

most-favored-nation treatment and national treatment to imports from other GATT contracting parties, licensing requirements, quantitative trade restrictions, subsidy practices as they affect trade, non-tariff charges and taxes, customs valuation and classification procedures, transparency in trade regulation and administration, and state trading practices and monopolies. The Working Party will want to receive information from each of the four countries concerning trade in services, intellectual property protection, trade-related investment measures, agricultural supports and subsidies, and sanitary and phytosanitary requirements.

In addition, as part of the accession process, each of these countries will conduct bilateral negotiations with interested GATT members to formulate schedules of tariff and non-tariff concessions in agriculture, goods, and services that will become part of the terms of GATT/WTO accession contained in the Protocol package. These concessions will consist of agreement by the acceding countries to bind against increase the tariff and non-tariff terms of market access applied to certain imports. Such concessions restrict their ability to block trade though non-tariff means or to increase the tariff rate applied to those items without offering appropriate compensatory tariff concessions on other items. The rates of duty and other conditions of market access for agriculture, goods, and services negotiated bilaterally, as well as all the other protections of GATT Articles and the WTO, will apply to the trade of all other GATT contracting parties and WTO members with whom these countries have GATT/WTO relations after accession or with whom they have other Most-Favored-Nation agreements.

As a member of the GATT/WTO, Bulgaria, Mongolia, Russia, and Ukraine will enjoy a multilateral guarantee of unconditional most-favored-nation treatment from countries with which they have GATT relations that is more comprehensive than that available through bilateral agreements. The bindings on tariffs and certain nontariff measures maintained in the schedules of other members of the GATT and the WTO that have formal GATT/WTO relations with these four countries will be extended to their exports as obligations, first under the GATT, and potentially under the WTO. They will also have recourse to GATT/WTO procedures to protect themselves from

unfair or unreasonable trade actions by these countries.

In return for these benefits, each country acceding to GATT/WTO will be expected to grant similar benefits to the trade of other GATT/WTO members, to conduct its trade policies in accordance with the rules set out in the General Agreement and the WTO, and to establish its own schedules of tariff and non-tariff commitments and concessions.

Authority: 15 CFR 2002.2

Frederick L. Montgomery,

Chairman, Trade Policy Staff Committee.

[FR Doc. 94-12200 Filed 5-18-94; 8:45 am]

BILLING CODE 3190-01-M

Identification of Foreign Countries That Deny Adequate and Effective Intellectual Property Protection or Market Access to Persons That Rely on Intellectual Property Protection

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of identification of foreign countries that deny adequate and effective intellectual property protection, or deny fair and equitable market access to persons who rely on intellectual property protection, pursuant to section 182(a) and section 182(e) of the Trade Act of 1974, as amended (Trade Act).

SUMMARY: Pursuant to section 182(a) of the Trade Act (19 U.S.C. 2242), the USTR has identified 36 countries that deny adequate and effective intellectual property protection or deny fair and equitable market access to persons who rely on intellectual property protection. Three trading partners, Argentina, China and India, were identified as presenting particularly serious problems requiring a review of their status in 60 days; six trading partners were placed on the priority watch list; and eighteen trading partners were placed on the watch list. Nine other countries received special mention. No countries were designated priority foreign countries under section 182(a)(2) of the Trade Act.

EFFECTIVE DATE: The USTR's identification was made on April 30, 1994.

FOR FURTHER INFORMATION CONTACT: Joseph Papovich, Deputy Assistant USTR for Intellectual Property (202) 395-6864, Keith Kupferschmid, Director for Intellectual Property (202) 395-6864, or Thomas Robertson, Assistant General Counsel (202) 395-6800.

SUPPLEMENTARY INFORMATION: Section 182(a) of the Trade Act requires the USTR to identify foreign countries that deny adequate and effective protection of intellectual property rights or that deny fair and equitable market access for persons that rely on intellectual property protection. From among these identified foreign countries, the USTR must designate as "priority foreign countries" those countries whose acts, policies or practices are the most onerous or egregious and have the greatest adverse impact (actual or potential) on relevant U.S. products. Countries may not be identified as priority foreign countries if they are engaged in good faith negotiations, or making significant progress in multilateral or bilateral negotiations to provide adequate and effective protection or enforcement of intellectual property rights.

Although the USTR identified no priority foreign countries in the 1994 special 301 review, he did note that Argentina, China and India presented particularly serious problems. The USTR stated that the status of each of these countries would be revisited in 60 days, and that if satisfactory progress had not been made by that time, they would be designated priority foreign countries.

The USTR also named trading partners to the administratively-created priority watch list and watch list. The trading partners named to the priority watch list include the European Union, Japan, Korea, Saudi Arabia, Thailand and Turkey. The trading partners named to the watch list include Australia, Chile, Colombia, Cyprus, Egypt, El Salvador, Greece, Guatemala, Indonesia, Italy, Pakistan, Peru, the Philippines, Poland, Spain, Taiwan, the United Arab Emirates, and Venezuela. Four of these trading partners—Egypt, El Salvador, Greece and the United Arab Emirates—will be subject to out-of-cycle reviews, which are formal mid-year reviews when the USTR will determine whether the problems or practices that resulted in those countries being placed on the list have been addressed. Finally, the trading partners warranting special mention of their practices, but not warranting placement on a formal list, include Brazil, Canada, Germany, Honduras, Israel, Panama, Paraguay, Russia and Singapore.

Ira S. Shapiro,
General Counsel.

[FR Doc. 94-12199 Filed 5-18-94; 8:45 am]

BILLING CODE 3190-01-M

Sunshine Act Meetings

Federal Register

Vol. 59, No. 96

Thursday, May 19, 1994

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).

FEDERAL ELECTION COMMISSION

DATE AND TIME: Tuesday, May 24, 1994, at 10 a.m.

PLACE: 999 E Street, NW., Washington, DC.

STATUS: This Meeting Will Be Closed to the Public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. § 437g

Audits conducted pursuant to 2 U.S.C. § 437g, § 438(b), and Title 26, U.S.C.

Matters concerning participation in civil actions or proceedings or arbitration

Internal personnel rules and procedures or matters affecting a particular employee

DATE AND TIME: Thursday, May 26, 1994, at 10 a.m.

PLACE: 999 E Street, NW., Washington, DC. (Ninth Floor.)

STATUS: This Meeting Will Be Open to the Public.

ITEMS TO BE DISCUSSED:

Correction and Approval of Minutes

Convention Regulations: Final Rules and Explanation and Justification (continued from meeting of May 11, 1994)

Advisory Opinion 1994-11: Mr. Alan R. Kidston of FMC Corporation

Advisory Opinion 1994-13: Mr. Peter Bagatelos on Behalf of Voter Education Project

Administrative matters

PERSON TO CONTACT FOR INFORMATION:

Mr. Ron Harris, Press Officer, Telephone: (202) 219-4155.

Delores Hardy,

Administrative Assistant.

[FR Doc. 94-12452 Filed 5-17-94; 3:22 pm]

BILLING CODE 6715-01-M

Corrections

Federal Register

Vol. 59, No. 96

Thursday, May 19, 1994

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF DEFENSE

48 CFR Part 217

Defense Federal Acquisition Regulation Supplement; Economy Act

Correction

In rule document 94-10582 beginning on page 22759, in the issue of Tuesday

May 3, 1994, make the following corrections:

On page 22759, in the third column, under **SUMMARY**, in the seventh line, "intragency" should read "interagency".

On the same page, in the third column, under **SUPPLEMENTARY INFORMATION**, under the heading **A. Background**, in the sixth line, "intragency" should read "interagency".

BILLING CODE 1505-01-D

DEPARTMENT OF DEFENSE

48 CFR Parts 225 and 252

Defense Federal Acquisition Regulation Supplement; Lifeboat Survival System

Correction

In rule document 94-9756 beginning on page 19145, in the issue of Friday, April 22, 1994, make the following correction:

On page 19145, in the third column, under **DATES**, in the fifth line, "May 23, 1994" should read "June 21, 1994".

BILLING CODE 1505-01-D

Testament

Thursday
May 19, 1994

Part II

Department of the Interior

Bureau of Indian Affairs

Jamestown S'Klallam Tribe Liquor Control Ordinance; Notice

DEPARTMENT OF THE INTERIOR**Bureau of Indian Affairs****Jamestown S'Klallam Tribe Liquor Control Ordinance**

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This Notice is published in accordance with authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 209 DM8, and in accordance with the Act of August 15, 1953, 67 Stat. 586, 18 U.S.C. 1161. I certify that Resolution No. 06-94, the Jamestown S'Klallam Tribe Liquor Control Ordinance was duly adopted by the Jamestown S'Klallam Tribe on February 22, 1994. The Ordinance provides for the regulation of the activities of the manufacture, distribution, sale, and consumption of liquor in the area of Jamestown S'Klallam Indian Country.

DATES: This Ordinance is effective as of May 19, 1994.

FOR FURTHER INFORMATION CONTACT: Chief, Branch of Judicial Services, Division of Tribal Government Services, 1849 C Street NW., MS 2611-MIB, Washington, DC 20240-4001; telephone (202) 208-4400.

SUPPLEMENTARY INFORMATION: The Jamestown S'Klallam Tribe, Resolution No. 06-94, Jamestown S'Klallam Tribe Liquor Control Ordinance is to read as follows:

Jamestown S'Klallam Tribe, Tribal Liquor Control Ordinance, Ordinance #01-94.

Part I Policy and Definitions**Section 1.1 Public Policy Declared**

This Ordinance shall be cited as the "Jamestown S'Klallam Tribal Liquor Control Ordinance". Under the inherent sovereignty of the Jamestown S'Klallam Tribe, this ordinance shall be deemed an exercise of the Tribe's power for the protection of the welfare, health, peace, morals and safety of the people of the Tribe. It is further the tribe's policy to assure that any transaction, importation, sale or consumption involving an alcoholic beverage, while within the Tribe's jurisdiction, shall occur in strict compliance with this Ordinance, the laws of the United States and where applicable, the State of Washington.

Section 1.2 Definitions

(a) **Alcoholic Beverage:** Shall mean any intoxicating liquor, beer, or any wine, as defined under the provisions of this Ordinance or other applicable law.

(b) **Council:** Shall mean the Tribal Council of the Jamestown S'Klallam Tribe.

(c) **Legal Age:** Shall mean the age requirements as defined in part 11, section 2.1.

(d) **Liquor Store:** Shall mean any store established by the Tribe for the sale of alcoholic beverages or any entity licensed by the Tribe to sell alcoholic beverages.

(e) **On-Site Dealer:** Shall mean the Jamestown S'Klallam Tribe or duly authorized licensee when it sells, or keeps for sale, any alcoholic beverage authorized under this Ordinance for consumption on the premises where sold.

(f) **On-Site Sale:** Shall mean the sale of any alcoholic beverage for consumption only upon the premises where sold.

(g) **Sale:** Shall mean the transfer of any bagged, bottled, boxed, canned or kegged alcoholic beverage, or the serving of any contents of any bagged, bottled, boxed, canned or kegged alcoholic beverage by any means whatsoever for a consideration of currency exchange.

(h) **Transaction:** Shall mean any transfer of any bagged, bottled, boxed, canned or kegged alcoholic beverage, or the transfer of any contents of any bagged, bottled, boxed, canned or kegged alcoholic beverage from any liquor store, on-site dealer or vendor to any person.

(i) **Vendor:** Shall mean any person employed or under the supervision by and of a liquor store or on-site dealer who conducts sales or transactions involving alcoholic beverages.

Section 1.3 General Prohibition

It shall be a violation of tribal law to manufacture for sale, sell, offer, or keep for sale, possess, transport or conduct any transaction involving any alcoholic beverage except in compliance with the terms, conditions, limitations and restrictions specified in this Ordinance.

Section 1.4 Tribal Control of Alcoholic Beverages

The council shall have the sole and exclusive right to authorize the importation of alcoholic beverages for sale or for the purpose of conducting transactions therewith, and no person or organization shall so import any such alcoholic beverage into the Jamestown S'Klallam Indian Country unless authorized by the Council.

Section 1.5 Community Liquor Store

The council may establish and maintain anywhere within the Jamestown S'Klallam Indian Country

that the council may deem advisable, a community liquor store or stores for the sale of alcoholic beverages in accordance with the provisions of this ordinance. The council may set the prices of alcoholic beverages sold.

Section 1.6 Community On-Site Dealer

The council may establish and maintain anywhere within the Jamestown S'Klallam Indian Country that the council may deem advisable, a community on-site dealer or dealers for storage and on-site sale of alcoholic beverages in accordance with the provisions of this Ordinance. The council may set the prices of alcoholic beverages sold.

Section 1.7 State of Washington Licenses and Agreements

The council or operator may negotiate an agreement or obtain a State of Washington liquor license for any tribally operated establishment that sells alcoholic beverages or conducts transactions involving alcoholic beverages to the extent required by applicable law to allow the tribe to sell liquor in Indian Country under its control.

Part II Compliance With the Laws of The State of Washington**Section 2.1 Applicability of State Law**

The council and its agents shall act in conformity with state laws regarding the sale of liquor to the extent required by applicable federal law including 18 U.S.C. 1161.

Section 2.2 Persons Under 21 Years of Age: Restrictions

The council shall comply with the State of Washington laws regarding restrictions on those persons under the age of 21 years in any Tribal establishment operating pursuant to the provisions of this ordinance.

Section 2.3 Restrictions on Intoxicated Persons

No tribally operated or licensed establishment shall sell, give, or furnish any alcoholic beverage or in any way allow any alcoholic beverage to be sold, given or furnished to a person who is obviously intoxicated.

Section 2.4 Hours and Days of Sale

No tribally operated or licensed establishment shall sell or furnish alcoholic beverages for on-site purposes during hours or on days not in compliance with applicable law.

Part III Tribal Licensing and Regulation

Section 3.1 Power to License and Tax

The power to establish tribal licenses and levy taxes under the provisions of this ordinance is vested exclusively with the council. If the council enters into any agreements with the state regarding the sale of liquor, the agreement shall be deemed tribal law.

Section 3.2 Tribally Owned Establishments

The council can issue by resolution an appropriate license to a tribally owned establishment upon determining the site for the establishment and obtaining the necessary licensing or agreement from the State of Washington.

Section 3.3 License of Retail Sales

3.3.1 The council shall have the power to issue licenses to any tribal or state chartered corporation, individual or partnership or other entity to undertake any sale or transaction which the tribe itself has the power to undertake under this ordinance for the sale of alcoholic beverages at a retail store.

3.3.2 Applications for licenses shall be submitted in the form prescribed by the council or its authorized employees. The council may, within its sole discretion and subject to the conditions in this ordinance issue or refuse to issue

the license applied for upon payment of such fee as the council may prescribe.

3.3.3 Every license shall be issued in the name of the applicant and no license shall be transferable or assignable without the written approval of the council nor shall the licensee allow any other person or entity to use the license.

3.3.4 The council may, for violations of this ordinance, suspend or cancel any license. A license is a privilege and no person shall have vested rights therein. Prior to cancellation or suspension the council shall send notice of its intent to cancel or suspend the license to the licensee.

3.3.5 No license under this ordinance shall be for a period longer than one year.

Section 3.4 Regulations

The council may, consistent with this ordinance, adopt regulations it deems necessary to implement this ordinance.

Part IV Construction

Section 4.1 Severability

If any part of this ordinance, or the application thereof to any party, person, or entity or to any circumstances, shall be held invalid for any reason whatsoever, the remainder of the section or ordinance shall not be affected thereby, and shall remain in full force and effect as though no part thereof had been declared to be invalid.

Section 4.2 Amendment or Repeal of Ordinance

This ordinance may be amended or repealed by a majority vote of the council.

Section 4.3 Sovereign Immunity

Nothing in this ordinance is intended to nor shall be construed as a waiver of the sovereign immunity of the Jamestown S'Klallam Tribe.

Section 4.4 Effective Date

This ordinance shall be effective upon the date that the Secretary of the Interior certifies this ordinance and publishes it in the **Federal Register**.

Section 4.5 Jurisdiction

Notwithstanding anything in this ordinance to the contrary, nothing herein is intended to nor shall be construed as a grant of jurisdiction from the Jamestown S'Klallam Tribe to the State of Washington beyond that provided by applicable law. The Tribe shall operate in conformity with state law and tribal law to the extent provided pursuant to 18 U.S.C. 1161.

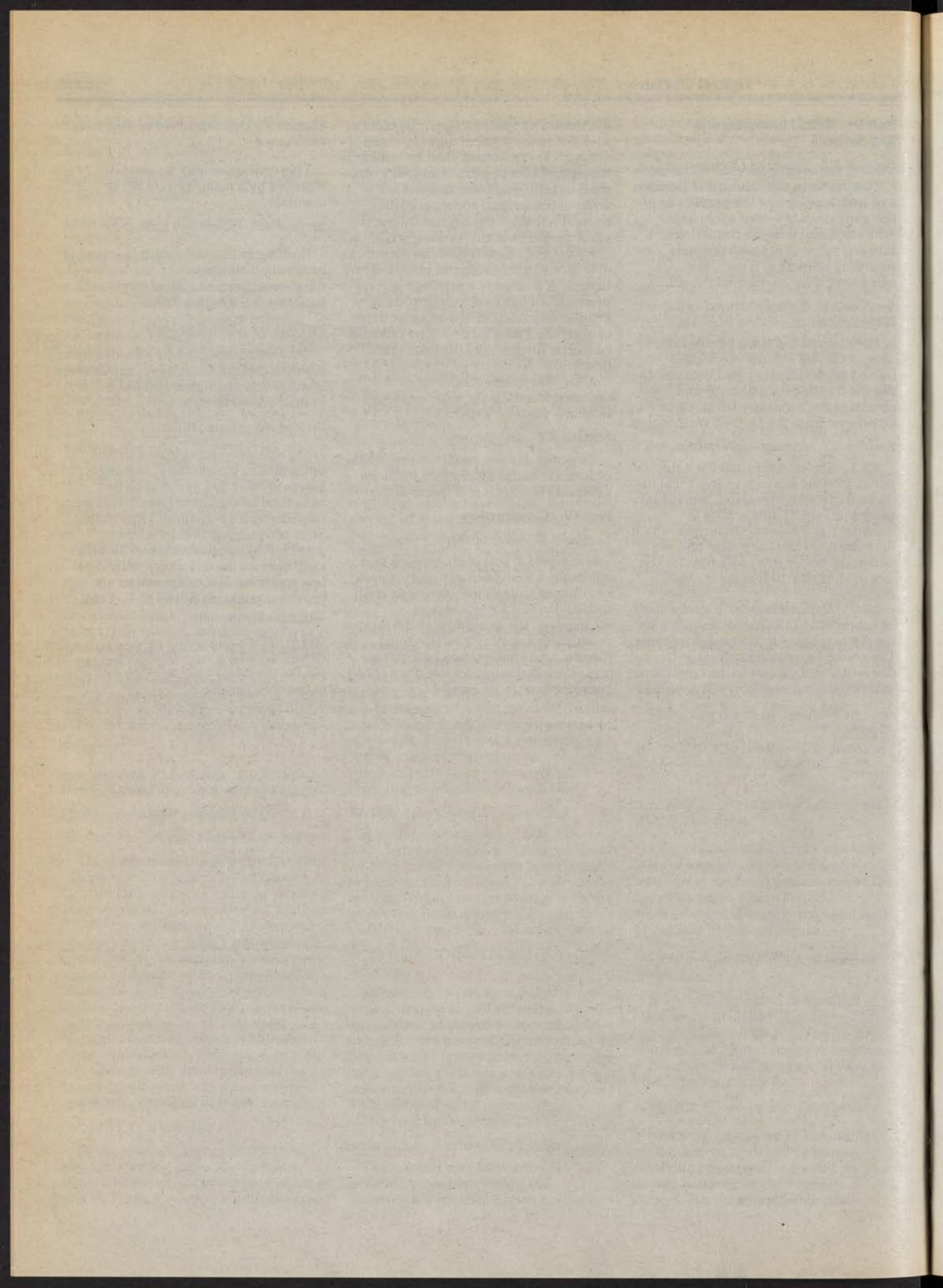
Dated: May 12, 1994.

Ada E. Deer,

Assistant Secretary—Indian Affairs

[FR Doc. 94-12157 Filed 5-18-94; 8:45 am]

BILLING CODE 4310-02-P



Test Report Federal Register

Thursday
May 19, 1994

Part III

Federal Emergency Management Agency

Continuation of Fiscal Year (FY) 1993
Methodology To Establish Fee for
Services To Support FEMA's Offsite
Radiological Emergency Preparedness
(REP) Activities; Notice

**FEDERAL EMERGENCY
MANAGEMENT AGENCY****Continuation of Fiscal Year (FY) 1993
Methodology To Establish Fee for
Services To Support FEMA's Offsite
Radiological Emergency Preparedness
(REP) Activities**

AGENCY: Federal Emergency
Management Agency (FEMA).

ACTION: Notice.

SUMMARY: The methodology established by FEMA's interim rule, 44 CFR part 354, published in the *Federal Register* on July 1, 1993 (58 FR 35770), for assessing and collecting fees from U. S. Nuclear Regulatory Commission (NRC) licensees for services provided by FEMA personnel for FEMA's REP Program will continue in effect for FY 1994.

DATES: The continuation of the methodology established by the interim rule, 44 CFR part 354, is effective for FY 1994 (October 1, 1993 to September 30, 1994).

FOR FURTHER INFORMATION CONTACT:
Linda H. Vasta, Chief, Regulatory
Services Coordination Unit,
Preparedness, Training, and Exercises

Directorate, Federal Emergency
Management Agency, Washington, DC
20472, (202) 646-4570.

SUPPLEMENTARY INFORMATION: As authorized by Public Law 103-124 (107 Stat. 1297), a fee will be charged to NRC licensees of commercial nuclear power plants for all site-specific and generic services provided by FEMA for FEMA's REP program. The policy and administrative basis for determining the fee was specified in FEMA's interim rule, 44 CFR part 354. All funds collected under this rule will be deposited in the U.S. Department of the Treasury to offset appropriated funds obligated by FEMA for its REP Program.

The hourly user fee rate for FEMA personnel is established on the basis of the methodology set forth in the referenced FEMA interim rule at 44 CFR 354.4(a), "Determination of costs for FEMA personnel," and will be used to assess and collect fees for site-specific and generic services rendered by FEMA personnel during FY 1994. The methodology provides for the determination of the exact FEMA personnel hourly rate for any FY at the completion of that FY.

FEMA will issue a user fee billing for the first half of FY 1994. Since, as

described above, the determination of the exact FEMA personnel hourly rate for a FY cannot be calculated until the end of that FY, FEMA will use the FY 1993 hourly user fee rate of \$122.88 for this mid-year billing. Any billing adjustments necessary after calculating the actual hourly rate will be made after the end of FY 1994. This hourly rate applies to charges for services provided by FEMA personnel, not charges for services provided by FEMA contractors. Charges for actual costs of contractor services will be in accordance with the interim rule at 44 CFR 354.4(b), except for generic contractor charges, for the recovery of appropriated funds obligated for the Emergency Management Planning and Assistance portion of FEMA's REP Program budget. The interim rule methodology precludes the assessment of generic contractor charges under part 354.4(b) until the end of the Fiscal Year. Charges under 44 CFR 354.4(c) will be assessed and adjusted, if necessary, at the end of the Fiscal Year.

James Lee Witt,
Director.

[FR Doc. 94-12191 Filed 5-18-94; 8:45 am]

BILLING CODE 6718-20-P

Federal Register

Thursday
May 19, 1994

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Ch. I

Medical Devices; Performance Standards
for Electrode Lead Wires; Requests for
Comments and Information; Public
Conference; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Ch. I**

[Docket No. 94N-0078]

Medical Devices; Performance Standards for Electrode Lead Wires; Requests for Comments and Information; Public Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; notice of public conference.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intent to establish special controls, including the promulgation of performance standards, for medical devices that use electrode lead wires. The agency is taking this action because it has determined that special controls are needed to prevent hazardous electrical connections between patients and electrical power sources. FDA is also announcing a public conference on this advance notice of proposed rulemaking (ANPRM). FDA will consider any comments or other information received in response to this ANPRM and information gleaned from the conference when proposing the special controls for devices using electrode lead wires.

DATES: Written comments by August 17, 1994. The public conference will be held on July 15, 1994, from 8:30 a.m. to 5 p.m. To register for the conference, please contact Sociometric, Inc. (address below) by June 24, 1994.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. The public conference will be held at the Sheraton Washington Hotel, 2660 Woodley Rd. NW., Washington, DC 20008.

FOR FURTHER INFORMATION CONTACT:

Regarding the ANPRM: Marquita B. Steadman, Center for Devices and Radiological Health (HFZ-84), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-4765.

Regarding the conference: Kathy Pointer, Sociometric, Inc., 8308 Colesville Rd., suite 550, Silver Spring, MD 20910, 301-608-2151 or 301-608-3542 (facsimile).

SUPPLEMENTARY INFORMATION:**I. Background**

FDA's Center for Devices and Radiological Health (CDRH) issued an alert letter in June 1985 to manufacturers, home user support organizations, and apnea monitor users, announcing that CDRH had received reports of one death and two electrical burns that occurred when unsupervised children plugged the male connector pins of the electrode lead wires from a home apnea monitor system into either alternating current (AC) power cords or a wall outlet, rather than into the patient cable which connects to the monitor (Ref. 1). In that letter, the agency announced its intention to embark on a cooperative effort with industry and the medical profession to resolve the problem of potential electrical connection between patients and electrical power sources. FDA also requested each manufacturer to evaluate its device for potential electrode lead wire and patient cable hazards and, when necessary, to consider design changes to preclude insertion of lead wire connectors into AC power cords and outlets. In response, manufacturers voluntarily began to redesign their electrode lead wires and patient cables for home apnea monitors. In addition to issuing the alert letter, CDRH's July 1985 Medical Devices Bulletin (a periodic publication that is distributed to the healthcare community and manufacturers) was devoted in great part to publicizing the lead wire hazard (Ref. 2).

Since 1985, FDA has cleared for marketing only those home use apnea monitors with patient cables and lead wires designed to prevent unsafe electrical connections. This protective design has also been required for all apnea monitors cleared for marketing since 1989, whether or not they were intended for home use. Nonetheless, some hospitals continue to use older units, or lead wires and patient cables from other devices, which do not have the protective design. Even with the new models, it may be possible for staff to switch patient cables and/or lead wires, thereby creating a hazard.

On August 25, 1993, a 12-day old infant being monitored for apnea was electrocuted in a hospital, in Chicago, IL. FDA's investigation of the incident confirmed that the patient electrode lead wires were unprotected. Specifically, the male connector pins were not protected to prevent unsafe electrical connections. Although the infant apnea monitor involved in that incident had been sold with safety protected lead wires and patient cable,

an unprotected patient cable from another manufacturer and unprotected lead wires from a third manufacturer were being used when the infant was electrocuted.

In response to this incident, on September 3, 1993, FDA issued a safety alert to hospital administrators, risk managers, and pediatric department directors, warning them that the use of unsafe electrode lead wires with an apnea monitor may be dangerous to the patient, and may be in violation of section 518(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360h(a)) (Ref. 3). FDA included in the alert a number of recommendations to help prevent these accidents.

On that same day, FDA also sent all apnea monitor manufacturers a notification letter under section 518(a) of the act (Ref. 4). Section 518(a) of the act authorizes the agency to require that notification be provided when it is necessary to eliminate an unreasonable risk of substantial harm to the public health and when no other practicable means is available under the act to eliminate such risk. FDA determined that manufacturer notification under section 518(a) of the act to all hospitals, clinics, distributors, and suppliers of apnea monitors was necessary to eliminate the unreasonable risk of harm to infants and other apnea monitor patients from unprotected lead wires and patient cables. FDA stated that notification should include replacement of unprotected lead wires and patient cables, and that a warning label should be permanently affixed to all monitors stating that unprotected lead wires and patient cables should not be used with the device because inappropriate electrical connections may pose an unreasonable risk of adverse health consequences or death. FDA also requested manufacturers of all apnea monitors to cease further distribution of unprotected lead wires and patient cables. On September 20, 1993, FDA issued a similar letter to all known manufacturers of patient cables and lead wires (Ref. 5).

FDA also has received reports of injuries associated with unsafe lead wires and patient cables involving medical devices other than apnea monitors (Ref. 6). In 1986, for example, a death resulted in a hospital from electrocardiogram (ECG) lead wires being plugged into an infusion pump power cord. Similarly, in 1990, a death occurred when neonatal monitor lead wires were inserted into a pulse oximeter power cord. FDA has received additional reports of similar events that resulted in electrical shocks and burns to patients. The agency also has

received reports of ECG monitor lead wires being inserted into power sources, causing patient injuries. Finally, FDA has received one report of patient shock involving an electroencephalograph cable.

Manufacturers of devices other than apnea monitors that utilize patient electrodes, e.g., ECG, have been encouraged by various organizations to modify their lead wires so that they cannot be inserted into AC power cords or outlets. In February 1987 and May 1993, the Emergency Care Research Institute (ECRI) issued hazard reports concerning electrical shock hazards from unprotected lead wires and patient cables in its publication "Health Devices" (Ref. 7). On July 15, 1991, the Underwriters Laboratories (UL) amended its Standard for Medical and Dental Equipment (UL 544) to require patient-connected lead wires to be designed to avoid connection to electrical power sources. This requirement became effective on December 1, 1991 (Ref. 8). In March 1993, the International Electrotechnical Commission (IEC) published a standard for ECG machines, including a safety requirement for leads (601-2-25) (Ref. 9). The IEC, as well as the Association for the Advancement of Medical Instrumentation (AAMI), are in the process of developing a standard for all leads. There is also an existing German standard (DIN 42 802) which has been adopted by some U.S. manufacturers in their design of safety protected lead wires (Ref. 10).

On December 28, 1993, FDA issued a Public Health Advisory to hospital nursing directors, risk managers, and biomedical/clinical engineering departments for distribution to all units in their hospitals and outpatient clinics, as well as to home health care providers and suppliers affiliated with those facilities, advising them of the hazards associated with use of electrode lead wires with unprotected male connector pins. (Ref. 11). In the Public Health Advisory, FDA expanded the scope of its September 3, 1993, apnea monitor safety alert to include all devices using patient electrodes. FDA noted that, even though manufacturers have changed the design of their devices to minimize the potential hazard, some facilities are still using older models that make it possible for staff to switch patient cables and/or lead wires, thus creating a hazard. FDA recommended various precautions to prevent the use of unsafe lead wires and patient cables.

II. Revisions Under Consideration

In accordance with section 513(a) of the act (21 U.S.C. 360c(a)), FDA has

classified medical devices intended for human use into one of three regulatory classes, i.e., class I, general controls; class II, special controls; and class III, premarket approval. Classification depends on the extent of control necessary to assure the safety and effectiveness of each device. Apnea monitors, as well as many other medical devices that use patient electrodes, are classified into class II. Class II devices are devices for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance (see 21 CFR 860.3(c)(2)). Possible special controls include the issuance of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 510(k) of the act (21 U.S.C. 360(k)), recommendations, and other appropriate actions as FDA deems necessary to provide such assurance. (See section 513(a)(1)(B) of the act.)

The agency recognizes that, despite efforts to eliminate the risk, unprotected lead wires and patient cabling systems are still distributed by some manufacturers as replacements for existing equipment, and may also be interchangeable among various medical devices. In order to reduce the risks to health presented by these devices, the agency is considering establishing special controls for devices that use lead wires. The agency believes these controls should include, but not be limited to, the development of a performance standard.

FDA believes that the development of a performance standard is necessary to reduce or eliminate the hazards of unprotected lead wires and patient cables. The DIN standard is a design, rather than a performance, standard, and may be too restrictive for application to all devices. While the proposed AAMI and IEC standards for all leads are more general, they are not yet completed. Therefore, the agency is considering establishing a standard that resembles the UL standard. The agency will consider other standards, however, that are finalized before completion of this rulemaking process. FDA is also considering revising CDRH's Office of Device Evaluation's "blue book" to reflect the agency's policy of not clearing for marketing unprotected male pins that may be used with any device with patient electrodes.

FDA is soliciting comments on the issuance of a performance standard that would eliminate the risk of burns and death associated with placing an unprotected electrode lead wire directly into a power source.

FDA is soliciting comments on all aspects of this ANPRM, and specifically requests comments on the following issues:

1. The current extent of manufacturing, distribution, and use of unprotected patient cables and electrode lead wires as replacement products.
2. Advantages, if any, of using unprotected electrode lead wires with particular medical devices.
3. The devices, if there are any, that cannot accept redesigned electrode lead wires or patient cables.
4. Cost to manufacturers and the user community to convert to protected electrode lead wires and patient cables for all medical devices.
5. Extent of substitution, if any, of unprotected nonmedical electrode lead wires and patient cables, for use as medical device electrode lead wires and patient cables.
6. Essential components of a performance standard for lead wires and patient cables.
7. Viability of applying a performance standard across device types.
8. Alternative solutions to the removal of all unprotected electrode lead wires from the market, such as banning them under 21 CFR part 895.

III. Public Conference

FDA, the Health Industries Manufacturers Association, and the American Hospital Association are sponsoring a public conference entitled "Unprotected Patient Cables and Electrode Lead Wires" to be held on July 15, 1994. The purpose of the conference is to: (1) Focus attention on medical devices that use unprotected electrode lead wires; (2) bring together patient cable and lead wire manufacturers, device manufacturers, distributors, users, and purchasers to facilitate understanding of the electrode lead wire problem and possible solutions, including the development of performance standards, and the announcement of new regulatory policy for all devices that use patient electrodes; (3) solicit industry and user input concerning FDA's intention to develop a new regulatory framework for devices that use patient electrodes; (4) identify the extent of existing and potential design and user problems, including design applicability for specific devices; and (5) identify the economic impact of the proposed solutions to these problems.

IV. Comments

FDA is particularly interested in comments from inventors, patient cable and lead wire manufacturers, device manufacturers, purchasers, and users of devices that use electrode lead wires. Comments from other interested individuals or groups are also welcome. FDA advises that, under 21 CFR 10.30(d), any comments submitted in response to this document will be included under the docket number found in brackets in the heading of this document.

Interested persons may, on or before August 17, 1994, submit to the Dockets Management Branch (address above), written comments regarding this ANPRM. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the

heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

V. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Form letter from FDA to manufacturers, home user support organizations, and apnea monitor users, June 1985.
2. Center for Devices and Radiological Health's Medical Devices Bulletin, July 1985.
3. FDA's September 3, 1993, Safety Alert.
4. Section 518(a) notification letter to apnea monitor manufacturers, September 3, 1993.
5. Section 518(a) notification letter to patient cable and lead wire manufacturers, September 20, 1993.

6. Information from FDA's medical device reporting (MDR) data base.

7. ECRI's publications, "Health Devices Alert," February, 1979, "Health Devices," May 1993.

8. Underwriters Laboratories' Standard for Safety Medical and Dental Equipment (UL 544).

9. International Electrotechnical Commissions' Safety Requirements for Medical Electrical Equipment (IEC Standard 601-1; 601-2-25).

10. German DIN Standard 42 802.

11. FDA Public Health Advisory: Unsafe Electrode Lead Wires and Patient Cables Used With Medical Devices, December 28, 1993.

Dated: May 12, 1994.

Michael R. Taylor,

Deputy Commissioner for Policy.

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