway Construction

Group 6: Bridge Crane; Chip Box Spreader (Flaherty type and similar); Concrete Conveyor or Concrete Pump, truck or equipment mounted, boom length to apply; Concrete Mixer Operator (paving or batch plant); Deck Engineer (marine); Drilling Machine Operator (well or diamond); Drilling and Boring Machinery, Horizontal and vertical (not to apply to waterliners, wagon drills, or jack hammers); Dual Drum Mixers; Elevating Grader Operator; Fuller Kenyon Pump and similar types; Heavy Duty Rotary Drill Rigs (such as Quarry Master, Joy Drills or equal); Hoist Operator - 2 drums; Lull High-lift (40 ft. or similar); Mechanical Burm, Curb and/or Curb and Gutter Machine, concrete or asphalt; Mechanical Finisher Operator (asphalt or concrete); Mine or Shaft Hoist; No-Joint Pipe Laying Machine; Pavement Breaker, Pavement Breaker with Compressor combination; Pavement Breaker, truck mounted, Compressor combination; Refrigeration Plant; Roller Operator or self-propelled Compactor; Self-propelled Compactor (with multiple-propulsion power units); Self-propelled Pipeline Wrapping Machine (Perault, CRC, or similar types); Self-propelled Compactor with or without Dozer; Slusher Operator; Tractor Operator (Sheep's Foot and Compacting Equipment); Tractor Compressor Drill Combination; Trenching Machine

Group 6-A: Side Boom Operator; Tractor Operator (Bulldozer or Tractor-drawn Scraper or Drag-type Shovel or Boom attachment, up to and including D-7 or similar); Instrumentman

Group 7: Asphalt Plant Engineer; Chicago Boom (including Stiff Leg and Sheer Pole); Combination Backhoe and Loader (3/4 cu. yds. or over M.R.C.); Combination Slusher and Motor Operator; Concrete Batch Plant (multiple units); Domor Loader and Adams Elegrader; Engineer, Crushing Plant; Euclid Loader and similar types; Loader Operator (over 2 cu. yds. up to and including 5 cu. yds. struck M.R.C.); Koehring Skooper (or similar)(up to 5 cu. yds. struck M.R.C.); Mechanical Trench Shield; Mucking Machine Operator Rubber-tired Scrapers (under 35 cu. yds. struck M.R.C.); Saurman type Dragline (under 5 cu. yds. struck M.R.C.); Self-propelled Boom-type Lifting device (center mount) (10-ton capacity or less M.R.C.); Self-propelled Elevating Grade Plane; Soil Stabilizer (P & H or equal); Tri-Batch Paver; Tunnel Mole (or similar)

POWER EQUIPMENT OPERATORS (Cont'd)
Heavy and Highway Construction

Group 7-A: Heavy Duty Repairman or Welder; Tractor Operator (Bulldozer or Tractor-drawn Scraper or Drag-type Shovel or boom attachment, larger than D-7 or similar)

Group 8: Combination Mixer and Compressor (gunite); Highline Cableway Signalman; Motor Patrol; Tower Crane (Linden type or similar designs and capacity)

Group 9: DW-10, 20, etc. (tandem scrapers); Loader Operator (over 5 cu. yds. up to and including 12 cu. yds. struck M.R.C.); Highline Cableway Operator; Lift Slab Machine (Vagtborg and similar types); Locomotive (over 100 tons) (single or multiple units); Pre-stress Wire Wrapping Machine; Saurman-type Dragline (5 cu. yds. and over struck M.R.C.); Self-propelled boom-type lifting device (center mount)(over 10 tons); Tractor (Tandem Scrapers); Universal Equipment Operator (Shovel, Backhoe, Dragline, Derrick, Derrick Barge, Clamshell, Crane, Grade-all, etc.)(up to and including 5 cu. yds. struck M.R.C.)

Group 10: Automatic Concrete Slip Form Paver; Koehring Skooper (or similar) (5 cu. yds. and over struck M.R.C.); Multiple-propulsion Power Unit Earthmovers (up to and including 75 cu. yds. struck M.R.C.); Power Equipment with shovel-type controls (over 5 cu. yds. up to and including 7 cu. yds. struck M.R.C.); Remote-controlled Cranes and Derricks; Rubber-tired Scrapers (35 cu. yds. and over struck M.R.C.); Slip Form Paver (concrete or asphalt); Sub-grader (automatic sub-grader - fine grader, CMI or similar); Tandem Tractors; Tower Cranes Mobile

Group 10-A: Loader Operator (over 12 cu. yds. struck M.R.C. up to 18 cu. yds. M.R.C.); Multi-purpose Earthmoving Machines (2 or more scrapers)(over 75 cu. yds. struck M.R.C); Power Shovels and Draglines (over 7 cu. yds. struck M.R.C)

Group 10-B: Operator of Helicopter (when used in erection work); Loader (18 cu. yds. and over)

Group 11: Cranes over 125 tons

Unlisted classification needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards contract clauses (29 CFR, 5.5(a)(i)(ii)).

POWER EQUIPMENT OPERATORS: Steel Erection	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr Tr
Group 1	$11.19	$1.28	$1.90	$1.00	.14
Group 2	11.60	1.28	1.90	1.00	.14
Group 3	12.72	1.28	1.90	1.00	.14
Group 4	12.88	1.28	1.90	1.00	.14
Group 4-A	13.21	1.28	1.90	1.00	.14
Group 5	13.76	1.28	1.90	1.00	.14
Group 6	14.23	1.28	1.90	1.00	.14
Group 6-A	14.88	1.28	1.90	1.00	.14
Group 7	16.03	1.28	1.90	1.00	.14
Piledriving					
Group 1-A	10.68	1.28	1.90	1.00	.14
Group 1-B	11.05	1.28	1.90	1.00	.14
Group 1-C	11.28	1.28	1.90	1.00	.14
Group 2-A	11.28	1.28	1.90	1.00	.14
Group 2-B	12.10	1.28	1.90	1.00	.14
Group 3	12.43	1.28	1.90	1.00	.14
Group 3-A	12.90	1.28	1.90	1.00	.14
Group 4	13.50	1.28	1.90	1.00	.14
Group 5	13.69	1.28	1.90	1.00	.14
Group 6	14.93	1.28	1.90	1.00	.14

Underground and Shaft Work:

Underground Work: Employees working underground shall receive $.30 per hour in addition to their straight-time hourly rate.

Shaft Work: Employees working within Shafts, Stopes and Raises shall receive $.50 per hour in addition to their straight-time hourly rate.

POWER EQUIPMENT OPERATORS
Steel Erection

Group 1: Assistant to Engineer (Oiler)

Group 2: Compressor Operator; Generator, gasoline or diesel driven (100 KW or over)(structural steel or tank erection only); Rodman, Chainman; Assistant to Engineer (Truck Crane Oiler)

Group 3: Compressors, Generators and/or Welding Machines or combination (2 to 6)(structural steel or tank erection only); Deck Engineer; Forklift; Instrumentman; Signalman (using mechanical equipment)

Group 4: Heavy Duty Repairman; Tractor Operator

Group 4-A: Combination Heavy Duty Repairman - Welder

Group 5: Dual purpose A-frame or Boom Truck; Boom Cat; Chicago Boom; Crawler Cranes and Truck Cranes (15 tons M.R.C. or less); Single drum Hoist; Self-propelled boom-type lifting device (center mount)(10 ton capacity or less M.R.C.); Tugger Hoist; Overhead Cranes(15 tons M.R.C. or less)

Group 6: Crawler Cranes and Truck Cranes (over 15 tons M.R.C.); Derricks; Gantry Rider (or similar equipment); Highline Cableway; Two or more drum Hoist; Self-propelled boom-type lifting device (center mount) (over 10 tons); Tower Cranes Mobile (including rail mounted); Universal Liebher and Tower Cranes (and similar types); Overhead Cranes (over 15 tons M.R.C.)

Group 6-A: Cranes (over 125 tons)

Group 7: Operator of Helicopter

POWER EQUIPMENT OPERATORS (Cont'd)
Piledriving

Group 1: Deckhand; Fireman; Oiler

Group 1-A: Compressor Operator

Group 1-B: Truck crane Oiler (Assistant to Engineer)

group 2-A: Operator of Tugger Hoist (hoisting material only)

Group 2-B: Compressor Operator (over 2); Generators; Pumps; Welding Machine (powered other than by electricity)

Group 3: A-Frames; Deck Engineer; Forklift Operators; Self-propelled boom-type lifting device (center mount)(10-ton capacity or less M.R.C.)

Group 3-A: Heavy Duty Repairman and/or Welder

Group 4: Operator of Piledriving Rigs, skid or floating and derrick barges; Operator of diesel or gasoline powered Crane Piledriver (without boiler)(up to and including 1 cu. yd. rating); Truck Crane Operator (up to and including 25 tons) (hoisting material only); Operating Engineer in lieu of Assistant to Engineer tending boiler or compressor attached to Crane Piledriver; Self-propelled boom-type lifting device (center mount)(over 10 tons)

Group 5: Operator of diesel or gasoline powered Crane Piledriver (without boiler)(over 1 cu. yd. rating); Operator of Crane (with steam, flash boiler, pump or compressor attached); Operator of steam powered Crawler or Universal type Driver (Raymond or similar type); Truck Crane Operator (over 25 tons) (hoisting material or performing piledriving work)

Group 6: Cranes (over 125 tons)

TRUCK DRIVERS*	Basic Hourly Rates	Basic Hourly Rates	Fringe Benefits Payments			
			H & W	Pensions	Vacation	Education and/or Appr Tr
	AREA 1	AREA 2				
Group 1	$10.025	$11.525	.98	$1.14	$1.00	.10
Group 2	10.075	11.575	.98	1.14	1.00	.10
Group 3	10.125	11.625	.98	1.14	1.00	.10
Group 4	10.15	11.65	.98	1.14	1.00	.10
Group 5	10.225	11.725	.98	1.14	1.00	.10
Group 6	10.25	11.75	.98	1.14	1.00	.10
Group 7	10.30	11.80	.98	1.14	1.00	.10
Group 8	10.40	11.90	.98	1.14	1.00	.10
Group 9	10.45	11.95	.98	1.14	1.00	.10
Group 10	10.475	11.975	.98	1.14	1.00	.10
Group 11	10.55	12.05	.98	1.14	1.00	.10
Group 12	10.575	12.075	.98	1.14	1.00	.10
Group 13	10.65	12.15	.98	1.14	1.00	.10
Group 14	10.70	12.20	.98	1.14	1.00	.10
Group 15	10.75	12.25	.98	1.14	1.00	.10
Group 16	10.95	12.45	.98	1.14	1.00	.10
Group 17	11.025	12.525	.98	1.14	1.00	.10
Group 18	11.125	12.625	.98	1.14	1.00	.10
Group 19	11.15	12.65	.98	1.14	1.00	.10
Group 20	11.20	12.70	.98	1.14	1.00	.10
Group 21	11.26	12.75	.98	1.14	1.00	.10
Group 22	11.35	12.85	.98	1.14	1.00	.10
Group 23	11.45	12.95	.98	1.14	1.00	.10
Group 24	11.47	12.97	.98	1.14	1.00	.10
Group 25	11.70	13.20	.98	1.14	1.00	.10
Group 26	11.95	13.45	.98	1.14	1.00	.10

*See AREA DEFINTIONS following TRUCK DRIVERS' Classifications

TRUCK DRIVERS

Group 1: Chauffeurs

Group 2: Flat Rack Trucks, Bulk Cement Trucks, Transport Trucks, Semi-Trailer (Pickup); Gas Station Attendants

Group 3: Water, Fuel and Oil Trucks (less than 1200 gallons)

Group 4: Flat Rack Trucks, Bulk Cement Trucks, Transport Trucks, Semi-Trailer (carrying capacity less than 10 tons)

Group 5: Washers

Group 6: Dump Trucks - water level capacity (bottom, end and side)(including Dumpster Trucks, Turnawagons, Turnarockers and Dumpcrete)(less than 8 yds.); Water, Fuel and Oil Trucks (1200 gallons to less than 2500 gallons)

Group 7: Flat Rack Trucks, Bulk Cement Trucks, Transport Trucks, Semi-Trailer (carrying capacity 10 tons and less than 15 tons)

Group 8: Dump Trucks - water level capacity (bottom, end and side)(including Dumpster Trucks, Turnawagons, Turnarockers and Dumpcrete)(8 yds. and less than 14 yds.); Flat Rack Trucks, Bulk Cement Trucks, Transport Trucks, Semi-Trailer (carrying capacity 15 tons and less than 20 tons); Water, Fuel and Oil Trucks (2500 gallons to less than 4000 gallons); Sweeper or Vacuum Truck

Group 9: Construction Job Serviceman, Fork Lift, Straddle Truck; Warehouseman (Counter Clerk)

Group 10: Transit Mix Trucks(less than 8 cu. yds.); Concrete Pumping Trucks

Group 11: Dump Trucks - water level capacity (bottom, end and side)(including Dumpster Trucks, Turnawagons, Turnarockers and Dumpcrete)(14 yds. and less than 35 yds.); Flat Rack Trucks, Bulk Cement Trucks, Transport Trucks, Semi-trailer (carrying capacity 20 tons and over)

Group 12: Transit Mix Trucks (over 8 cu. yds. to 14 cu. yds.)

Group 13: Tireman and Greaser

TRUCK DRIVERS (Cont'd)

Group 14: Water, Fuel and Oil Trucks (4000 gallons to less than 6000 gallons)

Group 15: Dump Trucks - water level capacity (bottom, end and side)(including Dumpster Trucks, Turnawagons, Turnarockers and Dumpcrete)(35 yds. and less than 55 yds.)

Group 16: Dump Trucks - water level capacity (bottom, end and side)(including Dumpster Trucks, Turnawagons, Turnarocker and Dumpcrete)(55 yds. and less than 75 yds.); Water Fuel and Oil Trucks (6000 gallons to less than 10,000 gallons); Oil Spreader Operator (on single man operation where Boot Man is not required)

Group 17: Teamster, driving two horses

Group 18: Teamster, driving three or more horses

Group 19: Dump Trucks - water level capacity (bottom, end and side)(including Dumpster Trucks, Turnawagons, Turnarocker and Dumpcrete)(75 yds. and less than 95 yds.)

Group 20: Water, Fuel and Oil Trucks (10,000 gallons to less than 15,000 gallons)

Group 21: Teamster Mechanics, Teamster Welder

Group 22: Dump Trucks - water level capacity (bottom, end and side)(including Dumpster Trucks, Turnawagons, Turnarockers and Dumpcrete)(95 yds. and less than 105 yds.)

Group 23: Water, Fuel and Oil Trucks (15,000 gallons to less than 20,000 gallons)

Group 24: Dump Trucks - water level capacity (bottom, end and side)(including Dumpster Trucks, Turnawagons, Turnarockers and Dumpcrete)(105 yds. and less than 130 yds.), (all 130 cu. yds. and over to be paid one-half cent ($0.005) per cu. yd. capacity per hour in addition to rate for 105 yds. and less than 130 yds.)

Group 25: Water, Fuel and Oil Trucks (20,000 gallons to less than 25,000 gallons)

Group 26: Water, Fuel and Oil Trucks (25,000 gallons and over)

Unlisted classifications needed for work not included within the scope of the classifications listed may be added after award only as provided in the labor standards contract clauses (29 CFR, 5.5(a)(1)(ii)).

AREA DEFINITIONS
Laborers
(Heavy and Highway Construction)

Power Equipment Operators

Truck Drivers

AREA 1: All area included in the description defined below which is based upon township and range lines as referenced to the Salt Lake City Base and Meridian:

Commencing at the intersection of the Utah/Nevada border and the Southerly line of township 35 south;
Thence easterly to the S.E. corner of township 35 south, range 17 west;
Thence northerly to the S.E. corner of township 34 south, range 17 west;
Thence easterly to the S.E. corner of township 34 south, range 16 west;
Thence northerly to the S.E. corner of township 30 south, range 16 west;
Thence easterly to the S.E. corner of township 30 south, range 15 west;
Thence northerly to the S.E. corner of township 25 south, range 15 west;
Thence easterly to the S.E. corner of township 25 south, range 14 west;
Thence northerly to the S.E. corner of township 24, south, range 14 west;
Thence easterly to the S.E. corner of township 24 south, range 13 west;
Thence northerly to the S.E. corner of township 23 south, range 13 west;
Thence easterly to the S.E. corner of township 23 south, range 12 west;
Thence northerly to the S.E. corner of township 18 south, range 12 west;
Thence easterly to the S.E. corner of township 18 south, range 11 west;
Thence northerly to the S.E. corner of township 16 south, range 11 west;
Thence easterly to the S.E. corner of township 16 south, range 10 west;
Thence northerly to the S.E. corner of township 15 south, range 10 west;
Thence easterly to the S.E. corner of township 15 south, range 9 west;
Thence northerly to the S.E. corner of township 14 south, range 9 west;

AREA DEFINITIONS (Cont'd)

AREA 1: (Cont'd)

Thence easterly to the S.E. corner of township 14 south, range 8 west;
Thence northerly along the easterly line of range 8 west, crossing the Salt Lake Base Line to the intersection of the easterly line of range 8 west and the northerly border of Utah;
Thence easterly along the northerly border of Utah crossing the Salt Lake Meridian to the Utah/Idaho/Wyoming border;
Thence southerly along the Utah/Wyoming border;
Thence easterly along the Utah/Wyoming border to the intersection of the Utah/Wyoming border and Longitude 111 degrees west;
Thence southerly along Longitude 111 degrees west crossing the Salt Lake Base Line to the intersection of Longitude 111 degrees west and the southerly line of township 4 south;
Thence easterly along the southerly line of township 4 south to the S.E. corner of township 4 south, range 17 east;
Thence northerly to the S.E. corner of township 1 south, range 17 east;
Thence easterly along the southerly line of township 1 south to the intersection of the Utah/Colorado border;
Thence southerly along the Utah/Colorado border to the intersection of the Utah/Colorado border and the southerly line of township 7 south;
Thence westerly along the southerly line of township 7 south to the S.W. corner of township 7 south, range 20 east;
Thence southerly to the S.E. corner of township 8 south, range 19 east;
Thence westerly along the southerly line of township 8 south to the S.E. corner of township 8 south, range 12 east;
Thence southerly along the easterly line of range 12 east to the S.E. corner of township 20 south, range 12 east;
Thence westerly along the southerly line of township 20 south to the S.E. corner of township 20 south, range 3 east;
Thence southerly along the easterly line of range 3 east to the S.E. corner of township 27 south, range 3 east;
Thence westerly to the intersection of the southerly line of township 27 south and the Salt Lake Meridian, thence southerly along the Salt Lake Meridian to the intersection of the Salt Lake Meridian and the southerly line of township 39 south;
Thence westerly crossing the Salt Lake Meridian to the S.E. corner of township 39 south, range 2 west;

AREA DEFINTIONS (Cont'd)

AREA 1: (Cont'd)

Thence southerly to the S.E. corner of township 41 south, range 2 west;
Thence westerly to the S.E. corner of township 41 south, range 3 west;
Thence southerly along the easterly line of range 3 west to the Utah/Arizona border;
Thence westerly along the Utah/Arizona border to the Utah/Arizona/Nevada border;
Thence northerly along the Utah/Nevada border to the point of beginning. Commencing at the intersection of the Utah/Colorado border and the southerly line of township 34 south;
Thence westerly to the S.W. corner of township 34 south, range 21 east;
Thence northerly to the S.W. corner of township 29 south, range 21 east;
Thence westerly to the S.W. corner of township 29 south, range 19 east;
Thence northerly to the N.W. corner of township 23 south, range 19 east;
Thence easterly to the N.W. corner of township 23 south, range 22 east;
Thence northerly to the N.W. corner of township 21 south, range 22 east;
Thence easterly to the N.E. corner of township 21 south, range 24 east;
Thence southerly to the N.E. corner of township 31 south, range 24 east;
Thence easterly along the northerly line of township 31 south, to the Utah/Colorado border;
Thence southerly along the Utah/Colorado border to the point of beginning.

AREA 2: All areas not included in Area 1 as defined.

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federal register

Friday
November 2, 1979

Part V

Department of the Interior

Fish and Wildlife Service

Proposed Listing With Endangered Status for Five Species of Foreign Reptiles

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Proposed Listing With Endangered Status for Five Species of Foreign Reptiles

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: The Service proposes that five species of foreign reptiles be listed as Endangered species. This action is being taken because these species have been subject, at least in part, to malicious killing, overcollection, competition and habitat destruction by introduced feral animals, and habitat destruction by human activities. The species included in this proposed rule are as follows: Fiji Island banded iguana *(Brachylophus fasciatus)*, Fiji iguana (*Brachylophus* sp.), San Esteban Island chuckwalla *(Sauromalus varius)*, and two Round Island boas *(Bolyeria multicarinata* and *Casarea dussumieri)*.

With the exception of the San Esteban Island chuckwalla, all are strictly protected in the country of origin. This rule would provide additional protection to wild populations of these Endangered reptiles.

DATES: Comments from the public and from the governments of the countries where these species occur must be received by January 31, 1980.

ADDRESSES: Submit comments to Director (OES), U.S. Fish and Wildlife Service, Department of the Interior, Washington, D.C. 20240. Comments and materials relating to this rulemaking are available for public inspection during normal business hours at the Service's Office of Endangered Species, 1000 N. Glebe Road, Arlington, Virginia.

FOR FURTHER INFORMATION CONTACT: Mr. John L. Spinks, Jr., Chief, Office of Endangered Species, U.S. Fish and Wildlife Service, U.S. Department of the Interior, Washington, D.C. 20240 (703/235-2771).

SUPPLEMENTARY INFORMATION:

Background

San Esteban Island chuckwalla. In the Federal Register of March 6, 1979, (44 FR 12391), the Fish and Wildlife Service published a Notice of Review on the status of the San Esteban Island chuckwalla based on a petition to list this species by Dr. Ted Case. Information contained in the notice summarized existing knowledge concerning its status and the reasons for conducting the review. Persons who desire to review these data should consult this document or the *Endangered Species Technical Bulletin* of March, 1979; these documents are available from the Office of Endangered Species, U.S. Fish and Wildlife Service, Washington, D.C. 20240.

A total of 3 comments were received in response to the notice. These comments are summarized below:

Charles K. Sylber (Colorado State University) provided additional support for observations on habitat destruction on San Esteban Island. He noted that since the Baja road opened, increasing numbers of iguanas have apparently been removed; he also noted that both Mexican and Seri Indians have increased their consumption of iguanas as food prices have risen. He agreed with Dr. Ted Case that the iguana's primary range is a single arroyo and that this arroyo is easily disturbed because of its accessibility.

Dr. Edward Shallenberger (Sealife Park) and A. G. Skinner both supported the listing of the species. Dr. Shallenberger, based on his studies of *Sauromalus* in the Gulf of California, believes a population estimate of 4500 animals to be a high estimate.

The status of each of the other species will be discussed below; information on these species was obtained from literature review, discussions with knowledgable individuals, and information presented at the joint annual meeting of the Herpetologist's League and Society for the Study of Amphibians and Reptiles held August 12-16, 1979 in Knoxville, Tennessee. Both species of boas are on Appendix I of the Convention on International Trade in Endangered Species of Wild Fauna and Flora.

Section 4(4) of the Act (16 U.S.C. 1531 et seq.) states:

General—(1) The Secretary shall by regulation determine whether any species is an endangered species or a threatened species because of any of the following factors: (1) the present or threatened destruction, modification, or curtailment of its habitat or range; (2) overutilization for commercial, sporting, scientific, or educational purposes; (3) disease or predation; (4) the inadequacy of existing regulatory mechanisms; or (5) other natural or man-made factors affecting its continued existence.

This authority has been delegated to the Director. The reptiles proposed for listing as Endangered species relate to these factors as follows (numbers refer to factors above):

Summary of Factors Affecting the Species

San Esteban Island chuckwalla. (1) This large lizard occurs only on 43 km² San Esteban Island in the Gulf of California where its main habitat is a single arroyo that runs along the southeast corner of the island. Although there are no permanent human settlements on the island, there has been some destruction of chuckwalla habitat, apparently in attempts to obtain specimens. Because of the limited extent of chuckwalla habitat, this area is extremely vulnerable to modification. (2) This is a major concern for the continued survival of this species. Commercial operations have visited the island and reportedly removed large numbers of individuals for the pet trade. Because of the life history characteristics of this species (as summarized in the March 6 Notice of Review), it is unlikely that the population can sustain such harvest. The removal of individuals to serve as exotic pets could clearly jeopardize this species. (3) Individuals are occasionally eaten by Mexicans and Seri Indians. (4) This species is currently not protected by international trade agreements although a collecting permit is required by Mexico. This requirement is difficult to enforce and may be circumvented by zealous collectors.

Fiji Island banded iguana and *Fiji iguana.* These iguanas are found only in the Pacific, the Fiji Island banded iguana on several islands in Fiji and Tonga and the recently discovered but as yet undescribed Fiji iguana only on a little (1 km²) remote island in the Fiji group. Both species face the same threats and are discussed together. (1) The felling of trees and forest for human purposes and habitat destruction caused by introduced goats are likely to eliminate the habitat of these species and thus lead to their extinction. (2) Because of the unique distribution, attractive coloration and limited range of these species, the threat of commercial exploitation is high. Indeed, specimens of the Fiji Island banded iguana were involved in a major reptile smuggling case as late as August 1977. Dr. John Gibbons, who discovered the new iguana, believes exploitation to be a threat to the species. (3) Predation by feral cats is believed to be a problem. (4) Killing by native Fijians is also a problem facing these species.

Round Island boas. These species are the sole surviving members of the subfamily Bolyerinae, a group of primitive boas. The numbers of *Bolyeria multicarinata* are unknown as there have been only six sightings since 1935, the last in 1975. the total population of *Casarea dussumieri* is estimated to be around 75 animals. (1) Rabbits and goats were introduced onto Round Island in 1840 and these animals have destroyed

the island's vegetation so that severe erosion has occurred. The resulting deterioration of the palm forest is the main threat to these snakes.

Effects of the Rulemaking

Endangered species regulations published in Title 50 of the Code of Federal Regulations set forth a series of general prohibitions and exceptions which apply to all Endangered species. The regulations referred to above, which pertain to Endangered species, are found at § 17.21 of Title 50, and are summarized below.

With respect to the five species of reptiles in this proposed rule, all prohibitions of Section 9(a)(1) of the Act, as implemented by 50 CFR 17.21, would apply. These prohibitions, in part, would make it illegal for any person subject to the jurisdiction of the United States to take, import or export, ship in interstate commerce in the course of a commercial activity, or sell or offer for sale these species in interstate or foreign commerce. It also would be illegal to possess, sell, deliver, carry, transport, or ship any such wildlife which was illegally taken. Certain exceptions would apply to agents of the Service and State conservation agencies.

Regulations published in the Federal Register of September 26, 1975 (40 FR 44412), codified at 50 CFR 17.22 and 17.23, provided for the issuance of permits to carry out otherwise prohibited activities involving Endangered or Threatened species under certain circumstances. Such permits involving Endangered species are available for scientific purposes or to enhance the propagation or survival of the species. In some instances, permits may be issued during a specified period of time to relieve undue economic hardship which would be suffered if such relief were not available.

Endangered Species Act Amendments of 1978

The Endangered Species Act Amendments of 1978 specify that the following be added at the end of subsection 4(a)(1) of the Endangered Species Act of 1973:

At the time any such regulation (any proposal to determine a species to be an Endangered or Threatened species) is proposed, the Secretary shall by regulation, to the maximum extent prudent, specify any habitat of such species which is then considered to be critical habitat.

Since Critical Habitat only applies to domestic species, and the species under consideration in the rulemaking are not domestic, this amendment does not apply.

The Endangered Species Act Amendments of 1978 further state the following:

(B) In the case of any regulation proposed by the Secretary to carry out the purposes of this section with respect to the determination and listing of endangered or threatened species and their critical habitats in any State (other than regulations to implement the Convention), the Secretary—

(i) shall publish general notice of the proposed regulation (including the complete text of the regulation), not less than 60 days before the effective date of the regulation

(I) in the Federal Register, and

(II) if the proposed regulation specifies any critical habitat, in a newspaper of general circulation within or adjacent to such habitat;

(ii) shall offer for publication in appropriate scientific journals the substance of the Federal Register notice referred to in clause (i)(I);

(iii) shall give actual notice of the proposed regulation (including the complete text of the regulation), and any environmental assessment or environmental impact statement prepared on the proposed regulation, not less than 60 days before the effective date of the regulation to all general local governments located within or adjacent to the proposed critical habitat, if any; and

(iv) shall—

(I) if the proposed regulation does not specify any critical habitat, promptly hold a public meeting on the proposed regulation within or adjacent to the area in which the endangered or threatened species is located, if request therefore is filed with the Secretary by any person within 45 days after the date of publication of general notice under clause (i)(I), and

(II) if the proposed regulation specifies any critical habitat, promptly hold a public meeting on the proposed regulation within the area in which such habitat is located in each State, and, if requested, hold a public hearing in each such State.

In the case of the five reptiles herein considered, Section 4(B)(i)(I) above is hereby complied with. In addition, the following scientific journals will be notified of the proposal and offered a copy of the Federal Register document for either publication or distribution to scientists: Copeia, Herpetologica, Herpetological Review, and the Journal of Herpetology. Since these species are not domestic and no critical habitat is included in the proposal, none of the other amended subsections of this Section are applicable.

Public Comments solicited

The Director intends that the rules finally adopted will be as accurate and effective as possible in the conservation of any Endangered or Threatened species. Therefore, any comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, private interests, or any other interested party concerning any aspect of these proposed rules are hereby solicited. Comments particularly are sought concerning:

(1) Biological or other relevant data concerning any threat (or the lack thereof) to the five reptiles;

(2) Additional information concerning the range and distribution of these species.

Environmental Considerations

A draft environmental assessment has been prepared pursuant to the Executive Order 12114 and is on file in the Service's Washington Office of Endangered Species, Suite 500, 1000 N. Glebe Road, Arlington, Virginia. It addresses this action as it involves these five reptiles.

The primary author of this rule is Dr. C. Kenneth Dodd, Jr., Office of Endangered Species (703/235-1975).

Regulations Promulgation

Accordingly, it is proposed that Part 17, Subchapter B of Chapter I, Title 50 of the U.S. Code of Federal Regulations be amended as follows:

1. By adding the five reptiles herein considered to the list, alphabetically, under "Reptiles" as indicated below:

§ 17.11 Endangered and threatened wildlife.

Species		Range			Status	When listed	Special rules
Common name	Scientific name	Population	Known distribution	Portion endangered			
Iguana, Fiji Islands banded	*Brachylophus fasciatus*	NA	Fiji, Tonga	Entire	E		NA
Iguana, Fiji	*Brachylophus* sp	NA	Fiji	Entire	E		NA
Chuckwalla, San Esteban Island	*Sauromalus varius*	NA	Mexico	Entire	E		NA
Boa, Round Islands	*Casarea dussumieri*	NA	Mauritius	Entire	E		NA
Boa, Round Islands	*Bolyeria multicarinata*	NA	Mauritius	Entire	E		NA

Note.—The Department of the Interior has determined that this rule is not a significant rule and does not require preparation of a regulatory analysis under Executive Order 12044 and 43 CFR Part 14.

Dated: October 15, 1979.

Robert S. Cook,

Deputy Director, Fish and Wildlife Service.

[FR Doc. 79-33978 Filed 11-1-79; 8:45 am]

BILLING CODE 4310-55-M

federal register

Friday
November 2, 1979

Part VI

Department of Health, Education, and Welfare

Office of Human Development Services

Enrollment and Attendance Policies in Head Start

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of Human Development Services

Enrollment and Attendance Policies in Head Start

AGENCY: Office of Human Development Services, HEW.

ACTION: Final program policy.

SUMMARY: This Head Start policy provides requirements that assist grantees in dealing with two continuing problems they encounter which hinder their ability in serving the target population efficiently: (1) Insuring that program enrollment is consistent with available resources and that resources are effectively utilized; and (2) insuring that children participate fully in the program consistent with sound child development practice.

The policy includes requirements which (1) insure successful recruitment and enrollment, (2) maintain appropriate enrollment and average daily attendance, and (3) stress the importance of family support services and program activities to foster the child's full participation in the program.

EFFECTIVE DATE: November 2, 1979.

FOR FURTHER INFORMATION CONTACT: D. C. Drohat or Taik M. Lee, Program Management and Operations Division, Head Start Bureau, Administration for Children, Youth and Families, Office of Human Development Services, Department of Health, Education, and Welfare, Washington, D.C. 20201 (202/755-7488).

SUPPLEMENTARY INFORMATION: The proposed policy on Enrollment and Attendance Policies in Head Start was published on December 1, 1976 (41 FR 52788) to issue policy instructions for Head Start agencies to insure successful recruitment, enrollment and attendance.

Head Start grantees, interested persons and organizations were invited to submit comments on or before January 3, 1977. Four hundred and fifty (450) comments were received from one hundred and fifty-two (152) individuals and organizations with regard to the proposed policy. Of one hundred and fifty-two (152) letters, one hundred and forty-one (41) came from Head Start agencies and parents. Many commenters objected to the mandatory requirements for overenrollment and ninety (90) percent average daily attendance. Thus, the Administration for Children, Youth and Families (ACYF) established a task force to evaluate the policy requirments in light of these comments.

The ACYF task force tentatively revised the policy based on the comments received. The task force then conducted a two day workshop at the Wisconsin Head Start Directors' Association Meeting and another two day workshop at the National Head Start Directors' Association Conference to solicit input in revising and refining the requirements in the policy. In addition, the task force sampled selected Head Start agencies to ascertain their average daily attendance rate and the resource implications for overenrollment. The result of the sample was used as a basis for discussion at the National Head Start Directors' Association Conference.

Upon completion of the two workshops ACYF made a critical analyses of all aspects of the policy requirements, which resulted in significant changes.

The following changes were made in the policy as a result of the comments, the two workshops and ACYF analyses:

1. It was suggested that the minimum requirements of 90 percent average daily attendance of the funded slots was unrealistically high in view of the fact that (1) Head Start is serving an age group that is very vulnerable to childhood diseases and illnesses, (2) severe weather prevents children from attending the classes in some areas, (3) some Head Start populations are transient, and (4) enforcement of a 90 percent average daily attendance requirement might lead some Head Start agencies to screen out children from families where attendance is considered likely to pose problems. ACYF concurred and made the following revisions:

(i) The minimum average daily attendance rate was changed from 90 percent of the funded slots to 85 percent of the funded slots.

(ii) Average daily attendance was defined in the same manner as for the Child Care Food Program administered by the Department of Agriculture to facilitate recordkeeping at the local program level.

(iii) A requirement was adopted which seeks to prohibit Head Start agencies from screening out children from families where attendance may be a problem. Greater emphasis was placed on outreach and support for hard-to-serve families whose children may derive particular benefits from participation in Head Start.

2. It was said that maintaining full enrollment is very difficult, if not impossible, because (1) some Head Start populations are transient, (2) Head Start agencies have to follow an established enrollment procedure which takes one to two weeks to complete, (3) most of the Head Start agencies close for the summer and Head Start staff return to work two to three weeks prior to beginning of the operating year. This leaves a very short period of time in which to reach full enrollment. ACYF understands these difficulties. However, these considerations must be balanced against the need to utilize resources efficiently to insure that the optimum number of children are served. Therefore, full enrollment must equal the number of funded slots. Moreover, programs with small class sizes, where child-adult ratios and other resources permit, are encouraged to enroll up to 110 percent of the funded slots at the beginning of the operating year to compensate for the fact that not every child initially enrolled may attend Head Start throughout the year. Safeguards and circumstances under which overenrollment may *not* be done by grantees and delegate agencies are spelled out in the policy.

3. Strong objections were raised on the proposed mandatory overenrollment provision when the average daily attendance rate drops below 90 percent of the funded slots. Some of the reasons for the objections were that (1) comprehensive health, education, social and nutrition services would not be available to all enrollees because Head Start does not have additional funds for such services, (2) emphasis on overenrollment might lead to a serious decline in the quality of services provided to children by emphasizing quantitative aspects rather than seeking to eliminate the causes of low attendance, (3) on the days that attendance exceeds 100 percent, the teacher-child ratio would be reduced and sound child development might be jeopardized, (4) Head Start is already in effect overenrolled due to the built-in turnover rate, as a result of which the number of children served in one year exceeds the number for which the program is funded, and (5) this could create an overcrowding of classrooms. At the same time many commenters recommend that ACYF give Head Start agencies the option to overenroll. ACYF concurred and revised the mandatory overenrollment requirement so that overenrollmemt is optional for Head Start agencies that meet certain specified criteria.

4. It was pointed out that the sanctions set out in the Scope section is that while one center is experiencing low enrollment and average daily attendance, another center under the same Head Start agency may have a waiting list. Thus, the sanction should

be on a center-by-center basis. ACYF believed that it would be difficult to administer all aspects of the policy on a center-by-center basis and the policy was not changed as a result of this comment.

5. It was also recommended that ACYF evaluate the impact of the minimum average daily attendance rate and the enrollment rate on Head Start agencies one year from the effective date of this policy. ACYF will monitor progress of the policy through semiannual reports from grantees and as part of on-site pre-review and validation.

6. Since it was recommended that ACYF define "center" and "classroom," these terms have been defined.

7. It was recommended that this policy should emphasize the importance of regular attendance, since it is a good habit which will assist a child and family in elementary school. ACYF concurred and has gone further to mandate family support procedures in cases where there are chronic problems of child attendance.

8. It was recommended that ACYF require Head Start agencies to document their enrollment plans. ACYF concurred and made the necessary provision.

9. It was recommended that ACYF change its requirement from follow-up on the fourth consecutive day to the third consecutive day of a child's absence. ACYF ascertained that this was a general practice of Head Start agencies and therefore ACYF concurred with the recommendations.

The purpose of this policy is to set requirements which will help Head Start agencies achieve successful recruitment, full enrollment and appropriate average daily attendance. Thus, Head Start agencies will be more effective in utilizing resources and providing needed services to larger numbers of children.

The basis for this policy is Section 517 of the Headstart-Follow Through Act, where the Secretary is directed to prescribe rules or regulations to insure that each Head Start agency shall observe standards of organization, management, and administration which will assure that all program activities are conducted in a manner consistent with the Act and the objective of providing assistance effectively and efficiently.

(Catalog of Federal Domestic Assistance Program No. 13.600—Administration for Children, Youth and Families—Head Start)

Dated: October 26, 1979.

Herschel Saucier,

Acting Commissioner for Children, Youth, and Families.

Approved: October 29, 1979.

Arabella Martinez,

Assistant Secretary for Human Development Services.

Chapter S-30-317-1 in the Head Start Policy Manual reads as follows:

S-30-317-1-00	Purpose.
S-30-317-1-10	Scope.
S-30-317-1-20	Enforcement.
S-30-317-1-30	Definitions.
S-30-317-1-40	Policy.

Authority: 42 U.S.C. 2928g.

S-30-317-1-00 Purpose.

This Chapter sets forth the policies formulated to maintain successful recruitment, full enrollment, and appropriate average daily attendance in each Head Start program.

S-30-317-1-10 Scope.

This policy applies to all Head Start programs operating one or more of the standard program options. However it does not apply to home-based programs nor does it apply to Parent-Child Centers, experimental and demonstration programs.

S-30-317-1-20 Enforcement.

Compliance with this policy will be checked by HEW regional offices during the on-site pre-review and validation visits or at any time during the operating year and from the grantee's Program Information Report. The responsible HEW official shall provide a period of thirty calendar days but no more than sixty calendar days for a Head Start Program whose actual enrollment has dropped below its funded enrollment to increase enrollment to or above 100 percent of the total number of funded slots. The responsible HEW official shall offer the necessary technical assistance for a Head Start program to increase enrollment. If a grantee does not achieve full enrollment by the end of the thirty to sixty day period established by the HEW regional office and considering the technical assistance requested and provided, the HEW official will take appropriate remedial action as follows:

1. Grant funds may be reduced in approximate relationship to the number of unfilled slots, i.e., the difference between actual and funded enrollment at the end of the thirty-sixty day compliance period. This would occur at the time of the refunding grant award immediately following the end of the compliance period or the subsequent grant award, whichever is reasonable considering the results of the grantee's apparent effort to achieve funded enrollment and the time relationship between the end of the compliance period and the grantee's next budget year.

2. In the case of flagrant or continued failure of a grantee to reach funded enrollment, consideration will be given to the denial of refunding in accordance with 45 CFR Part 1303.20 et. seq., on the basis of ineffective use of Federal funds. The responsible HEW official would reach a conclusion of continued underenrollment, for example, if a grantee experienced repeated periods of substantial underenrollment in spite of its own special efforts and HEW technical assistance and compliance periods.

For grantees which fail to provide family support services when average daily attendance falls below 85 percent, enforcement shall be on the same basis as failure to implement any other of the program performance standards and may be the occasion for denial of refunding or termination.

S-30-317-1-30 Definitions.

1. "Average Daily Attendance" is the aggregate days attendance in the classroom of all children divided by the number of days the classroom is in operation during the period. The average daily attendance for groups of classrooms having varying lengths of terms is the sum of the average daily attendance for the individual classrooms. This definition is the same as that used in the Child Care Food Program administered by the Department of Agriculture to simplify local program recordkeeping and reporting.

2. "Classroom" means a space in a Head Start center where children are engaged in Head Start activities.

3. "Documented excused absence" means an absence for the following reasons for which there is acceptable documentation or written evidence:

a. A child is hospitalized.

b. A child is incapacitated due to a serious illness or injuries.

c. A child contracts a communicable disease.

d. A child has other health ailments which temporarily prevent attendance, such as asthma.

e. There is a death in a child's family.

f. A child cannot attend class because he or she has to receive medical treatment or therapy at the time when the class is being held.

g. The child's attendance is affected by temporary family situations.

4. "Eligible children" (see 45 CFR Part 1305 Eligibility Requirements for Enrollment in Head Start)

5. "Enrollment" means official acceptance of a family by a Head Start agency and completion of all procedures necessary for a child to begin attending class.

6. "Family support services" means home visits and other family contacts and services to support the child's regular attendance and otherwise to insure that the child and family receive full benefits of Head Start participation.

7. "Head Start center" means a facility used by a Head Start program where one or more classes are held.

8. "Head Start program", or "Program", means a program funded under the Headstart-Follow Through Act, and carried out by a Head Start agency that provides ongoing comprehensive child development services.

9. "Overenrollment" means the total number of children enrolled in the program exceeds the total number of funded slots.

10. "Recruitment" means systematic ways in which each Head Start program identifies families whose children are eligible for Head Start and enlists them to participate in the program.

11. "Responsible HEW official" means the official of the Department of Health, Education, and Welfare having authority to make the grant assistance in question or his or her designee.

12. "Total number of funded slots" or "full enrollment" means the number of children which the Head Start program is designated to serve as set forth in the approved grant application.

13. "Vacancy" means a child's leaving the program or failure to participate. A child's slot shall be considered vacant when the child does not participate for a period of more than 30 calendar days of unexcused absences despite the provisions of family support services.

S-30-317-1-40 Policy.

A. General Provisions

1. *Recruitment.*

a. Although recruitment is an on-going activity, each grantee shall develop a system designed to insure full enrollment within the first thirty calendar days of the school year. Whenever a child leaves the program and a vacancy occurs, steps should be taken to fill the vacancy immediately. All vacancies must be filled within thirty calendar days.

b. Recruitment procedures shall conform with Head Start Program Performance Standards (45 CFR Part 1304, Subpart D) and Eligibility Requirements for Enrollment in Head Start (45 CFR Part 1305).

c. Recruitment activity shall include but not necessarily be limited to some of the following activities:

i. Canvassing of local community.

ii. News release and advertising.

iii. Use of family referral.

iv. Contact with other public agencies.

d. At the time of recruitment, the importance of the child's regular attendance must be emphasized to the parents. At the same time, the family must be oriented to the range of Head Start child and family support services designed to facilities attendance.

e. Recruitment shall be carried out in such a way as to minimize selection on the basis of personal bias. Thus, a Head Start recruiter shall not accept or reject a family solely on the recruiter's judgement as to the likelihood of the child's regular attendance. Children should be recruited based on an expectation that, with adequate program support over time for the child and family the child is likely to benefit from participation in Head Start.

2. *Enrollment.*

a. Enrollment is an on-going process, and maintenance of a full enrollment level depends upon the success of the recruitment program. The Head Start program must maintain an enrollment level equal to its funded slots.

b. A Head Start program must try to fill vacancies as soon as they occur in order to maintain full enrollment. All vacancies must be filled within 30 calendar days.

c. A Head Start program must develop an enrollment plan which will be approved by the policy council. This plan shall include: (1) Priority ranking of children on a waiting list in accordance with the community needs assessment, and (2) projected overenrollment, if any, including a statement as to the adequacy of resources and the child-adult ratios and group sizes (see 2. e).

d. At the time of enrollment, orientation and parent-teacher sessions, a Head Start program must make every effort to convince parents of the importance of their child's regular attendance and to explain the benefits that the child and parents will receive as a result of good attendance. Parents should also be oriented regarding program support services to facilitate the child's attendance.

e. A Head Start program may overenroll children at any time during the year up to 110 percent of funded enrollment under the following conditions:

(1) There are adequate program resources to provide to *all* children the full range of services required by the Head Start Program Performance Standards (45 CFR Part 1304) including the required classroom and outdoor space.

(2) There are adequate staff and other adults to insure appropriate child-adult ratios, taking into account the ages and developmental circumstances of the children, including the need for special and related services for handicapped children. Preferred group sizes and child-adult ratios for Head Start classrooms are as indicated below:

Child-Adult Ratios

Children age[1]	Number in classroom[2]	Child-adult ratios	Adults in classrooms
3 years	10-12	No more than 4 to 1	1 teacher, 1 aide, 1 volunteer.[3]
4 years	12-15	No more than 5 to 1	1 teacher, 1 aide, 1 volunteer.[3]
5 years	15-21	No more than 7 to 1	1 teacher, 1 aide, 1 volunteer.[3]

Appropriate allowance should be made for services to handicapped children, which may require a lower child-staff ratio in certain classrooms.

[1] Where more than 50 percent of the class falls in the younger age, the ratio for the younger age, is applicable.

[2] These numbers reflect actual attendance.

[3] Volunteers can be counted as full-time adults if they are in the classroom 50 percent or more of the program time.

A grantee or delegate agency which operates *any* classroom exceeding these preferred ratios and groups sizes must *not* overenroll. This is a safeguard to avoid possible loss of developmental benefits to Head Start children. Any grantee or delegate agency that operates classrooms generally within the preferred child-adult ratios and group sizes, but that experiences chronic attendance problems in particular centers or classrooms, is encouraged to consider overenrollment when other attempts to improve child attendance do not solve the problem. Under no circumstances can a grantee or delegate agency that practices overenrollment maintain any classrooms in which actual attendance exceeds the preferred child-adult ratios and group size. The program should move to correct this

condition, then overenroll if circumstances warrent such action.

f. A Head Start program should consider overenrollment at the beginning of the operating year to compensate for anticipated dropouts among the children who are initially enrolled. Under no circumstances should overenrollment be more than 110 percent of full enrollment. Any grantees or delegate agencies practicing a strategy of overenrollment must not exceed the child-adult ratios and group sizes cited in 2.e.

3. *Attendance.* There are four major reasons for absenteeism that are beyond the control of the Head Start program. They are: (1) Illness which affects a whole center, (2) weather conditions, (3) transportation problems and (4) documented excused absences.

a. When the average daily attendance rate drops below 85 percent, a Head Start program must analyze the causes of absenteeism. The analysis shall include, but not be limited to, a study of the pattern of absence for each child. The program must initiate action based on results of the analysis. If the absences are due to illness or other conditions which require closing a center or if the absences are a result of well documented excused absences, no special action in required. If, however, the absences result from other factors, including temporary family problems or other circumstances that affect a child's regular attendance, the program must institute appropriate family support procedures for all children with three or more consecutive unexcused absences. These procedures must include home visits or other direct contact with the child's parents. Contacts with the family should emphasize the benefits of regular attendance, while remaining sensitive to the wisdom of parental discretion in deciding on any particular day that the child may be better off at home than in the preschool classroom. In the case of chronic attendance difficulties, the program should explore with the family the feasibility of other program models, including the home based option. In circumstances where the situation persists and it seems infeasible to include the child in the program, the child's slot should be treated as a vacancy.

b. In order to qualify as an excused absence, each specific situation must be documented.

c. If a child is absent three consecutive days, a Head Start program shall contact the family to ascertain the reason and what it reasonably can do to facilitate the return of the child to the program as soon as possible. This effort must be documented.

E. Compliance

It shall be the responsibility of a Head Start program to maintain appropriate and accurate records that will demonstrate compliance with this policy. The records shall be sufficient to serve the following purposes:

1. On-site review by regional office staff

2. Completion of the semi-annual Program Information Report

3. Annual grantee self-assessment.

The minimum record requirements to be kept for examination are the enrollment plan (as in 2.c.), monthly reports of average daily attendance, and procedures pertaining to documented, excused absences and absentee follow-up, and special family support service activities related to attendance.

[FR Doc. 79-33992 Filed 11-1-79; 8:45 am]
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federal register

Friday
November 2, 1979

Part VII

Equal Employment Opportunity Commission

Job Segregation and Wage Discrimination Under Title VII and the Equal Pay Act; Public Informational Hearing

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Job Segregation and Wage Discrimination Under Title VII and the Equal Pay Act; Public Informational Hearing

Notice is hereby given that the Equal Employment Opportunity Commission has scheduled public hearing to gather information relating to the problem of wage discrimination. The purpose of the hearing is to determine whether wage rates of jobs in which women and minorities have been historically segregated are likely to be depressed because those jobs are occupied by these groups. The hearing will examine the nature and present extent of job segregation, the relationship between job segregation and wage differentials, and how segregation may adversely influence the setting of wages for segregated jobs. When the Commission has analyzed the information developed at the hearing, it will determine what action, if any, it should take in connection with the issues.

On July 1, 1979, the Commission assumed jurisdiction over the Equal Pay Act pursuant to Reorganization Plan No. 1 of 1978. For the first time, the Commission is responsible for the orderly and harmonious interpretation of both the Equal Pay Act and Title VII as they relate to discrimination on the basis of sex. In addition, Executive Order 12067 requires the EEOC to exercise leadership in development and implementation of a uniform and harmonious body of law concerning employment discrimination. Therefore, it is necessary for the Commission to address questions of wage rate discrimination to assure that both statutes will be interpreted in accordance with the Congressional intent to provide equal employment opportunity.

Federal law has prohibited some forms of discrimination with respect to wages since the passage of the Equal Pay Act of 1963. Similarly, occupational segregation, which restricted minorities and women to less desirable and low paying jobs was expressly condemned and all adverse effects of such segregation made unlawful by Title VII of the Civil Rights Act of 1964. However, by and large, neither the Equal Pay Act nor the more general prohibition of Title VII on employment discrimination because of race, sex, religion or national origin have been applied to the question of wage rates paid for jobs into which minorities and women have been traditionally segregated. Thus, despite the express prohibition against job segregation in Title VII, it has been the Commission's experience that job segregation by race, sex and national origin remains a major characteristic of industrial life. For the most part, men and women do not do the same kinds of work; and minority males do not do the same kinds of work as white males.

There is evidence that the low rates of pay associated with such segregated jobs constitute the major explanation for the "earnings gap" between minority and female workers on the one hand and white males on the other. This gap has long been considered a major benchmark of the extent of employment discrimination. The gap has continued to grow in the last fifteen years despite the enactment of Title VII and the Equal Pay Act.

One reason why the problem has not been addressed is that the question of wage discrimination generally has not been viewed as part of the problem of job segregation under Title VII. Previous studies suggest that job segregation and wage discrimination are not separate problems; the two are intimately related. Wherever there is job segregation, the same forces which determine that certain jobs or job categories will be reserved for women or minorities also determine that the economic value of those jobs is less than if they were "white" or "male" jobs. Thus, those women and minorities who are channeled into segregated jobs are not only deprived of initial hiring and meaningful transfer opportunities in other jobs, but are also paid a wage for the job which they do get which is discriminatorily depressed.

The purpose of the hearing is: (a) To identify the extent of the problem of depressed wages of jobs held largely by minorities and women; and (b) to establish if these depressed wage rates are in fact the result of forces which include discrimination.

The hearing will be held in January 1980 in Washington, D.C. at a date and place to be announced later in the Federal Register.

Information is sought from interested persons who have experience in this area. Specifically, the Commission is soliciting information from economists, sociologists, historians, anthropologists, psychologists, and the affected individuals or groups, who have studied or experienced the relationship between job segregation and wage discrimination.

Further, the Commission desires information from the business and labor communities regarding their experience on this matter.

Persons wishing to testify before the Commission should submit a request to the Executive Secretariat, at the address shown below. The request should include a written summary of the testimony to be offered. Individuals who wish to testify should submit a request no later than December 10, 1979.

Because of time limitations, not all interested persons may be allowed to testify. The Commission will inform persons who have requested an opportunity to testify whether they are scheduled to testify not later than one week prior to the scheduled hearing date. Individuals not able to testify because of time limitations will be given the opportunity to submit a written statement. Individuals wishing to provide information to the Commission but not wishing to testify are encouraged to submit a written statement to the Commission. Such statement must be submitted no later than December 31, 1979 to the Executive Secretariat at the address shown below.

Any information provided the Commission, either by oral testimony or in writing, shall be used only for informational purposes by the Commission.

All statements received by the Commission in connection with the public hearing may be reviewed by members of the public in the Equal Employment Opportunity Commission Reading Room between 9:30 a.m. and 4:30 p.m. Monday through Friday, Library, Room 2303, Equal Employment Opportunity Commission, 2401 E Street, NW., Washington, D.C. 20506.

The hearings will be open to the public. For further information contact: Frederick D. Dorsey, Director, Office of Policy Implementation, Room 4002, 2401 E Street, NW., Washington, D.C. 20506, telephone: (202) 634-7060 or (202) 254-7489, between the hours of 9:00 a.m. and 5:00 p.m. eastern standard time.

Requests to testify and written statements should be addressed to: Executive Secretariat, Equal Employment Opportunity Commission, 2401 E Street, NW., Washington, D.C. 20506.

All correspondence submitted in connection with this announcement should be marked "Wage Discrimination Hearing" at the lower left hand corner of the envelope.

Signed this 30th day of October 1979.

For the Commission.

Eleanor Holmes Norton,

Chair, Equal Employment Opportunity Commission.

[FR Doc. 79-34045 Filed 11-1-79; 8:45 am]

BILLING CODE 6570-06-M

federal register

Friday
November 2, 1979

Part VIII

Department of Agriculture

Animal and Plant Health Inspection Service

Revision of Definitions, Regulations, and Standards for the Humane Handling, Care, Treatment, and Transportation of Dogs, Cats, and Certain Other Warmblooded Animals; Conforming Changes in Requirements for Accredited Veterinarians

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 1, 2, 3, 160, and 161

Revision of Definitions, Regulations, and Standards for the Humane Handling, Care, Treatment, and Transportation of Dogs, Cats, and Certain Other Warmblooded Animals; Conforming Changes in Requirements for Accredited Veterinarians.

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: This document amends the definitions, regulations, and standards under the Animal Welfare Act concerned with the humane handling, care, treatment, and transportation of certain warmblooded animals used for purposes of research, teaching, exhibition, or as pets. The revisions contained in these amendments provide for (1) a clarification of the definitions, an amendment of the term, "Veterinary Services representative", and the addition of two terms; (2) automatic termination of licenses for failure to pay the annual renewal fee, payment of license fees by personal check, and deletion of the applicant-affidavit method to ascertain compliance with standards for premises, facilities, and equipment; (3) issuance of certificates of acclimation to lower temperatures by USDA accredited veterinarians, (4) the use of certificates of acclimation to lower temperatures by private individuals; and (5) removal of special requirements for the transportation of coursing hounds. This document also makes conforming changes in the requirements and standards for accredited veterinarians. The revisions contained herein are the result of various petitions for reconsideration received by the Department which made new facts and evidence available that appeared to warrant such action.

EFFECTIVE DATE: November 2, 1979.

FOR FURTHER INFORMATION CONTACT: Dr. Dale F. Schwindaman, Senior Staff Veterinarian, Animal Care Staff, Veterinary Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Room 703, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-8271.

SUPPLEMENTARY INFORMATION: On August 3, 1979, the Department published a notice of proposed rulemaking containing changes and additions to Parts 1, 2, and 3 of Subchapter A—Animal Welfare, Chapter I, Title 9 of the Code of Federal Regulations (44 FR 45912–45916) which provided for (1) a clarification of defined terms, an amendment of the definition of "Veterinary Services representative," and an addition of the terms "indoor housing facility" and "outdoor housing facility" to the definitions; (2) provision for automatic termination of licenses for failure to pay the annual renewal fee; (3) provision for payment of license fees by means of personal check; (4) the deletion of the applicant-affidavit method for ascertaining compliance with standards for premises, facilities and equipment; (5) provision for allowing the use of certificates of acclimation to temperatures lower than those provided for in the standards by persons other than licensees, registrants, or departments, agencies, or instrumentalities of the United States; (6) provision that all certificates of acclimation must be issued by USDA accredited veterinarians; and (7) removal of special requirements for the transportation of coursing hounds.

A total of 15 comments were received within the comment period in response to the proposed changes. Although this is a relatively small number, many interest groups were represented, i.e., registered research facilities; dealers, breeders and brokers; humane groups; and the American Veterinary Medical Association and specific veterinary clinicians. Many of the comments raised questions or made suggestions which, because of their validity, warranted some changes of the proposed standards. Certain other editorial changes were also made for clarification purposes.

Discussion of Major Proposed Items and Comments

Definitions

The present regulations do not preface the list of terms which are defined in § 1.1 of Part 1, Subchapter A—Animal Welfare, Chapter I of the CFR with any explanation of the applicability of singular forms versus plural forms or the masculine form versus the feminine form within the context of each term's definition. Without such explanation, clarity and completeness are lacking in the definition of certain terms. The Department proposed to clarify this matter and received no negative comments regarding such proposal. The Department thus provides that within the definition of each of the terms in § 1.1, unless the context of the definition of an individual term otherwise requires, the singular form shall also import the plural and the masculine form shall also import the feminine. Further, it is provided that words which are undefined within the regulations and standards shall have the meaning attributed to general usage as reflected by definition in a standard dictionary, such as "Webster's."

The Department proposed to amend § 1.1(h) of the present regulations to change the definition of the term, "Veterinary Services representative," by deleting the term "full-time" from the definition. The proposal would allow the employment of both full-time and part-time personnel in order to effectively administer and enforce the Animal Welfare Act and its regulations and standards. However, a representative of a pharmaceutical firm, which is a registered research facility, indicated concern regarding such change because of the possibility that an employee of a competitor could be hired by the Department to inspect such firm's facilities and records. Such concern stems from the inspector's access to a company's testing areas and records. Such access could provide an opportunity to gain information useful to the competitor. The Animal and Plant Health Inspection Service (APHIS) has issued a written directive to Department Veterinarians in Charge of the various areas of this country, who are responsible for the hiring and assignment of animal welfare inspectors, to assure that work assignments are made in a manner which will preclude any possible opportunity for pirating of confidential business procedures or records of one research institution or business by the employee of a competitor. Accordingly, the definition of the term, "Veterinary Services representative," is amended herein by the deletion of the word "full-time."

Automatic Termination of License

The Animal Welfare Act (7 U.S.C. 2131–2156) requires that in order to obtain a license, a dealer or exhibitor must demonstrate that his facilities comply with standards promulgated by the Secretary of Agriculture. In addition, dealers and exhibitors must apply in writing and pay a prescribed fee in order to obtain the license.

The present regulations require that on or before each anniversary date of his license, the licensee must submit the required fee for annual renewal of such license. The regulations also require the filing of an annual report by licensees within 30 days prior to the anniversary date of their license. The Department proposed to amend the regulations to provide that if the required annual dealer's or exhibitor's fees are not paid,

or if the required report is not filed on or before the date required by the regulations, the license of such dealer or exhibitor shall automatically terminate. However, the licensee would be notified by the Department and given an opportunity (60 days) to comply with the payment and reporting provisions of the regulations prior to such automatic termination.

Comments received agreed with the Department's proposal recognizing the efficiency of a licensing procedure whereby licenses are issued for a period of 1 year and renewal of such licenses is dependent upon the payment of an annual license fee and submission of a completed license renewal form. One comment complained that the proposed "grace" period of 60 days following the anniversary date for license renewal is too short; that 90 days would be more appropriate. The Department however, finds that many government licensing agencies provide no additional time or a shorter "grace" period (30 days or less) for delinquent payment of fees for renewal of licenses. Such action is based on their experience that an overly lenient policy regarding delinquent license renewals encourages procrastinating licensees to delay, even further, action to renew a required license. Therefore, the Department provides herein that failure by a licensee to pay the annual license fee as required by §§ 2.1 and 2.6 of the regulations or to file the annual report as required by § 2.7 on or before the anniversery date of his license will result in automatic termination of the license. However, prior to such termination, the licensee shall be notified and given an opportunity to comply with the appropriate requirements. Failure to comply with the annual license fee and reporting requirements within 60 days from receipt of such notice shall result in an automatic termination of the license.

Payment by Personal Check

In response to complaints from persons who are required to be licensed under the Animal Welfare Act about the inconvenience and additional cost of paying their license fees by one of the three methods provided in the regulations, i.e., certified check, cashier's check, or money order, the Department proposed to allow payment of license fees by personal check. Response to this proposal was positive. Therefore, the Department finds that the convenience of using personal checks to pay license fees and the ability of the Department to withhold issuance of a license pending clearance of a personal check for sufficient funding provides valid basis to allow payment of license fees by personal check.

Inspection of License Applicant's Premises

The Animal Welfare Act requires, in addition to a written application and payment of reasonable fees, that dealers and exhibitors demonstrate that their facilities comply with the standards promulgated by the Secretary. Presently, the Department allows license applicants to demonstrate compliance with the Department's standards by either of two methods, i.e., inspection of applicants' premises, facilities, and equipment by a Veterinary Services representative or submission of an affidavit by applicants to the effect that their premises, facilities, and equipment comply with the Department's standards.

Because the Department has experienced some abuse of the applicant-affidavit method of ascertaining compliance with the Department's standards for premises, facilities, and equipment by license applicants, it proposed to delete the applicant-affidavit method. All comments received agreed that such a proposal was overdue. Therefore, the Department provides herein that licenses for dealers and exhibitors will be issued only to those applicants whose premises, facilities, and equipment are inspected by a Veterinary Services representative and found to comply with the standards.

Deletion of Requirements for Coursing Hounds

The Department's present standards for primary enclosures used to transport live dogs and cats (reference, 9 CFR 3.12) require that the shipping containers used to transport coursing hounds with a spinal arch, i.e., greyhounds, whippets, borzois, and Italian greyhounds, must be narrow enough to prevent the animals from turning around in their enclosures. However, a subsequent review of available scientific data indicates that although possible spinal weakness expressed in the form of an injury can occur during conditions wherein great force is exerted on the musculoskeletal system of the hounds, such as is encountered during actual coursing, such force exceeds that which may occur at rest or in confinement. Consequently, the Department proposed to revise § 3.12(c) of the standards by deleting the requirement that the primary enclosures for coursing hounds with a spinal arch must be narrow enough to prevent the animal from turning around. The Department received no comments or data contradicting this proposal, and therefore, it is provided herein that primary enclosures used to transport all live dogs and cats shall be large enough to ensure that each animal contained therein has sufficient space to turn about freely in a standing position using normal body movements, to stand and sit erect, and to lie in a natural position.

Certificates of Acclimation to Lower Temperatures; All Certificates to be Issued by Accredited Veterinarians

In the final rulemaking published December 1, 1978, in the Federal Register (43 FR 56213–56217), the Department provided for the use of certificates of acclimation to colder temperatures by licensees, registrants, or agencies, departments, or instrumentalities of the United States when shipping animals in commerce. The Department also acknowledged the problem of hobby breeders and individual pet owners who were not afforded the opportunity to present to carriers and intermediate handlers certifcates of acclimation to lower temperatures when shipping animals which are known to be so acclimated. After reconsideration of the matter, it was decided that such persons should also be allowed to use certificates of acclimation to colder temperatures. However, in order to provide an element of control, it was determined that such certificates would be required to be issued by Department accredited veterinarians. The Department therefore proposed to provide certificates of acclimation to lower temperatures executed by USDA accredited veterinarians for use by persons, i.e., hobby breeders, and individual pet owners, not provided such option by the final rulemaking of December 1, 1978.

An "accredited" veterinarian is a licensed veterinarian who has been officially authorized by the Deputy Administrator of the Department's Veterinary Services to perform certain functions in connection with programs and laws which the Department administers (reference, 9 CFR 161.1). In the proposed rulemaking of August 3, 1979, the Department provided that certificates of acclimation to lower temperatures presented to carriers or intermediate handlers by any department, agency, or instrumentality of the United States or by "any person" must be executed by an accredited veterinarian. It was the Department's intent that all certificates of acclimation to lower temperatures (those presented by public persons as well as by private persons) be required to be issued by accredited veterinarians in order to provide for a method of accountability.

Proposed § 3.11 has been reworded to clarify this intent. With respect to public persons, it was intended that subdivisions of State or local governments should have the same right to utilize acclimation certificates as agencies of the United States. They are therefore included herein. By proposing to require that such certificates be executed by accredited veterinarians, the Department felt that it could exercise an element of control over such certificates by holding the accredited veterinarian accountable for the validity and accuracy of the certificates.

Several comments indicated concern for the ability of veterinarians to determine if an animal is acclimated to temperatures lower than 45° F. A representative of the American Veterinary Medical Association indicated that few veterinarians have sufficient firsthand knowledge of the day-to-day living pattern of the pet animals they treat to be able to appraise, with confidence, the animal's acclimation to hot or cold temperatures. Further, it was indicated that there is no simple method available for testing for such acclimation. This would require an accredited veterinarian to rely on the word of the owner or handler when determining whether or not an animal is acclimated to temperatures lower than 45° F. The Department believes that a licensed veterinarian, by virtue of his professional training and experience, should possess the qualifications and judgment necessary to determine whether or not an animal is able to safely withstand a particular range of temperatures. Accredited veterinarians must meet requirements and take examinations in addition to those required for licensure. Furthermore, since accredited veterinarians are responsible to the Department, it is expected that determinations regarding acclimation will be made in a professionally responsible manner.

There were comments indicating that other persons should be authorized to execute the acclimation certificates, i.e., licensed but non-accredited veterinarians, biologists, researchers, etc. The Department rejects this suggestion since it does not have the type of control over such people's actions as it does over the actions of accredited veterinarians.

Two comments criticized the proposal for the burden of the open-ended accountability placed on the accredited veterinarian who executes a certificate of acclimation to temperatures lower than 45° F. for animals transported in commerce and who could subsequently be held responsible for any deleterious effects of colder temperatures on such animals during the course of transportation. The Association of Primate Veterinary Clinicians agreed with the requirement of holding the accredited veterinarian accountable for the validity of the certificates of acclimation but suggested that the accredited veterinarian be held responsible for deleterious effects which occur only within a specified temperature range. If the animal suffer deleterious effects due to exposure to temperatures which were colder than the stated minimum acclimation temperature, the carrier or intermediate handler would be held accountable. The intent of this amendment with respect to acclimation is to provide private individuals the same flexibility as is now provided licensees, registrants, etc. This is accomplished by allowing carriers and intermediate handlers whose facilities fail to meet the minimum temperature requirement (45° F.) to accept animals for shipment, provided that they are accompanied by an acclimation certificate executed by an accredited veterinarian. It is expected that the veterinarian will make a determination regarding each animal as to whether such animal is or is not acclimated to temperatures it will encounter during its transportation. If he determines that the temperatures the animal will encounter could be detrimental, the veterinarian should take this into account when deciding whether or not to issue an acclimation certificate.

Two comments suggested that the Department also require the accreditation number assigned to the certifying veterinarian be included on acclimation certificates to provide additional identification and to discourage fraud. The Department believes the suggestion to be helpful and provides this requirement in §§ 3.11(c); 3.35(c); 3.60(c); 3.85(c); 3.112(c); and 3.136(c) of the transportation standards.

One comment complained that there are at present very few "accredited" veterinarians in the country and that most accredited veterinarians are large animal practitioners. The Department's Veterinary Services' records indicate that approximately 29,000 veterinarians, engaged in both large and small animal practices, are accredited.

Other Comments

A number of comments were received which were beyond the scope of the proposed rulemaking. Several comments provided no supporting evidence for the criticism indicated or for the suggested changes to the regulations or standards. Without the basis for such comments being enunciated, they could not be properly evaluated. Therefore, it was difficult to consider them in this rulemaking proceeding.

Other Considerations

This rulemaking provides for acclimation certificates to be executed by accredited veterinarians in accordance with provisions in Parts 1, 2, and 3 of Subchapter A, Chapter I, Title 9, CFR. Accredited veterinarians are governed by Parts 160 and 161 of Subchapter I, Chapter I, Title 9, CFR. It therefore becomes necessary to make conforming changes in Parts 160 and 161 to include the additional responsibilities under these regulations and standards and those veterinarians who issue such acclimation certificates.

Accordingly, Parts 1, 2, 3, 160, and 161 of Title 9, CFR, are amended in the following respects:

PART 1—DEFINITION OF TERMS

1. Section 1.1 (9 CFR 1.1) is amended by revising the introductory paragraph to read as set forth below and by making the following redesignations: paragraph (ss) is designated (tt); paragraph (rr) is redesignated (ss); paragraph (qq) is redesignated (rr); paragraph (pp) is redesignated (qq); paragraph (oo) is redesignated (pp); paragraph (nn) is redesignated (oo); paragraph (mm) is redesignated (nn); paragraph (ll) is redesignated (mm); paragraph (kk) is redesignated paragraph (ll); paragraph (jj) is redesignated (kk); paragraph (ii) is redesignated (jj); and by adding a new paragraph (ii) and revising paragraphs (h) and (hh) to read as follows:

§ 1.1 Definitions.

For the purposes of this part, unless the context otherwise requires, the following terms shall have the meanings assigned to them in this section. The singular form shall also import the plural and the masculine form shall also import the feminine. Words undefined in the following paragraphs shall have the meaning attributed to general usage as reflected by definition in a standard dictionary, such as "Webster's."

* * * * *

(h) "Veterinary Services representative" means any inspector or other person employed by the Department who is responsible for the performance of the function involved.

* * * * *

(hh) "Indoor housing facility" means any structure or building, housing or intended to house animals, which has the capability of controlling the environment within the enclosure

created by the continuous connection of a roof, floor, and walls with at least one opening for entry and exit that is provided with a door or any movable structure used to close off the opening and typically consisting of a panel of wood, glass, metal, etc., which slides on rollers or swings on hinges: *Provided, however,* That any openings which provide natural light shall be covered with a transparent material, e.g., glass, plastic, etc.

(ii) "Outdoor housing facility" means any structure or building, housing or intended to house animals, which does not meet the definition of "indoor housing facility."

* * * * *

PART 2—REGULATIONS

2. The Table of Contents cited in Part 2—REGULATIONS is amended to read as follows:

Licensing

Sec.
2.1 Application.
2.2 Acknowledgement of standards.
2.3 Demonstration of compliance with standards.
2.4 Issuance of licenses.
2.5 Duration of license.
2.6 Annual license fees.
2.7 Annual report by licensees.
2.8 Notification of change of name, address, control, or ownership of business.
2.9 Officers, agents, and employees of licensees whose licenses have been suspended or revoked.
2.10 Licensees whose licenses have been suspended or revoked or terminated automatically.
2.11 Denial of license.

Registration

2.25 Requirements and procedures.
2.26 Acknowledgement of standards.
2.27 Notification of change of operation.
2.28 Annual report of research facilities.

Identification of Animals

2.50 Time and method of identification.
2.51 Form of official tag.
2.52 How to obtain tags.
2.53 Use of tags.
2.54 Lost tags.
2.55 Removal of tag.

Records

2.75 Records, dealers and exhibitors.
2.76 Records, research facilities.
2.77 Records, operators of auction sales.
2.78 Records, carriers and intermediate handlers.
2.79 Health certification and identification.
2.80 C.O.D. shipments.
2.81 Records, disposition.

Compliance With Standards and Holding Period

2.100 Compliance with standards.
2.101 Holding period.

Miscellaneous

Sec.
2.125 Information as to business; furnishing of by dealers, exhibitors, operators of auction sales, and research facilities.
2.126 Access and inspection of records and property.
2.127 Publication of names of persons subject to the provisions of this part.
2.128 Inspection for missing animals.
2.129 Confiscation and destruction of animals.
2.130 Minimum age requirements.

Authority: Secs. 3, 5, 6, 10, 11, 12, 13, 14, 16, 17, 21; 80 Stat. 351, 352, 353; 84 Stat. 1561, 1562, 1563, 1564; 90 Stat. 418, 419, 420, 423; 7 U.S.C. 2133, 2135, 2136, 2140, 2141, 2142, 2143, 2144, 2146, 2147, 2151.

3. Section 2.1 (9 CFR 2.1) is amended by revising paragraph (b) to read as follows:

§ 2.1 Application.

* * * * *

(b) Any person who is not a dealer or exhibitor, but who desires to obtain a license, shall follow the requirements for dealers and exhibitors set forth in paragraph (a) of this section and in §§ 2.2 and 2.3, and shall agree in writing, on a form furnished by Veterinary Services, to comply with all the requirements of the Act and the provisions of this subchapter. A license will be issued to any such applicant when the requirements of §§ 2.2 and 2.3 have been met, and when the applicant has submitted to the Veterinarian in Charge a fee of $5 by certified check, cashier's check, personal check, or money order. In addition to the fee required to be paid upon application for a license, such licensee shall submit to the Veterinarian in Charge a fee of $5, by certified check, cashier's check, personal check, or money order, on or before each anniversary date of his license. The failure of any such person to comply with any provisions of the Act, or any of the provisions of the regulations or standards in this subchapter, shall constitute grounds for automatic termination of such license or for its suspension or revocation by the Secretary.

4. Section 2.3 (9 CFR 2.3) is revised as follows:

§ 2.3 Demonstration of compliance with standards.

Each applicant must demonstrate that his premises and any facilities or equipment used in his business comply with the standards set forth in Part 3 of this subchapter. Upon request by the Veterinarian in Charge, the applicant must make his premises, facilities, and equipment available at a time or times mutually agreeable to said applicant and Veterinary Services representative for the purpose of ascertaining compliance with said standards. If the applicant's premises, facilities, or equipment do not meet the requirements of the standards, the applicant will be advised of existing deficiencies and the corrective measures that must be taken and completed to bring such premises, facilities, and equipment into compliance with the standards.

5. Section 2.4 (9 CFR 2.4) is revised as follows:

§ 2.4 Issuance of licenses.

Except as otherwise provided in §§ 2.10, and 2.11, a license will be issued to any applicant when the requirements of §§ 2.1, 2.2, and 2.3 have been met, when the Secretary has determined that the applicant's premises, facilities, and equipment comply with the standards and when the applicant has submitted to the Veterinarian in Charge the annual fee as prescribed in § 2.6 by certified check, cashier's check, personal check, or money order.

6. Section 2.5 (9 CFR 2.5) is revised to read as follows:

§ 2.5 Duration of license.

(a) A license issued under this part shall be valid and effective unless:

(1) Said license has been revoked or suspended pursuant to section 19 of the Act.

(2) Said license is voluntarily terminated upon the request of the licensee in writing to the Veterinarian in Charge.

(b) Failure by a licensee to pay the annual license fee as required by §§ 2.1 and 2.6 or to file the annual report as required by § 2.7 on or before the anniversary date of his license shall result in automatic termination of the license: *Provided, however,* That prior to such termination the licensee shall be given notice and opportunity to comply with the annual license fee and reporting requirements. Failure to comply with the annual license fee and reporting requirements within 60 days from receipt of such notice shall result in automatic termination of license.

(c) A license which is invalid under paragraph (a) of this section shall be surrendered to the Veterinarian in Charge in the State where the license was issued.

7. Section 2.6 (9 CFR 2.6) is amended by revising paragraph (a) to read as set forth below and by deleting paragraph (f).

§ 2.6 Annual license fees.

(a) In addition to the fee required to be paid upon application for a license under § 2.4, each licensee shall submit to the Veterinarian in Charge the annual fee prescribed in this section, by

certified check, cashier's check, personal check, or money order, on or before each anniversary date of his license.

* * * * *

8. Section 2.7(b) (9 CFR 2.7(b)) is revised as follows:

* * * * *

(b) A person licensed as a dealer shall set forth in his annual report the dollar amount of business, upon which the license fee is based, from the sale of animals, directly or through an auction sale, to research facilities for research, testing, experimentation, or teaching purposes; dealers; exhibitors; retail pet stores; and persons for use as pets, by the licensee during the preceding business year (calendar or fiscal) and such other information as may be required thereon.

9. Section 2.10 (9 CFR 2.10) is revised to read as follows:

§ 2.10 Licensees whose license have been suspended or revoked or terminated automatically.

Any person whose license has been suspended for any reason shall not again be licensed in his own name or in any other manner within the period during which the order of suspension is in effect, and any person whose license has been revoked shall not be eligible to apply for a new license in his own name or in any other manner for a period of 1 year from the effective date of such revocation. No partnership, firm, corporation, or other legal entity in which any such person has a substantial financial interest, will be licensed during such period. Any person who desires the reinstatement of a license which has automatically terminated must follow the procedure applicable to new licensees as explained in § 2.1.

PART 3—STANDARDS

10. Subpart F in the Table of Contents of Part 3—STANDARDS of Title 9, CFR, is amended to read as follows:

Subpart F—Specifications for the Humane Handling, Care, Treatment, and Transportation of Warmblooded Animals Other Than Dogs, Cats, Rabbits, Hamsters, Guinea Pigs, Nonhuman Primates, and Marine Mammals.

Facilities and Operating Standards

Sec.
3.125 Facilities, general.
3.126 Facilities, indoor.
3.127 Facilities, outdoor.
3.128 Space requirements.

Animal Health and Husbandry Standards

3.129 Feeding.
3.130 Watering.
3.131 Sanitation.
3.132 Employees.
3.133 Separation.
3.134 Veterinary care.
3.135 Handling.

Transportation Standards

3.136 Consignments to carriers and intermediate handlers.
3.137 Primary enclosures used to transport live animals.
3.138 Primary conveyances (motor vehicle, rail, air, and marine).
3.139 Food and water requirements.
3.140 Care in transit.
3.141 Terminal facilities.
3.142 Handling.

§ 3.1, 3.25, 3.50, 3.75, 3.100 and 3.125. [Amended]

11. In §§ 3.1(a), 3.25(a), 3.50(a), 3.75(a), 3.100(a), and 3.125(a) wherever the reference to "housing facilities" appears, the reference "indoor and outdoor housing facilities" is substituted therefor.

§ 3.11 [Amended]

12. Section 3.11(c) of the standards (9 CFR 3.11(c)) is revised to read as follows:

* * * * *

(c) Carriers or intermediate handlers whose facilities fail to meet the minimum temperature allowed by the standards, may accept for transportation or transport, in commerce, any live dog or cat consigned by any department, agency, or instrumentality of the United States or of any State or local government, or by any person (including any licensee or registrant under the Act, as well as any private individual) if the consignor furnishes to the carrier or intermediate handler a certificate executed by a veterinarian accredited by this Department pursuant to Part 160 of this title on a specified date which shall not be more than 10 days prior to delivery of such dog or cat for transportation in commerce, stating that such live dog or cat is acclimated to air temperatures lower than those prescribed in §§ 3.16 and 3.17. A copy of such certificate shall accompany the shipment to destination. The certificate shall include at least the following information:

(1) Name and address of the consignor;

(2) Tag number or tattoo assigned to each dog or cat pursuant to §§ 2.50 and 2.54 of the regulations;

(3) A certifying statement (e.g., "I hereby certify that the animal(s) in this shipment is (are), to the best of my knowledge, acclimated to air temperatures lower than 7.2° C. (45° F.)."); and

(4) The signature of the USDA accredited veterinarian, assigned accreditation number and date.

* * * * *

§ 3.12 [Amended]

13. Section 3.12(c) (9 CFR 3.12(c)) is revised to read as follows:

* * * * *

(c) Primary enclosures used to transport live dogs and cats shall be large enough to ensure that each animal contained therein has sufficient space to turn about freely in a standing position using normal body movements, to stand and sit erect, and to lie in a natural position.

* * * * *

§ 3.35 [Amended]

14. Section 3.35(c) of the standards (9 CFR 3.35(c)) is revised to read as follows:

* * * * *

(c) Carriers or intermediate handlers whose facilities fail to meet the minimum temperature allowed by the standards may accept for transportation or transport, in commerce, any live hamster consigned by any department, agency, or instrumentality of the United States or of any State or local government, or by any person (including any licensee or registrant under the Act, as well as any private individual) if the consignor furnishes to the carrier or intermediate handler a certificate executed by a veterinarian accredited by this Department pursuant to Part 160 of this title on a specified date which shall not be more than 10 days prior to delivery of such hamster for transportation in commerce, stating that such live hamster is acclimated to air temperatures lower than those prescribed in §§ 3.40 and 3.41. A copy of such certificate shall accompany the shipment to destination. The certificate shall include the following information:

(1) Name and address of the consignor;

(2) The number of hamsters in the shipment;

(3) A certifying statement (e.g., "I hereby certify that the animal(s) in this shipment is (are), to the best of my knowledge, acclimated to air temperatures lower than 7.2° C. (45° F.)."); and

(4) The signature of the USDA accredited veterinarian, assigned accreditation number, and date.

* * * * *

§ 3.60 [Amended]

15. Section 3.60(c) of the standards (9 CFR 3.60(c)) is revised to read as follows:

* * * * *

(c) Carriers or intermediate handlers whose facilities fail to meet the minimum temperature allowed by the standards may accept for transportation or transport, in commerce, any live rabbit consigned by any department, agency, or instrumentality of the United States or of any State or local government, or by any person (including any licensee or registrant under the Act, as well as any private individual) if the consignor furnishes to the carrier or intermediate handler a certificate executed by a veterinarian accredited by this Department pursuant to Part 160 of this title on a specified date which shall not be more than 10 days prior to delivery of such rabbit for transportation in commerce, stating that such live rabbit is acclimated to air temperatures lower than those prescribed in §§ 3.65 and 3.66. A copy of such certificate shall accompany the shipment to destination. The certificate shall include at least the following information:

(1) Name and address of the consignor;

(2) The number of rabbits in the shipment;

(3) A certifying statement (e.g., "I hereby certify that the animal(s) in this shipment is (are), to the best of my knowledge, acclimated to air temperatures lower than 7.2° C. (45° F.).)"; and

(4) The signature of the USDA accredited veterinarian, assigned accreditation number, and date.

* * * * *

§ 3.85 [Amended]

16. Section 3.85(c) of the standards (9 CFR 3.85(c)) is revised to read as follows:

* * * * *

(c) Carriers or intermediate handlers whose facilities fail to meet the minimum temperature allowed by the standards may accept for transportation or transport, in commerce, any live nonhuman primate consigned by any department, agency, or instrumentality of the United States or of any State or local government, or by any person (including any licensee or registrant under the Act, as well as any private individual) if the consignor furnishes to the carrier or intermediate handler a certificate executed by a veterinarian accredited by this Department pursuant to Part 160 of this title on a specified date which shall not be more than 10 days prior to delivery of such nonhuman primate for transportation in commerce, stating that such live nonhuman primates is acclimated to air temperatures lower than those prescribed in §§ 3.90 and 3.91. A copy of such certificate shall accompany the shipment to destination. The certificate shall include the following information:

(1) Name and address of the consignor;

(2) The number of nonhuman primates in the shipment;

(3) A certifying statement (e.g., "I hereby certify that the animal(s) in this shipment is (are), to the best of my knowledge, acclimated to air temperatures lower than 7.2° C. (45° F.)"); and

(4) The signature of the USDA accredited veterinarian, assigned accrediation number, and date.

* * * * *

§ 3.112 [Amended]

17. Section 3.112(c) of the standards (9 CFR 3.112(c)) is revised to read as follows:

* * * * *

(c) Carriers or intermediate handlers whose facilities fail to meet the minimum temperature allowed by the standards may accept for transportation or transport, in commerce, any marine mammal consigned by any department, agency, or instrumentality of the United States or of any State or local government, or by any person (including any licensee or registrant under the Act, as well as any private individual) if the consignor furnishes to the carrier or intermediate handler a certificate executed by a veterinarian accredited by this Department pursuant to Part 160 of this title on a specified date which shall not be more than 10 days prior to delivery of such animal for transportation in commerce, stating that such marine mammal is acclimated to air temperatures lower than those prescribed in §§ 3.117 and 3.118. A copy of such certificate shall accompany the shipment to destination. The certificate to include at least the following information:

(1) Name and address of the consignor;

(2) The number of animals in the shipment;

(3) A certifying statement (e.g., "I hereby certify that the animal(s) in this shipment is (are), to the best of my knowledge, acclimated to air temperatures lower than 7.2° C. (45° F.)"); and

(4) The signature of the USDA accredited veterinarian, assigned accreditation number, and date.

* * * * *

§ 3.136 [Amended]

18. Section 3.136(c) of the standards (9 CFR 3.136(c)) is revised to read as follows:

* * * * *

(c) Carriers or intermediate handlers whose facilities fail to meet the minimum temperature allowed by the standards may accept for transportation or transport, in commerce, any live animal consigned by any department, agency, or instrumentality of the United States or of any State or local government, or by any person (including any licensee or registrant under the Act, as well as any private individual) if the consignor furnishes to the carrier or intermediate handler a certificate executed by a veterinarian accredited by this Department pursuant to Part 160 of this title on a specified date which shall not be more than 10 days prior to delivery of such animal for transportation in commerce, stating that such live animal is acclimated to air temperatures lower than those prescribed in §§ 3.141 and 3.142. A copy of such certificate shall accompany the shipment to destination. The certificate shall include at least the following information:

(1) Name and address of the consignor;

(2) The number of animals in the shipment;

(3) A certifying statement (e.g., "I hereby certify that the animal(s) in this shipment is (are), to the best of my knowledge, acclimated to air temperatures lower than 7.2° C. (45° F.)"); and

(4) The signature of the USDA accredited veterinarian, assigned accrediation number, and date.

* * * * *

PART 160—DEFINITION OF TERMS

§ 160.1 [Amended]

19. Section 160.1(d) (9 CFR 160.1(d)) is amended to read as follows:

* * * * *

(d) "Accredited Veterinarian." [1] A veterinarian approved by the Deputy Administrator in accordance with the provisions of Part 161 of this subchapter to perform functions specified in Parts 1, 2, 3, and 11 of Subchapter A, and Subchapters B, C, and D of this chapter, and to perform functions required by cooperative State-Federal disease control and eradication programs.

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PART 161—REQUIREMENTS AND STANDARDS FOR ACCREDITED VETERINARIANS AND SUSPENSION OR REVOCATION OF SUCH ACCREDITATION

§ 161.2 [Amended]

20. Section 161.2(b) [9 CFR 161.2(b)] is amended to read as follows:

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(b) An accredited veterinarian shall not sign any certificate, form, record or report, or permit such a certificate, form, record, or report to be used until, and unless, he has ascertained that it has been accurately and fully completed clearly identifying the animal(s) or bird(s) to which it applies and showing the results of the inspection, test, or vaccination, etc., he has conducted, except as provided in paragraph (c) of this section. An accredited veterinarian shall not sign any certificate provided for by the Animal Welfare Act or its regulations and standards unless he has ascertained that the statements contained therein are complete, clear and accurate. The accredited veterinarian shall distribute copies of certificates, forms, records and reports, according to instructions issued to him by the Veterinarian in Charge or the State Animal Health Official.

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§ 161.2 [Amended]

21. Section 161.2(h) [9 CFR 161(h)] is amended to read as follows:

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(h) An accredited veterinarian shall keep himself currently informed on Federal and State regulations governing the movement of animals and poultry, and on procedures applicable to disease control and eradication programs, including emergency programs, and on definitions, regulations, and standards under the Animal Welfare Act, and any legislation amendatory thereof, and on regulations under the Horse Protection Act of 1970, and any legislation amendatory thereof. He shall carry out all of his responsibilities under the applicable Federal programs and cooperative programs in accordance with such regulations and instructions issued to him by the Veterinarian in Charge or the State Animal Health Official, or both.

It does not appear that further 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 further notice and other public procedure with respect to these amendments are impracticable and unnecessary.

This final rule has been reviewed under the USDA criteria established to implement Executive Order 12044, "Improving Government Regulations." A determination has been made that this action should not be classified "significant" under those criteria. An Approved Final Impact Statement is available from the Deputy Administrator, USDA, APHIS, VS, Room 703, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782.

Done at Washington, D.C., this 31st day of October 1979.

Pierre A. Chaloux,

Deputy Administrator, Veterinary Services.

[FR Doc. 79-34081 Filed 11-1-79; 8:45 am]

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Part IX

Department of Agriculture

Food and Nutrition Service

Food Stamp Program: 1979 Amendments on Social Security Numbers, Fraud, and Group Homes

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Parts 271, 272, 273, and 278

[Amdt. No. 154]

1979 Amendments to the Food Stamp Act of 1977: Provision of Social Security Numbers; Fraud Disqualification and Recoupment; and Group Living Arrangements

Note.—This document originally appeared in the Federal Register for Wednesday, October 31, 1979. It is reprinted in this issue to meet requirements for publication on an assigned day of the week. (See OFR notice 41 FR 32914, August 6, 1976.)

AGENCY: Food and Nutrition Service.

ACTION: Proposed rule.

SUMMARY: This proposed rulemaking amends the regulations, published October 17, 1978 (43 FR 47846), which implemented major portions of the Food Stamp Act of 1977. All of the amendments proposed in this rulemaking are the result of changes in the Food Stamp Act brought about by the enactment of Pub. L. 96–58, 93 Stat. 389, August 14, 1979.

The amendment sets forth procedures by which social security numbers will be obtained for all members of food stamp households as authorized by Section 4 of Pub. L. 96–58. That section amended the Food Stamp Act of 1977 to enable the Department to require as a condition of eligibility for participation in the Food Stamp Program, that each household member furnish to the State agency their social security account number or numbers.

In addition, this proposal would amend the regulations so that individuals subject to disqualification from program participation for fraudulent conduct would be required to agree to either a reduction in the household's food stamp allotment or to a repayment in cash in order to again participate in the Food Stamp Program as mandated by Section 5 of Pub. L. 96–58.

This proposal would also amend Part 273 to permit each State agency to retain 50 percent of the value of all funds or allotments recovered or collected through prosecutions or other State activities directed against individuals who fraudulently obtain food stamp allotments to reflect changes brought about by Section 6 of Pub. L. 96–58. The proposed rulemaking also sets forth procedures for implementing a provision for certain blind and disabled residents of State certified small group living arrangements to participate in the Food Stamp Program as mandated by Sections 7 and 8 of Pub. L. 96–58.

DATE: Comments must be received on or before December 17, 1979, in order to be assured of consideration. The Department is under a statutory mandate to issue final rulemaking on the changes dealing with social security numbers, fraud disqualification and recoupment 150 days from the date the law was enacted, August 14, 1979. Because of this mandate, Robert Greenstein, Administrator, Food and Nutrition Service, has determined that there be a 45-day comment period; a 60-day comment period would preclude the Department from meeting the mandated time for publishing final rules. While the changes by Sections 7 and 8 of Public Law 96–58 are not under the same legislative deadline, the Department believes that the legislative intent was for expeditious processing of all changes required by the amendments. Consequently, these changes were included as part of the proposed rulemaking on Sections 4 through 6 of the statute. The Department urges interested parties to comment as early as possible within the 45 day comment period since comment analysis must begin immediately after the comment period in order to publish final rules within 150 days of enactment. The Department will carefully review all comments received by the 45th day and will give them serious consideration before final rulemaking is published. The Department cannot guarantee consideration of comments received after the 45th day.

ADDRESS: Comments should be submitted to: Alberta C. Frost, Acting Deputy Administrator for Family Nutrition Programs, Food and Nutrition Service, USDA, Washington, D.C. 20250. All written comments will be open to public inspection at the offices of the Food and Nutrition Service during regular business hours (8:30 a.m. to 5:00 p.m., Monday through Friday) at Room 678, 500 12th Street, SW, Washington, D.C.

FOR FURTHER INFORMATION CONTACT: Susan McAndrew, Chief, Program Standards Branch, Program Development Division, Food and Nutrition Service, Washington, D.C. 20250. Phone (202) 447–6535.

SUPPLEMENTARY INFORMATION:

Social Security Numbers

Provision of social security numbers. Public Law 96–58 amended the Food Stamp Act of 1977 to allow the Secretary to require, as a condition of eligibility for participation in the Food Stamp Program, that each household member furnish to the State agency their social security number (SSN) (or numbers, if they have more than one.)

In addition, this amendment specifically allows State agencies to use social security numbers "in the administration of the Food Stamp Program" and grants the Secretary and State agencies the same access to data pertaining to Supplemental Security Income (SSI) recipients as the access provided to the Security of the Department of Health, Education and Welfare (DHEW) to the extent the Secretary and the Secretary of DHEW determine necessary for the purpose of determining or auditing a household's eligibility to receive assistance or the amount thereof under the program or verifying information related thereto.

Implementation. Although the legislation does not mandate a specific implementation date, it does require that final regulations implementing Section 4 of the act be issued within 150 days after the date of enactment. In keeping with Congress' mandate to promulgate these regulations expeditiously, the Department proposes that State agencies begin obtaining household members' SSN's as soon as possible after final rules are published, but no later than 120 days from the date of publication of final rules. It is the Department's opinion that the impact of obtaining SSN's for food stamp applicants and/or participants will be lessened since SSN's are already available for significant portions of the food stamp caseload. For that portion of the caseload which also receives public assistance (PA) there will already be recorded SSN's for all household members since this is already a requirement for PA households. In addition, individuals receiving social security or SSI benefits and the working members of non-assistance households will also have SSN's. The Department estimates that less than half the food stamp caseload will not have or will not know their SSN's. The Department is proposing that State agencies obtain individuals' SSN's at the time of application, recertification or at any office contact. This would eliminate the need for a massive desk review effort and gives State agencies an opportunity to gradually meet this requirement; this should avoid seriously increasing a State agency's workload.

Requiring the SSN as a condition of eligibility. The amendment states that "the Secretary and State agencies may (1) require, as a condition of eligibility for participation in the Food Stamp

Program, that each household member furnish to the State agency their social security account numbers * * *

In proposing that social security numbers be required as a condition of eligibility, the Department researched the Congressional intent in passing this amendment. It is clear from the legislation background that Congress views the requiring of an SSN as a condition of eligibility as an antifraud provision (Cong. Rec. July 27, 1979 p. S10778). The intent is to use social security numbers in computer matching and other techniques to prevent duplicate participation and to allow States to more readily identify those households that have unreported earnings or have reported their earnings incorrectly (Cong. Rec. July 27, 1979, p. S10779). The Department shares the concerns of Congress expressed in the legislative history and is therefore proposing to mandate the requiring of SSN's as a condition of eligibility.

While it is clear, as explained above, that obtaining household members' SSN's must be a requirement for applicants and participants, it is also apparent that Congress intended that provisions be made to allow an individual's participation pending receipt of an SSN from the Social Security Administrative (SSA). In Cong. Rec. August 2, 1979 H7067, it is stated that individuals not previously assigned a social security number would be eligible to participate while waiting for the SSN to be assigned, as long as the individuals apply for and susequently furnish SSN's. Congress also specifically indicated that individuals entitled to expedited service would be permitted to furnish a social security number after receiving their first allotment: this is intended to avoid delay in benefits simply because a social security number cannot be immediately furnished (Cong. Rec. August 2, 1979, H7076). Consequently, the Department is proposing that any household member who does not have an SSN, does not know the SSN, or does not know if he or she has an SSN, and does apply for the SSN, may continue to participate for 90 days pending receipt of the number. The Department researched with SSA the length of time it takes to process an paplication for an SSN. Based on study information, the average processing time from the completion of the application for an SSN to the date of SSN issuance is approximately 31 days. However, because the processing time may vary depending on the difficulty in obtaining required verification and on the particular office handling the application, the Department believes that the proposed 90 day time frame (for participation pending receipt) is needed to allow ample time.

In this situation the Department feels it is justifiable to ask individuals to provide documentation that they have, in fact, applied for and SSN and why it is delayed (e.g. problems with locating a birth certificate etc.) and this is reflected in the proposed rules. As long as the individual has applied for an SSN and has provided SSA, to the best of ability, with all necessary information, it is the Department's opinion that the household member should not be penalized for processing delays and thus may continue to participate. Further, a household's certification will not be delayed solely to validate an SSN provided for any household member. The Department is proposing that as soon as all other steps necessary for certification have been completed a household must be certified rather than wait for validation of a social security number. If all other certification steps are completed in less than 30 days, the household should be certified at that point, rather than be required to wait until later in the 30 day period because the State agency has not completed validation of an SSN.

Obtaining and verifying the SSN. The proposed rules state that for those household members who have an SSN, the State agency shall, at the time of application, recertification, or any office contact, record the SSN and verify it either by matching the reported number with computer tapes from SSA (such as BENDEX or SDX tapes) or printouts from SSA, or by viewing a document with the social security number on it, (such as a driver's license, or a social security card). It is the Department's opinion, after discussion with SSA, that verification of the SSN is important; reporting the numbers verbally often results in inaccurate transcription and if there is anything questionable about an SSN it should be completely validated to avoid the confusion caused by an incorrect SSN. Once an SSN has been validated, verification must be recorded by the State agency to prevent the need for reverification in the future.

The Department is proposing two possible procedures for obtaining SSN's of household members who do not have a number, do not know their SSN or do not know if they have a number. The individual needing an SSN may either apply for the number directly at the SSA office or the State agency can offer to complete the application for a social security number, Form SS-5, and note on the SS-5 the documentation provided by the individual as verification of identity, age, and citizenship/alien status. However, the latter procedure shall only be used in States which have a agreement with SSA which allows the States to take the SS-5 application and record the necessary verification in the same way an SSA staff person does in their District Offices. Currently, 33 State agencies have such an agreement with SSA and handle obtaining SSN's for AFDC and/or medicaid in this manner. These States will need to renegotiate their agreements with SSA since most of the existing agreements apply only to AFDC and/ medicaid. The remaining State agencies require their clients for those two programs to apply directly at SSA offices. The Department does want to offer the household members all assistance possible in meeting the SSN requirement and consequently proposes that, when individuals opt to apply directly to SSA, the State agency inform the individual where to apply and discuss with them what they will need to present as evidence of identity, age, and citizenship or alien status.

Failure to comply. The legislative background to the amendment clearly indicates the Congressional intent relative to those individuals failing to comply with this requirement. In the Cong. Rec. August 2, 1979, p. H7067, it is stated that the provision requiring social security numbers as a condition of eligibility

> * * * would permit an individual to be barred from receiving food stamps if that individual had been assigned a social security number, but refused to provide it to the State agency. Individuals not previously assigned a social security number could also be prevented from participating unless the individual applied for and subsequently furnished a social security number. The income and resources of the individual disqualified for failure to provide a social security number would be counted in the same way an individual's income and resources are counted when a person is disqualified for fraud or for failure to meet the student work registration requirement during the school year.

The proposed regulations follow the Congressional intent. In addition, the Department is proposing a good cause provision. It is the Department's position that household members should not be penalized when they have applied for an SSN, and through no fault of their own, do not receive it in a timely manner. Consequently, if the State agency determines that a household member has been unable to obtain an SSN, with good cause, that individual will not be disqualified. Examples of good cause would include a delay in SSA processing the application for an SSN, a delay in obtaining a birth certificate, a

delay in obtaining alien status papers, etc.

The Department discussed with SSA whether or not all legal aliens can obtain an SSN. Currently, SSA issues SSN's to aliens admitted for permanent residence, for refugees, and for those legal temporary aliens who are given employment authorization by the Immigration and Naturalization Service (INS). Legal temporary aliens who do not have documentation to show that they are "employment authorized" are only issued SSN's when they have valid nonwork reasons.

Preliminary discussions with SSA indicate that eligibility for food stamps would be considered a justification for a legal temporary alien to be issued an SSN.

Use of SSN. The Department believes it was Congress' intent that SSN's be used as an antifraud device. The legislative background indicates that Congress envisioned State agencies using the SSN's to prevent duplicate participation and to detect underreported or unreported income by matching reported income against data from other federal programs.

The amendment, as enacted, specifies that State agencies shall have the same access that has been provided to HEW to the information regarding individual food stamp program applicants and participants who receive benefits under title XVI of the Social Security Act, provided that the Secretary of DHEW concurs that access to SSI information is within the purposes set forth in the statute. This access will enable State agencies to determine SSI households' eligibility to receive benefits, the amount of the benefits and to verify reported income information. The proposed regulations provide for this type of suage of SSN's.

Mass changes. The Department believes that prompt implementation of the SSN requirement will greatly facilitate making mass changes, specifically the SSI and social security cost-of-living changes which occur annually. In the past, some States have made cost-of-living increases for recipients of social security and SSI benefits automatically while other have made such changes on an as reviewed or as reported basis. This has resulted in a lack of uniformity and inequity in benefit levels since some individuals' benefits were reduced more quickly than others. Because of the availability of information on these changes from SSA, by social security number, the Department expects mass changes in social security and SSI benefits to be reflected more promptly. Therefore, tighter time frames for making these changes are incorporated into this proposal. For the July 1980 changes, States must adjust benefit levels within 180 days and beginning in July 1981, within 90 days. If, by July 1980, all cases containing individuals who receive SSI or social security benefits, have not had SSN's obtained or recorded through recertification or any office contact, the State agency will have to identify these individuals by means of a desk review. The desk review will serve to identify individuals for whom SSN's are needed and will allow the State agency to contact these individuals and obtain their SSN's for use in making the annual cost-of-living increase adjustments. Since all individuals receiving social security or SSI will already have SSN's, obtaining them for food stamp purposes should be neither costly nor time consuming. The Department expects that the availability of SSN's in the future will readily identify persons affected by benefit changes from other programs as well, since SSN's are widely used as an identifier. The use of SSN's to make changes for increases in social security and SSI benefits is of particular significance given the cost constraints on the program.

The Department's proposal to allow 180 days for the July 1980 changes and 90 days thereafter is designed to allow State agencies which cannot make these changes by computer to schedule recertifications for households with SSI or social security income during these periods.

Fraud Disqualification and Recoupments

Section 5 of Pub. L. 96-58 amends Section 6(b) of the Food Stamp Act of 1977 to provide that following any disqualification from the program for fraud no individuals shall be eligible to participate in the program unless he or she agrees to repayment of the fraudulently received benefits. Repayment may be made through either a reduction in the allotment the household would otherwise receive or through repayment in cash, in accordance with a reasonable schedule, over a period of time sufficient to reimburse the amount of the fraudulently received benefits. If the individual elected repayment in cash but failed to meet the repayment schedule, the household is subject to appropriate allotment reductions.

Implementation. State agencies would implement the program changes contained in this proposal on fraud disqualification and recoupments on or before July 1, 1980. Within 120 days of implementation the Food and Nutrition Service would begin returning to each State agency 50 percent of the value of all funds or allotments recovered or collected through prosecution or other State activities directed against individuals who fraudulently obtain food stamps.

Disqualification for failure to repay. If the individual who committed fraud does not agree to a reduction in the household's allotment or does not agree to pay the fraud claim in cash, this proposed rulemaking would allow the State agency to disqualify the individual until the person agrees to repay in cash or agrees to the allotment reduction. The household would be sent an agreement letter at the time of disqualification, and a follow-up letter sent the month prior to the end of the disqualification period if the household failed to respond initially. The period of disqualification would then be extended immediately if the household again failed to respond. The income and resources of the individual disqualified for failure to repay the fraud claim would be counted in the same way an individual's income and resources are currently counted when that person is disqualified for fraud or for failure to meet the student work registration requirement during the school year. The income of the disqualified member is prorated and the amount, less the disqualifed member's share, is considered available to the remaining members. The disqualified members resources are considered available in total.

Collection of fraud claims. In order to collect fraud claims, States must currently rely on voluntary repayment by the household or incur the expense of initiating a civil court action to obtain repayment. The 1979 Amendments provide, through allotment reduction, a simple and efficient mechanism for collecting fraud claims if the household cannot or will not make cash repayments. As a result, it is anticipated that the percentage of fraud claims collected will substantially increase without increasing the administrative costs of collecting these claims. These collection procedures should also discourage persons from committing fraud.

State share of recovery. States are currently required to return to the Federal Government all funds collected from housedholds that have repaid the value of any food stamps overissued to them. The Food Stamp Act Amendments of 1979 revise Section 16(a) of the Food Stamp Act of 1977 to allow each State to retain 50 percent of the funds it recovers or collects from persons that have committed fraud as determined in accordance with the Food Stamp Act of 1977. This provision will provide an

incentive for States to pursue collection of fraud claims, particularly in those cases where recoupment of disqualification is currently ineffective because the household is ineligible.

The Department is proposing a new method for States to submit funds recovered from all types of overissuances. States would no longer forward checks to FNS for overissuance recoveries. The letter of credit would be amended quarterly to reflect 50 percent retention of funds recovered from fraud claims and to reflect the full value of nonfraud claims which are still fully payable to FNS. If needed, the letter of credit would also be adjusted to reflect recovery of funds from claims resulting from State negligence. States would continue to report claims on Form FNS-209, Status of Claims Against Households. The amount of fraud claims would be indicated on the FNS-209 and on other letter of credit documents as required by FNS. This new method will permit States to retain funds to meet administrative costs until such time as the letter of credit is adjusted.

This proposal, in accordance with the 1979 amendments, also provides that persons involved in making fraud determinations are not to benefit from the amount of such recoupments or collections. This prohibition on the use of revenues collected in this manner will assure the impartiality of officials making fraud adjudications.

Repayment schedules. As discussed earlier, the 1979 Amendments direct the Secretary to establish a reasonable restitution schedule, either through cash repayment or recoupment through allotment reduction, that will be sufficient over time to reimburse the Federal Government for the value of fraudulently obtained food stamps.

If the individual agrees to a repayment in cash, the Department proposes that the claim be collected in full if the individual is financially able to pay the indebtedness in one lump-sum. If, however, the individual is financially unable to pay the indebtness in one lump-sum, the Department suggests that installment payments be accepted that are at least equal to the minimum allotment for the size of the household of which such individual is a member.

In developing a recoupment schedule, the Department considered three options: recoupment of a flat percentage of the food stamp allotment; recoupment of any amount over and above the minimum bonus; and recoupment of the whole allotment. The Department proposes to recoup a flat percentage of the food stamp allotment, primarily because it is a uniform standard and employs a single mathematical calculation. A flat percentage also has the advantage of encouraging households to continue program participation, thereby ensuring that the overissuances are recovered. The Department is proposing that 25 percent of the food-stamp allotment be recouped, except in special circumstances, but welcomes comments on this particular issue as we recognize that this proposal is of substantial concern.

In the event the household member found guilty of fraud joins another food stamp household, the Department proposes that the State agency initiate collection action against the household containing the fraudulent individual. This proposal conforms most closely to the language in the law which states that no disqualified individual shall be eligible to participate in the Food Stamp Program unless such individual agrees to a reduction in the allotment of the household of which such individual is a member.

In addition, the Department proposes that when a court of appropriate jurisdiction fails to specify a specific disqualification period for fraudulent conduct that a six-month disqualification period be employed since the Food Stamp Act of 1977 mandates a period of not less than six and not more than twenty-four months. This change is proposed to make the processing of court-handled cases more equitable with that of fraud cases processed through administrative hearings. A period of disqualification is always imposed where guilt is established in fraud hearings. This is also proposed to more closely follow the legislative history of the 1977 Act which indicates that persons committing fraud should be subject to separate actions-punishment and recovery.

Administrative fraud hearing. It has come to the Department's attention that some State agencies are not vigorously applying the administrative fraud hearing provisions specified in Section 273.16(d) of the Food Stamp Regulations. Some State agencies are choosing to interpret this regulatory language as being discretionary permitting them to either conduct or refuse to conduct administrative fraud hearings at their option on a Statewide basis. Regardless, this system is mandated and must be available for use.

The Department recognizes that there have been factors influencing State agency hesitancy to pursue fraud hearings in the past. However, with the new provisions on recoupment as a method of overissuance recovery as well as the 50 percent payment to the State for monies recovered, additional incentives to pursue fraud hearings will be in place. One additional change the proposed regulations will permit is that administrative fraud hearings for currently ineligible participants be initiated by the State agency to substantiate fraud and that a period of disqualification be instituted if the household member ever becomes eligible for the program again.

Likewise, because the Department recognizes that some State agencies are concerned about the cost of conducting an administrative fraud hearing and have suggested that the $35 limit, below which fraud hearings could not be conducted, be raised, the Department will accept comments on the limit to be imposed. These comments will be carefully considered in determining the amount below which fraud hearings would not be conducted.

It is hoped that intensive public scrutiny will assist the Department in drafting final regulations. In formulating comments, particular attention should be given in the area of percentages of allotments to be recouped. However, comments on all aspects of the proposed rules will be considered. In reading this proposed rulemaking on collection of fraud claims, it will be useful to refer to other rulemakings of the Department. These other publications are the final rules implementing major aspects of the Food Stamp Act of 1977 published on October 17, 1978, (43 FR 47846) and the preamble to the May 2, 1978 proposal (43 FR 18874).

Group Living Arrangements

One of the objectives of the 1979 amendments to the Food Stamp Act of 1977 is to provide that certain disabled or blind residents of State certified small group living arrangements are permitted to participate in the Food Stamp Program if otherwise eligible. These disabled or blind residents must be receiving social security benefits under title II (Social Security Disability) or title XVI (Supplemental Security Income—SSI), and they must be living in a public or private nonprofit group living arrangement that serves no more than sixteen residents and is certified by the appropriate State agency under regulations issued under Section 1616(e) of the Social Security Act.

In reading this proposed rulemaking on the group living arrangement provisions in the 1979 amendments to the Food Stamp Act of 1977, it will be helpful to refer to other rulemakings of the Department.

These other publications are the final rules implementing major aspects of the Food Stamp Act of 1977 published on October 17, 1978; the regulations

pertinent to Authorized Firms published on September 22, 1978 (43 FR 43272) and Food Stamps' Miscellaneous Amendments and interpretations published on June 8, 1979 (44 FR 33380). This is of particular significance since treatment of these households has been structured much the same as for residents of drug and alcoholic treatment facilities in keeping with legislative intent. Among the provisions carried over from the treatment facilities regulations are the disqualification of group homes found to have misappropriated coupons.

Implementation. The 1979 Amendments to the Food Stamp Act of 1977 require that the provision for certain disabled or blind residents of State certified small group living arrangements to be able to participate in the Food Stamp Program be implemented in all States by July 1, 1980.

Definitions. The Department proposes to amend definitions in Part 271 concerning: "Eligible food", and "Retail food store" and to added a new definition: "Group living arrangement."

Eligible food. A revision similar to the one described above is proposed to provide that meals prepared for elderly persons or SSI recipients, or both, are eligible foods. In addition, the eligible foods definition is revised to include, as eligible food, meals prepared for blind or disabled residents by authorized group living arrangement facilities. Public Law 96-58 calls for the participation of group living arrangements in the Program.

Group Living Arrangements. The Department has taken the definition of group living arrangements from Pub. L. 96-58 and has added a provision that group living arrangement facilities provide care and/or protective oversight for their residents. The regulations would require that group living arrangement facilities must provide care or protective oversight for no more than sixteen residents and must be certified by the appropriate State agency or agencies under regulations issued under section 1616(e) of the Social Security Act. Additionally, these residents must be receiving benefits under social security disability (title II) or Supplemental Security Income—SSI (title XVI)—of the Social Security Act.

Purpose. The proposed regulations provide for certain disabled or blind residents of State certified small group living arrangement facilities to participate in the Food Stamp Program under the same conditions currently in effect for drug addicts and alcoholics in residential treatment programs.

The proposed regulations exempt from the definition of institution public or private nonprofit group living arrangements that serve no more than sixteen residents and that are State certified under regulations issued under section 1616(e) of the Social Security Act. Basic policy is, and has been, that residents of institutions are not eligible because the institution provides all meals to the individual. the intent here is to cover alternatives that come closer to family or household living arrangements in which individuals may assume some responsibility for food purchase and preparation even though these group living arrangement facilities provide care and/or protective oversight over their residents.

Certain disabled or blind residents in these group living arrangements may be able to participate in the Food Stamp Program since they will no longer be considered residents of an institution. However, disabled or blind residents who receive title II or title XVI benefits are not categorically eligible for Food Stamp Program benefits. They must meet all Food Stamp Program eligibility criteria. If eligible, these residents will be certified to participate in the Food Stamp Program as one-person households.

Responsible staff members of group living arrangements facilities will act as authorized representatives for residents. These authorized representatives will make application for and receive and spend the coupon allotments on behalf of eligible residents.

The group living arrangement facility may spend the coupon allotment in authorized retail food stores. If it wishes to redeem food coupons through wholesalers, the group living arrangement facility must be authorized by FNS as a retail food store.

Approval of retail food stores and wholesale food concerns. On June 8, 1979, the Department published final rules which included an amendment stating that alcoholic and drug addiction treatment and rehabilitation programs do not have to be authorized as retail food stores in order for their residents to be certified to participate in the Program. Therefore, treatment and rehabilitation programs will be authorized only if they wish to redeem food stamps through wholesalers. The proposed regulations include this provision. In addition, a paragraph is added to the section on approval of retail food stores to allow the participation of group living arrangement facilities in the program in accordance with Public Law 96-58.

Section 278 is amended to state that group living arrangement facilities authorized as retail food stores may not redeem food stamps at banks.

Therefore, it is proposed that Parts 271, 272, 273, and 278 be amended as follows:

PART 271—GENERAL INFORMATION AND DEFINITIONS

1. In § 271.2 it is proposed that the definitions of "eligible foods" and "retail food store" be amended and a new definition for "group living arrangement" be added to read as follows:

§ 271.2 Definitions

* * * * *

"Eligible foods" means (1) any food or food product intended for human consumption except alcoholic beverages, tobacco, and hot foods and hot food products prepared for immediate consumption; (2) seeds and plants to grow foods for the personal consumption of eligible households; (3) meals prepared and delivered by an authorized meal delivery service to households eligible to use coupons to purchase delivered meals; or meals served by a communal dining facility for the elderly, or SSI households, or both, to households eligible to use coupons for communal dining; (4) meals prepared and served by an authorized drug addict or alcoholic treatment and rehabilitation center to households eligible to use coupons to purchase those meals; (5) meals prepared and served by an authorized group living arrangement facility to residents who are blind or disabled recipients of benefits under title II or XVI of the Social Security Act; and (6) in the case of certain eligible households living in areas of Alsaka where access to food stores is extremely difficult and the households rely on hunting and fishing for subsistence, equipment for the purpose of procuring food for eligible households, including nets, lines, hooks, fishing rods, harpoons, knives, and other equipment necessary for subsistence hunting and fishing but not equipment for the purpose of transportation, clothing, or shelter nor firearms, ammunition or other explosives.

* * * * *

"Group living arrangement" means a public or private nonprofit facility which provides care and/or protective oversight for no more than sixteen disabled or blind residents who are recipients of benefits and under title II (Social Security Disability) or title XVI (Supplemental Security Income (SSI)) of the Social Security Act, and which is certified by the appropriate State agency or agencies under regulations issued

under Section 1616(e) of the Social Security Act.

* * * * *

"Retail food store" means (1) an establishment or recognized department of an establishment, or a house-to-house trade route, whose eligible food sales volume is more than 50 percent staple food items for home preparation and consumption; (2) public or private communal dining facilities and meal delivery services and drug addict or alcoholic treatment and rehabilition programs and public or private nonprofit group living arrangements; (3) any store selling equipment for procuring food by hunting and fishing to eligible households in Alaska, as specified in the definition of eligible food; (4) any private nonprofit cooperative food purchasing venture, including those whose members pay for food prior to receipt of the food; and (5) a farmers' market.

* * * * *

PART 272—REQUIREMENTS FOR PARTICIPATING STATE AGENCIES

2. A new subparagraph (9) is added to § 272.1(g) to read as follows:

§ 272.1 General terms and conditions.

* * * * *

(g) *Implementation.* * * *

(9) *Amendment 154.* State agencies shall implement the program changes required by Amendment 154 as follows:

(i) State agencies shall require social security numbers for all new applications and recertifications no later than 120 days from the date of publication of final rules. Participating households shall be requested to provide or apply for social security numbers (SSN) for all household members at recertification or at the time of office contact for any other reason. For those households which contain individuals receiving social security and/or SSI, and whose recertifications are not scheduled until after July 1980, the State agency, in order to meet the requirements for mass changes as contained in § 273.12(e)(3) as amended, shall review such cases in order to contact those households so that they may obtain SSN's within 180 days from July 1, 1980.

(ii) If any member(s) of a household cannot provide their SSN at the time of application, recertification, or any office contact they shall apply for a SSN in accordance with § 273.6 as amended.

(iii) State agencies shall implement the fraud disqualification procedures and the fraud claim procedures contained in §§ 273.16, 273.17 and 273.18 no later than 120 days from the date of publication of final rules.

(iv) FNS shall return to each State agency 50 percent of the value of all funds or allotments recovered or collected 120 days from the date of publication of final rules through prosecutions or other State activities directed against individuals who fraudently obtained food stamps.

(v) State agencies shall implement the provisions regarding group living arrangements on or before July 1, 1980.

PART 273—CERTIFICATION OF ELIGIBLE HOUSEHOLDS

3. In § 273.1, it is proposed that a new subparagraph (3) be added to § 273.1(e) and subparagraph § 273.1(f)(2) be amended to read as follows:

§ 273.1 Household concept.

* * * * *

(e) *Residents of institutions.* Individuals shall be considered residents of an institution when the institution provides them with the majority of their meals as part of the institution's normal services and the institution has not been authorized to accept coupons. Residents of institutions are not eligible for participation in the program, with the following three exceptions:

* * * * *

(3) Disabled or blind recipients of benefits under title II or title XVI of the Social Security Act who are residents of group living arrangements as defined in § 271.2.

* * * * *

(f) *Authorized representatives.* * * *

(2) *Drug addict/alcoholic treatment centers and group homes as authorized representatives.* Narcotic addicts or alcoholics who regularly participate in a drug or alcoholic treatment program on a resident basis and disabled or blind recipients of benefits under title II or title XVI of the Social Security Act who are residents of group living arrangement facilities as defined in § 271.2 may elect to participate in the Food Stamp Program. The residents shall apply and be certified for program participation through the use of an authorized representatives who shall be an employee of and designated by the private nonprofit organization or institution that is administering the treatment and rehabilitation program or public or private nonprofit group living arrangement. The organization or institution shall apply on behalf of each addict or alcoholic or each disabled or blind resident receiving benefits under title II or title XVI of the Social Security Act and shall receive and spend the coupon allotment for food prepared by and/or served to the addict or alcoholic or disabled or blind resident receiving benefits under title II or title XVI of the Social Security Act. The organization or institution shall also be responsible for complying with the requirements set forth in § 273.11(e).

* * * * *

4. In § 273.2, a new subparagraph (v) is added to § 273.2(f)(1), subparagraph (i) of § 273.2(f)(9) is revised, and subparagraphs 273.2(i)(3)(ii) and (4)(i) are amended to read as follows:

§ 273.2 Application processing.

* * * * *

(f) *Verification.* * * *

(1) *Mandatory verification.* * * *

(v) *Social Security Numbers.* The social security number(s) (SSN) reported to the State agency by the household shall be verified by the State agency. However, the State agency shall not delay certification of an otherwise eligible household solely to validate any member's SSN, even if the 30 day processing period has not expired. As soon as all other steps necessary to certify a household are completed except for validation of an SSN, the State agency must certify the household. Verification shall be completed either at initial application or at the time of or prior to the household's next recertification. The SSN (s) shall be verified in one of the following ways:

(A) Matching the reported SSN with information supplied by the Social Security Administration (SSA) (such as BENDEX or SDX computer tapes or printouts); or

(B) Observing the household member's social security card or any document containing the SSN. If the individual has no social security card or the social security number appears questionable, the State agency shall verify the number on the card either by matching it with SSA tapes or submitting or having the individual submit Form SS-5, Application for a Social Security Number, to the Social Security Administration. In the latter case, the State agency shall advise the individuals where to file and discuss with them what evidence will be needed. Once an SSN has been verified, the State must annotate its file accordingly to prevent the need for reverification in the future.

* * * * *

(9) *Verification subsequent to initial certification.* (i) *Recertification.* At recertification, the State agency shall verify a change in income, medical expenses or actual utility expenses claimed by a household if the source has

changed or the amount has changed by more than $25 since the last time they were verified. State agencies may verify income, actual utility expenses, or medical expenses claimed by households which are unchanged or have changed by $25 or less, provided verification is, at a minimum, required when information is questionable as defined in paragraph (f)(2) of this section. Unchanged information, other than income and medical or utility expenses, shall not be verified at recertification unless the information is questionable as defined in paragraph (f)(2) of this section. Newly obtained social security numbers shall be verified at recertification in accordance with verification procedures outlined in § 273.2(f)(1)(v).

* * * * *

(i) *Expedited service.* * * *

(3) *Processing Standards.* * * *

(ii) *Drug addicts and alcoholics, group living arrangement facilities.* For residents of drug addiction or alcoholic treatment and rehabilitation centers and residents of group living arrangement facilities who are entitled to expedited service, the State agency shall mail an ATP or coupons or have the ATP or coupons available for pick-up no later than seven working days following the date the application was filed.

* * * * *

(4) *Special procedures for expediting service.* * * *

(i) To expedite the certification process, the State agency shall postpone the verification required by § 273.2(f). However, the household's identity and residency shall be verified through a collateral contact or readily available documentary evidence. Examples of acceptable documentary evidence which the household may provide include, but are not limited to, a driver's license, work or school I.D., voter registration card or birth certificate. Households entitled to expedited service shall be permitted to furnish or apply for a social security number after receiving their first allotment in accordance with paragraph (iii). The household's income statements shall be verified through a collateral contact, or readily available documentary evidence whenever it can be done in sufficient time to meet the expedited processing standards. However, benefits shall not be delayed beyond the delivery standard described in paragraph (i)(3) of this section solely because income has not been verified.

5. In § 273.6 SSI cash-out States is renumbered § 273.20 and § 273.6 is retitled Social Security Numbers. The new § 273.6 reads as follows:

§ 273.6 Social security numbers.

(a) *Requirement for participation.* (1) The State agency shall require that a household participating or applying for participation in the Food Stamp Program provide the State agency with the social security number (SSN) (or numbers if they have more than one number) of each household member. The State agency shall explain to applicants and participants that refusal to provide an SSN will result in disqualification of the individual who refuses to comply in accordance with paragraph (c) of this section. The State agency shall also inform applicants and participants how the SSN will be used.

(2) If any household member(s) is unable to provide the State agency with an SSN prior to certification or recertification, the member who does not have an SSN, and therefore must apply for one, shall be allowed to participate for 90 days from the date of application pending receipt of the social security number.

(3) If the SSN has not been obtained within the 90 days and the participant cannot show good cause why an SSN has not been obtained, the participant shall be disqualified in accordance with subparagraph 273.6(c). If the SSN has not been obtained within the time limit but good cause has been established, then the participant may continue to participate provided the individual has documentation indicating they have, in fact, applied for the SSN. Household members without an SSN shall be eligible to participate while waiting for the Social Security Administration (SSA) to issue an SSN as long as they have applied for the number, made effort to provide SSA with th necessary information; and can document this. If SSA determines that an applicant will not qualify for an SSN then that individual shall be disqualified from participation in the Food Stamp Program.

(b) *Obtaining SSN's for all food stamp household members.* (1) for those individuals who provide SSN's prior to certification, recertification or at any office contact, the State agency shall record the SSN and verify it in accordance with § 273.2(f)(1)(v).

(2) For those individuals who do not have an SSN, the State agency shall use one of the following two procedures:

(i) In a State where an agreement exists between the State agency and SSA which allows the State agency to complete the application for an SSN, Form SS-5, the State agency shall offer to and shall complete this form at the household's request. To complete the form, the State agency can complete the SS-5 only when this agreement between SSA and the State exists.

(ii) If the household member elects to complete the SS-5 and apply to the SSA directly, or in a State in which no agreement with SSA exists, the State agency shall inform the household member where to apply and what information will be needed. The State agency should suggest that the household member ask for proof of application from SSA, in the event their application is not processed within the 90 days time period described in paragraph (a) of this section. The SSA normally uses the Receipt for Application for a Social Security Number, Form SSA-5028, as evidence that an individual has applied for an SSN.

(3) for those individuals who do not know if they have an SSN, or are unable to find their SSN, the State agency shall follow the procedures described in subparagaph (2) (i) and (ii) above.

(c) *Failure to comply.* It the State agency determines that a household member(s) has refused to provide an SSN or has failed without good cause to obtain an SSN, that individual(s) shall be ineligible to participate until that individual complies. This disqualification applies to the individual(s) alone and not to the entire household. The earned or unearned income of an individual disqualified from the household for failure to comply with this requirment shall be handled as outlined in § 273.9(b)(3) of these regulations.

(d) *Determining good cause.* In determining if good cause exists for failure to comply with the requirement to provide the State agency with an SSN, the State agency shall consider information from the household member, the Social Security Administration and the State agency (especially if the State agency was designated to send the SS-5 to SSA and either did not process the SS-5 or did not process it in a timely manner). Documentary evidence or collateral information that the household has applied for the number and made every effort to supply SSA with the necessary information shall be considered good cause for not complying timely with this requirement.

(e) *Ending disqualification.* The household member(s) disqualified may become eligible upon providing the State agency with an SSN or demonstrating that an application has been made at SSA for a social security number.

(f) *Use of SSN.* With the concurrence of the Secretary of the Department of Health, Education, and Welfare, the State agency shall use social security numbers in the administration of the

Food Stamp Program. State agencies shall have access to information regarding individual Food Stamp Program applicants and participants who receive benefits under title XVI of the Social Security Act to determine such a household's eligibility to receive assistance and the amount of assistance, or to verify information related to the benefits of these households. State agencies shall use the State Data Exchange [SDX] to the maximum extent possible. The State agency should also use the SSN's to prevent duplicate participation, to facilitate mass changes in Federal benefits as described in § 273.12(e)(3) and to determine the accuracy and/or reliability of information given by households.

6. In § 273.9, it is proposed that subparagraph (b)(3) be revised to read as follows:

§ 273.9 Income and deductions.

* * * * *

(b) *Definition of income.* * * *

(3) The earned or unearned income of an individual disqualified from the household for fraud in accordance with § 273.16, for failing to comply with the student work registration requirements in § 273.7(b)(9)(i) or for failing to comply with the requirement to provide an SSN in accordance with § 273.6, shall continue to be counted as income, less the pro rata share for the individual. Procedures for calculating this pro rata share are described in § 273.11.

7. In § 273.10(f)(3) it is proposed that a new subparagraph (iv) be added as follows:

§ 273.10 Determining household eligibility and benefit levels.

* * * * *

(f) *Certification periods.* * * *

(3) * * *

(iv) Households receiving SSI and social security benefits, in States which do not have the capability to effect at a point in time, mass changes in benefits due to the annual cost-of-living increases, shall be assigned certification periods that ensure that they are due for recertification at the time of or immediately after the SSI and social security cost-of-living increase. Households entitled to a certification period of up to 12 months as discussed in § 273.10(f)(3)(v) shall, on a one-time basis, be certified for less than a year in order to comply with this provision.

* * * * *

8. In § 273.11, it is proposed that a new subparagraph (iii) be added to (c)(5), paragraph (f) be relettered as paragraph (g) and the new paragraph (f) is added to read as follows:

§ 273.11 Action on households with special circumstances.

* * * * *

(c) *Treatment of income and resources of disqualified members.* Individual household members may be disqualified for fraud, for failure to meet the student work registration requirements during the school year or for failure to obtain, or refusal to provide, an SSN. During the period of time a household member is disqualified, the eligibility and benefit level of any remaining household members shall be determined as follows:

* * * * *

(5) *Reduction or termination of benefits within the certification period.* * * *

(iii) *SSN disqualification.* If a household's benefits are reduced or terminated within the certification period because one or more of its members is being disqualified for failure to meet the SSN requirement, the State agency shall issue a notice of adverse action which informs the household that one or more of its members is being disqualified, the reason for the disqualification, and the eligibility and benefit level of the remaining members.

* * * * *

(f) *Residents of group living arrangements who receive social security disability or SSI payments.* (1) Disabled or blind recipients of social security disability or SSI payments who reside in a group living arrangement facility as defined in § 273.1(e)(3) may voluntarily apply for the Food Stamp Program. Resident disabled or blind recipients of social security disability or SSI payments shall have their eligibility determined as a one-person household. The State agency shall certify these individuals by using the same provisions that apply to all other households except that certification must be accomplished through an authorized representative as described in § 273.1(f)(5). The guidelines for issuing FNS retailer authorizations to these group living arrangement facilities are set forth in § 278.1(e).

(2) Each group living arrangement facility shall provide the State agency with a certified list of currently participating residents. The State agency shall require the list on a periodic basis. In addition, the State agency shall conduct periodic random onsite visits to assure the accuracy of the listings and that the State agency's records are consistent and up to date.

(3) The following provisions apply to residents of group living arrangements who receive social security disability of SSI payments:

(i) When expedited processing standards as described in § 273.2(i) are necessary, eligibility for the initial application shall be processed on an expedited basis, and the State agency shall complete verification and documentation requirements prior to issuance of a second coupon allotment;

(ii) When normal processing standards apply, the State agency shall complete the verification and documentation requirements prior to making an eligibility determination for the initial application;

(iii) The State agency shall process changes in household circumstances and recertifications by using the same standards that apply to all other food stamp households; and

(iv) Resident households shall be afforded the same rights to notices of adverse action, to fair hearings, and to entitlement to lost benefits as are all other food stamp households.

(4) The group living arrangement facility shall notify the State agency, as provided in § 273.12(a) of changes in the household's income or other household circumstances and of when the individual leaves the group living arrangement. The group living arrangement shall return to the State agency a household's ATP card or coupons if they are received after the household has left the group living arrangement facility.

(5) The group living arrangement facility shall provide resident disabled or blind recipients of social security disability or SSI payments with their ID card and any untransacted ATP cards issued for the household when the household leaves the group living arrangement. If the ATP card has already been transacted and the household leaves the group living arrangement prior to the 16th day of the month, the group living arrangement facility is no longer allowed to act as that household's authorized representative. The group living arrangement facility shall, if possible, provide the household with a change report form to report to the State agency the individual's new address and other circumstances after leaving the group living arrangement, and shall advise the household to return the form to the appropriate office of the State agency within 10 days.

(6) The group living arrangement facility shall be responsible for any misrepresentation or fraud which it knowingly commits in the certification of its residents. As an authorized representative, it must be knowledgeable about household circumstances and should carefully review those circumstances with

residents prior to applying on their behalf. The group living arrangement facility shall be strictly liable for all losses or misuse of food coupons held on behalf of resident households and for all overissuances which occur while the household is a resident of the group living arrangement.

(7) The group living arrangement facility may be penalized or disqualified, as described in § 278.6, if it is determined administratively or judicially that coupons were misappropriated or used for purchases that did not contribute to a certified household's meals. The State agency shall promptly notify FNS when it has reason to believe that a group living arrangement facility is misusing coupons in its possession. However, the State agency shall take no action prior to FNS action against the group living arrangement facility. The State agency shall establish a claim for overissuance of food coupons held on behalf of resident clients as stipulated in paragraph (f)(6) of this section if any overissuance are discovered during an investigation or hearing procedure for redemption violations. If FNS disqualifies a group living arrangement facility as an authorized retail food store, the State agency shall suspend its authorized representative status for the same period.

9. In § 273.12, it is proposed that subparagraph (e)(3) be revised to read as follows:

§ 273.12 Reporting changes.

* * * * *

(e) *Mass changes.* * * *

(3) *Mass changes in Federal benefits.* (i) State agencies shall treat cost-of-living increases received in July 1981 and all other subsequent years and any other mass changes in social security and SSI payments as a mass change for food stamp purposes. The household shall not be responsible for reporting these changes. The State agency shall be responsible for automatically adjusting a household's food stamp benefit level to reflect the change in accordance with the procedures in paragraph (e)(2) of this section, or as noted in paragraph (e)(3)(ii) of this section.

(ii) State agencies which do not have the capability to perform a point-in-time adjustment of the entire caseload as required by paragraph (e)(2) of this section, shall schedule all households containing one or more members who receive social security or SSI payments for recertification during July, August, and September of each year so that the cost-of-living increase can be reflected in a timely manner.

(iii) For cost-of-living increases scheduled for July 1980, State agencies which currently have the capability shall treat the increases as a mass change in accordance with the procedures in paragraph (e)(2) of this section. A State agency is capable of treating these changes as a mass change if the State agency's computer system can identify by social security number individual household members receiving social security or SSI payments and the amount of these payments, and the computer system can extract on a timely basis the new income data from BENDEX and SDX for each recipient. All other State agencies shall, within 180 days of the effective date of the increase, identify cases receiving social security and SSI payments and reflect the cost-of-living increase in the household's allotment.

10. In § 273.16, it is proposed that paragraphs (a), (d), (d)(9)(ii), and (e)(3) be amended and a new subparagraph (4) be added to § 273.16(e) to read as follows:

§ 273.16 Fraud disqualification.

(a) *Fraud disqualification penalties.* Individuals found to have committed fraud through an administrative fraud hearing shall be ineligible to participate in the program for 3 month. Individuals found guilty of criminal or civil fraud by a court of appropriate jurisdiction shall be ineligible for not less than 6 months and not more than 24 months as determined by the court. If the court fails to specify a disqualification period for the fraudulent act, the State agency shall impose a six-month disqualification period. State agencies shall disqualify only the individual convicted of fraud and not the entire household. After any specified period of disqualification, the individual found guilty of fraud will continue to be ineligible to participate in the Food Stamp Program if the individual fails to agree to either a repayment in cash or a reduction in the food stamp allotment of the household of which such individual is a member in accordance with the procedures established in § 273.18(e)(2). After the disqualification period, if the individual fails to make cash payments in accordance with an agreed to schedule, the individual's household will be subject to allotment reductions in accordance with the procedures established in § 273.18(e)(2)(i). Individuals shall be permitted to make restitution during the period of disqualification in accordance with the established procedures for recoupment or cash repayment.

* * * * *

(d) *Administrative disqualification.* Each State agency shall establish procedures for conducting fraud hearings which must conform with the procedures outlined in this section. An administrative fraud hearing should be initiated by the State agency in cases in which the State agency has sufficient evidence to substantiate that an individual has committed one or more acts of fraud as defined in paragraph (b) of this section. Such cases may include those in which the State agency believes the facts of the individual case do not warrant civil or criminal prosecution through the appropriate court system, or has previously referred the case for such prosecution and prosecution was declined by the appropriate legal authority. The State agency may initiate an administrative fraud hearing regardless of the current eligibility of the individual. The disqualification period for individuals no longer participating at the time the hearing decision is final shall be deferred until the individual applies for and is determined eligible for program benefits. Fraud hearings shall not be conducted if the amount the State agency suspects has been fraudulently obtained is less than $35 or if the value of the ineligible items that have been purchased with food stamps is under $35. The burden of proving fraud is on the State agency. The administrative fraud hearing may still be conducted regardless of whether other legal action is planned against the household member.

* * * * *

(9) *Notification of hearing decision.* * * *

(ii) If the administrative fraud hearing finds that the household member committed fraud, the State agency shall mail a written notice to the household member prior to disqualification. The notice shall inform the household member of the decision and the reason for the decision. The notice shall also advise the remaining household members, if any, of either the allotment they will receive during the period of disqualification, or that they must reapply because the certification period has expired. The procedures for handling the income and resources of the disqualified member are described in § 273.11. For State level decisions, the notice shall inform the household member of the date disqualification will take effect. For local level decisions, the notice shall inform the household member of the deadline for requesting a State level hearing, the date disqualification will take effect unless a State level hearing is requested, and that benefits will be continued pending a

State level hearing if the household is otherwise eligible. If the individual is no longer participating, the notice shall inform the individual that the period of disqualification will be deferred until such time as the individual again applies for and is determined eligible for program benefits. A list of the household member's rights as contained in § 273.15(p) and the State level hearing procedures shall be enclosed with the local fraud hearing decision notice. In addition, the State agency shall initiate fraud claim collection activities in accordance with § 273.18(c).

* * * * *

(e) *Court imposed disqualifications.* * * *

(3) State agencies shall disqualify an individual found guilty of fraud for the length of time specified by the court. If disqualification is ordered but a date for initiating the disqualification period is not specified, the State agency shall initiate the disqualification period for currently eligible individuals with the first month following the date the disqualification was ordered. If the court fails to specify a specific disqualification period for the fraudulent conduct, the State agency shall impose a six-month disqualification period which shall begin the first month following the date the court found a currently eligible individual guilty of civil or criminal fraud. If the individual is not eligible for the program at the time the disqualification period is to begin, the period shall be postponed until the individual applies for and is determined eligible for benefits. A court ordered disqualification may run concurrently with the 3-month period of disqualification imposed as a result of an administrative fraud hearing. The State agency shall not initiate or continue a court imposed or administratively imposed fraud disqualification period contrary to a court order.

(4) If the court finds that the household member committed fraud, the State Agency shall mail a written notice to the household member prior, whenever possible, to disqualification. The notice shall inform the household member of the decision and the reason for the decision. The notice shall also advise the remaining household members, if any, of the allotment they will receive during the period of disqualification or that they must reapply because the certification period has expired. The procedures for handling the income and resources of the disqualified member are described in § 273.11. The notice shall also inform the household member of the date disqualification will take effect. In addition, the State agency shall initiate fraud claim collection activities in accordance with § 273.18(c).

* * * * *

11. In § 273.18, it is proposed that paragraphs (c)(3), and (4) be deleted and subparagraph (c)(2), and paragraphs (d) and (e) be amended; subparagraph (f)(2) renumbered as (f)(3) and subparagraphs (f)(1) and (f)(2) amended. The amended paragraphs read as follows:

§ 273.18 Claims against households.

* * * * *

(c) *Fraud claim.* * * *

(2) *Collecting fraud claims.* (i) If a household member is found to have committed fraud by either an administrative fraud hearing or a court of appropriate jurisdiction, the State agency shall, prior whenever possible to disqualification, send the individual a written agreement letter for restitution, designed by FNS, which informs the individual of the amount owed, the reason for the claim, the period of time the claim covers, any offsetting that was done to reduce the claim, the types and terms of each restitution schedule which is offered, the date restitution must commence, the penalties involved for default as well as the household member's right to a fair hearing if the individual disagrees with the State agency's determination of the claim. In addition to the written agreement letter for restitution, a personal contact shall be made, if possible. The State agency shall initiate such collection unless the household has repaid the overissuance as a result of nonfraud demand letters, the State agency has documentation which shows the household cannot be located, or the legal representative prosecuting a member of the household for fraud advises, in writing, that collection action will prejudice the case. In cases where a household member was found guilty of fraud by a court, the State agency shall request the matter of restitution be brought before the court.

(ii) Mandatory restitution shall begin the month following the month the period of disqualification ends. If the disqualified individual fails to agree to make restitution, their period of disqualification shall continue until an agreement is made. The individual who committed fraud or the household may begin restitution prior to or during the period of disqualification set by a hearing. However, the penalities in § 273.16(a) shall not apply except in cases of mandatory restitution. The State agency shall follow the procedures for collecting and submitting payments as well as the applicable accounting procedures prescribed in paragraphs (e), (f), (g), and (h) of this section. FNS may grant deviations from the designed demand letter under conditions specified in § 273.2(b). A written demand letter for a fraud claim shall be sent even if the household has previously received a nonfraud demand letter, because the time period covered by the claim is different for fraud and nonfraud claims, unless the overissuance is repaid as a result of the nonfraud collection efforts. In addition to the written demand letter, a personal contact shall be made, if possible.

(iii) One month prior to the end of the specified period of disqualification, if the household member found guilty of fraud has not responded to the written agreement letter, the State agency shall send one additional follow-up letter advising the individual that he will continue to be ineligible to participate in the Food Stamp Program if the individual fails to agree to either a reduction in the household's food stamp allotment or to a repayment in cash in accordance with the procedures established in paragraph (e)(2) of this section. Individuals who fail to agree to make restitution in accordance with the terms of the written agreement shall continue to be ineligible to participate in the Food Stamp Program. The State agency shall mail a written notice to the household member informing such individual of the decision and the reason for the decision. The notice shall also advise the remaining household members, if any, of either the allotment they will receive during the period of disqualification or that they must reapply because the certification period has expired. The procedures for handling the income and resources of the disqualified member are described in § 273.11. The period of disqualification continues until the fraudulent individual agrees to make restitution. The State agency may also initiate civil court action to obtain the claim.

(iv) If after the specified period of disqualification, the household member agrees to make restitution, the State agency shall follow the procedures prescribed in paragraph (e)(2) of this section for collecting and submitting payments or the procedures for reducing the food stamp allotment of the household of which such individual found guilty of fraud is a member.

(v) The State agency shall suspend collection action at any time it has documentation that the household member found guilty of fraud cannot be located. A claim shall be determined uncollectible after it is held in suspense for three years. The State agency may

use an uncollectible claim to offset benefits in accordance with § 273.17.

(d) *Changes in household composition.* (1) *Nonfraud claims.* If a household's membership has changed since the overissuance occurred, the State agency shall initiate collection action against the head of the household. If the head of the household is no longer living or cannot be located, the State agency shall initiate collection action against the household containing a majority of the individuals who were household members at the time the error occurred.

(2) *Fraud claims.* If the household member found guilty of fraud moves, resulting in a change in household membership, the State agency shall initiate collection action against the household currently containing the fraudulent individual.

(e) *Methods of collecting payments.* (1) State agencies shall collect payments for nonfraud claims in one of the following ways:

(i) *Lump-sum.* State agencies shall collect payments from households in one lump sum if the household is financially able to pay the claim in one lump sum.

(ii) *Installments.* If the household has insufficient liquid resources or is otherwise financially unable to pay the claim in one lump sum, payments shall be accepted by the State agency in regular installments. If the full amount of the claim cannot be liquidated in 3 years, the State agency shall compromise the claim by reducing it to an amount that will allow the household to pay the claim in 3 years. A State agency may use the full amount of the claim to offset in accordance with § 273.17.

(2) State agencies shall collect payments for fraud claims in one of the following ways:

(i) *Reduction in food stamp allotment.* If the household member found guilty of fraud agrees to a reduction in the household's food stamp allotment, the State agency shall discuss with the household the amount of food stamps to be recouped each month. The amount of food stamps to be recouped each month shall be 25 percent of the household's monthly allotment. Recoupment of less than 25 percent shall be accepted only of it results in equal increments or if the full amount can be recovered within a year using a lesser percentage. If the full amount of the claim cannot be liquidated in 3 years, the State agency shall compromise the claim by reducing it to an amount that will allow the household to make restitution within 3 years. A State agency may use the full amount of the claim to offset benefits in accordance with § 273.17.

(ii) *Repayment in cash.* If the household member found guilty of fraud agrees to a repayment in cash, and the individual is financially able to repay the claim in full, the State agency shall collect the payment in one lump-sum. However, if the household has insufficient liquid resources or is otherwise unable to pay the claim in one lump sum, payments shall be accepted in regular installments. If the full amount of the claim cannot be liquidated in 3 years, the State agency shall compromise the claim, by reducing it to an amount that will allow the individual to pay the claim in 3 years. A State agency may use the full amount of the claim to offset benefits in accordance with § 273.17. If the household member fails to make a payment in accordance with the established restitution schedule, the State agency shall initiate one of the following actions:

(A) If the household member fails to make any payments, the State agency shall send one follow-up notice. If the household member again fails to make any payments, the State agency shall follow the procedures prescribed in paragraph (e)(2)(i) of this section for reducing the household's food stamp allotment.

(B) If the household member makes a payment that is less than the amount established in the restitution schedule, the State agency shall determine if the household's economic circumstances have changed necessitating a reduction in the amount of the payments. If so, the State agency and the household member shall execute a revised repayment schedule. If, however, the household's economic circumstances have not changed and the household is still financially able to pay the established claim, then the State agency shall follow the procedures established in paragraph (e)(2)(i) of this section for reducing the household's food stamp allotment.

(3) State agencies may initiate civil court action to obtain payment of the claim prior to the end of the disqualification period. However, the State agency shall not deny, terminate or reduce a household's benefits for failure to repay a claim, to agree to a repayment schedule or to make the agreed upon payment, unless the State agency's request for repayment of a claim is after the period of disqualification and the household member found guilty of fraud fails to agree to make restitution in accordance with the procedures prescribed in this section.

(f) *Submission of payments.* (1) Effective July 1, 1980, the State agency shall no longer forward to FNS value of all funds collected for claims. This amount includes the total value of allotments recouped to repay fraud claims. Alternatively, FNS will amend the State's letter of credit on a quarterly basis. This amendment will reflect State's retention of 50 percent of the value of all funds collected or allotments recouped through prosecutions or other State activities directed against individuals who fraudulently obtain food stamps as well as full retention by FNS of all nonfraud overissuance recoveries.

(2) Each State shall also submit a Form FNS-209, Status of Claims Against Households, monthly to FNS to detail the State's activities relating to claims against households. This report is due no later than 30 days after the end of each calendar month and shall be submitted even if the State agency has not collected any payments. In addition to reporting the amount of funds recovered from fraud claims each month on Form FNS-209, the State agency shall also report this amount on other letter of credit documents as required. In accounting for fraud claim collections, the State agency shall include in the collections cash repayments, and the value of the allotments recouped or offset by restoration of lost benefits. However, the value of allotments reduced during periods of disqualification, including disqualification due to an individual's failure to agree to repay a fraud claim, shall not be considered recouped allotments and shall not be used to offset a fraud claim. In addition, each State agency shall establish controls to ensure that officials responsible for fraud determinations will not benefit from the State share of recoveries.

* * * * *

PART 278—PARTICIPATION OF RETAIL FOOD STORES, WHOLESALE FOOD CONCERNS, AND BANKS

13. In § 278.1, it is proposed that paragraph (e) be revised and a new paragraph (f) added and paragraphs (f) through (1) relettered (g) through (m). The revised paragraph (e) and the new paragraph (f) reads as follows:

§ 278.1 Approval of retail food stores and wholesale food concerns.

* * * * *

(e) *Treatment programs.* Drug addict or alcoholic treatment and rehabilitation programs wishing to redeem through wholesalers food stamps received from or on behalf of their particpants must, in addition to meeting the requirements of paragraph (a), (b) and (d)(1) of this section, be certified by the State agency or agencies designated by the Governor

as responsible for the State's programs for alcoholics and drug addicts under Public Law 91-616, "Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1972," and Public Law 92-255, "Drug Abuse Office and Treatment Act of 1972," as providing treatment that can lead to the rehabilitation of drug addicts and alcoholics. In addition, the certification must show that the treatment program meets the standards required of treatment programs under the supervision of the State agency or agencies designated by the Governor as responsible for the State's programs for alcoholics and drug addicts. Approval to participate is automatically cancelled at any time that a program loses its certification from the State agency or agencies.

(f) *Group living arrangement facilities.* Group living arrangement facilities wishing to redeem through wholesalers food stamps received from or on behalf of their residents must, in addition to meeting requirements of paragraphs (a), (b), and (d)(1) of this section, be certified by the appropriate State agency or agencies under regulations' issued under section 1616(e) of the Social Security Act. Approval to participate is automatically cancelled at any time that a program loses its certification from the State agency or agencies.

* * * * *

§ 278.2 [Amended]

14. In § 278.2, it is proposed that paragraph (g) be revised by adding the words "and authorized group living arrangement facilities" after the word "programs" in the final sentence.

Note.—Food Stamp forms are being revised in accordance with the requirements of this amendment. The reporting and/or record keeping requirements anticipated in this amendment resulting from the forms revisions will be forwarded to the Office of Management and Budget for approval in accordance with the Federal Reports Act of 1942.

* * * * *

(91 Stat. 958 (7 U.S.C. 2011-2027))

Note.—This proposal has been reviewed under the USDA criteria established to implement, Executive Order 12044, "Improving Government Regulations." A determination has been made that this action should not be classified as significant. Robert Greenstein, Administrator of the Food and Nutrition Service has determined that an emergency situation exists which warrants less than a full 60-day public comment period on this proposal because of the legislatively imposed publication and implementation dates. An impact statement has been prepared and is available from Claire Lipsman, Director, Program Development Division, Food and Nutrition Service, U.S. Department of Agriculture, Washington, D.C., 20250.

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

Dated: October 26, 1979.

Carol Tucker Foreman,

Assistant Secretary.

[FR Doc. 79-33694 Filed 10-30-79; 8:45 am]

BILLING CODE 3410-30-M

Reader Aids

Federal Register
Vol. 44, No. 214
Friday, November 2, 1979

INFORMATION AND ASSISTANCE

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

Federal Register, Daily Issue:

202-783-3238	Subscription orders (GPO)
202-275-3054	Subscription problems (GPO)
	"Dial-a-Reg" (recorded summary of highlighted documents appearing in next day's issue):
202-523-5022	Washington, D.C.
312-663-0884	Chicago, Ill.
213-688-6694	Los Angeles, Calif.
202-523-3187	Scheduling of documents for publication
523-5240	Photo copies of documents appearing in the Federal Register
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523-5235	Public Papers of the Presidents, and Weekly Compilation of Presidential Documents

Public Laws:

523-5266	Public Law Numbers and Dates, Slip Laws, U.S.
-5282	Statutes at Large, and Index
275-3030	Slip Law Orders (GPO)

Other Publications and Services:

523-5239	TTY for the Deaf
523-5230	U.S. Government Manual
523-3408	Automation
523-4534	Special Projects
523-3517	Privacy Act Compilation

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CFR PARTS AFFECTED DURING NOVEMBER

At the end of each month, the Office of the Federal Register publishes separately a list of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

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AGENCY PUBLICATION ON ASSIGNED DAYS OF THE WEEK

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

Monday	Tuesday	Wednesday	Thursday	Friday
DOT/SECRETARY*	USDA/ASCS		DOT/SECRETARY*	USDA/ASCS
DOT/COAST GUARD	USDA/APHIS		DOT/COAST GUARD	USDA/APHIS
DOT/FAA	USDA/FNS		DOT/FAA	USDA/FNS
DOT/FHWA	USDA/FSQS		DOT/FHWA	USDA/FSQS
DOT/FRA	USDA/REA		DOT/FRA	USDA/REA
DOT/NHTSA	MSPB/OPM		DOT/NHTSA	MSPB/OPM
DOT/RSPA	LABOR		DOT/RSPA	LABOR
DOT/SLSDC	HEW/FDA		DOT/SLSDC	HEW/FDA
DOT/UMTA			DOT/UMTA	
CSA			CSA	

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

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

***NOTE: As of July 2, 1979, all agencies in the Department of Transportation, will publish on the Monday/Thursday schedule.**

REMINDERS

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

Rules Going Into Effect Today

Note: There were no items eligible for inclusion in the list of Rules Going Into Effect Today.

List of Public Laws

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's List of Public Laws.

Last Listing November 1, 1979

THE FEDERAL REGISTER: WHAT IT IS AND HOW TO USE IT

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

WHO: The Office of the Federal Register.

WHAT: Free public briefings (approximately 2½ hours) to present:

1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
2. The relationship between Federal Register and the Code of Federal Regulations.
3. The important elements of typical Federal Register documents.
4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them, as part of the General Services Administration's efforts to encourage public participation in Government actions. There will be no discussion of specific agency regulations.

WASHINGTON, D.C.

WHEN: Nov. 16* and 30; Dec. 14; at 9 a.m. (identical sessions)

WHERE: Office of the Federal Register, Room 9409, 1100 L Street N.W., Washington, D.C.

RESERVATIONS: Call Mike Smith, Workshop Coordinator, 202-523-5235 or Gwendolyn Henderson, Assistant Coordinator, 202-523-5234.

*Note: The November 16 briefing will feature an interpreter for hearing impaired persons. For further information contact Melanie Yager Williams on the TTY number at the Office of the Federal Register: 202-523-5239.

DALLAS, TEXAS

WHEN: December 8, 1979 at 9:30 a.m.

WHERE: Dunfey Dallas Hotel
3800 West Northwest Highway
Dallas, Texas

RESERVATIONS: Call Mary Peters (214) 445-0055