Substances	Limitations
* * *	* * * *
High-purity furnace black (CAS Reg. No. 1333–86–4) containing total polynuclear aromatic hydrocarbons not to exceed 0.5 parts per million, and benzo[a]pyrene not to exceed 5.0 parts per billion, as determined by a method entitled ''Determination of PAH Content of Carbon Black,'' dated July 8, 1994, as developed by the Cabot Corp., which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the Office of Premarket Approval (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be examined at the Center for Food Safety and Applied Nutrition's Library, 200 C St. SW., rm. 3321, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.	For use at levels not to exceed 2.5 percent by weight of the polymer.
* * *	* * * *

Dated: May 2, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–12156 Filed 5–8–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Medicated Feed Applications; Semduramicin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pfizer, Inc. The supplemental NADA provides for revised assay limits for Type C medicated semduramicin chicken feed to 80 to 110 percent of labeled claim.

EFFECTIVE DATE: May 9, 1997.

FOR FURTHER INFORMATION CONTACT: William G. Marnane, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0678.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed supplemental NADA 140–940, which provides for revising the assay limits for Type C medicated chicken feed containing Aviax™ (semduramicin sodium) from 85 to 110 percent of labeled claim to 80 to 110 percent. The supplemental NADA is approved as of April 8, 1997, and the regulations are amended in 21 CFR 558.4(d) to reflect the approval.

Revision of the assay limits for a Type C medicated feed is based on the evaluation of the assay procedure used to analyze the feed and analysis of the assays of those feeds. The initial assay limits were established based on the results of the method trial. Evaluation of the feeds used in the market support trials, comparable to commercial manufacturing operations, support a wider assay range. This action did not require reevaluation of the safety and effectiveness data supporting the original approval. Therefore, a freedom of information summary is not required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.4 [Amended]

2. Section 558.4 *Medicated feed applications* is amended in paragraph (d), in the table entitled ''Category I,'' in the entry for ''Semduramicin,'' in the last column by removing the assay limits ''85–110'' and adding in its place ''80–110.''

Dated: April 30, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 97–12257 Filed 5–8–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 898

[Docket No. 94N–0078]

Medical Devices; Establishment of a Performance Standard for Electrode Lead Wires and Patient Cables

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule establishing a performance standard for electrode lead wires and patient cables. The agency is taking this action because it has determined that a performance standard is needed to prevent electrical connections between patients and electrical power sources. The final rule will substantially reduce the risk of electrocution from unprotected electrode lead wires and patient cables.

DATES: This regulation is effective August 7, 1997, except that § 898.14 (21 CFR 898.14) is stayed pending Office of Management and Budget (OMB) clearance for information collection. FDA will announce the effective date of § 898.14 in the **Federal Register**. Submit written comments on the information collection provisions of this final rule by July 8, 1997.

For information on the compliance dates, see 21 CFR 898.13(a) and (b).

ADDRESSES: Submit written comments on the information collection provisions of this final rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Ave., Rockville, MD 20850, 301–827–2974.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 19, 1994 (59 FR 26352), FDA published an advance notice of proposed rulemaking (ANPRM) and announced the need for further FDA action to address the risk of patient exposure to macro shock or electrocution due to the inappropriate connection of a patient-connected cable or electrode lead wire to an alternating current (AC) power source. In that ANPRM, FDA described various regulatory actions it had taken since the first reported incidents in 1985 of exposed male connector pins of electrode lead wires being inserted into either AC power cords or a wall outlet, rather than into the patient cable that connects to the device monitor. The ANPRM also described actions that various organizations, such as, the Emergency Care Research Institute (ECRI) and outside standard setting bodies have taken to prevent electrode lead wires from being connected to electrical power sources. A summary of these actions is provided in section VII. of this document. In the ANPRM, FDA stated that ''despite efforts to eliminate the risk, unprotected electrode 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.'' (See 59 FR 26352 at 26353.) In the ANPRM, FDA further announced that it, in conjunction with the Health Industry Manufacturers Association and the American Hospital Association (AHA), was sponsoring a public conference entitled ''Unprotected Patient Cables and Electrode Lead Wires.'' The conference was held on July 15, 1994, and provided a forum for device users, manufacturers, and other health care professionals to offer and to hear comments for FDA's consideration during the rulemaking process.

The need for FDA action to resolve the hazard of the use of unprotected electrode lead wires and patient cables with medical devices was further emphasized in a letter dated August 2, 1994, to FDA Commissioner David A. Kessler, from the Honorable Ron Wyden, then Chairman, U.S. House of Representatives, Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Technology (Ref. 1). In that letter, Mr. Wyden stated that ''shocks, burns, and electrocutions occur despite warnings issued by the FDA to hospitals, manufacturers, and others.''

Specifically, Mr. Wyden wrote that:

> Hospitals have been told to purchase and use only protected wires and cables. They have also been told to remove unprotected equipment and to alert staff members of possible hazards to patients.
>
> Manufacturers have been encouraged to modify their designs to prevent lead wires from being inserted into electrical outlets.
>
> Despite warnings and other communications, some manufacturers still distribute to hospitals unprotected [patient cables and] lead wires as replacements for deteriorated equipment.
>
> It is clear that regulatory action, as well as additional education and training, is needed to stop the slow but steady flow of children (and adults) who are burned or electrocuted.

FDA's records of incidents with unprotected electrode lead wires and patient cables reveal the following:

Between 1985 and 1994, 24 infants or children received ''macro-shock'' (large externally applied currents) from electrode lead wires or cables, including five children who died by electrocution (Ref. 2). The most recent death (1993), of a 12-day old infant, occurred in a hospital. The apnea monitor involved in the incident had been sold to the hospital with a protected electrode lead wire and patient cable. However, when the infant was electrocuted, an unprotected patient cable from a second manufacturer and unprotected prewired electrodes from a third manufacturer were being used instead of the protected configuration.

There are reports of injuries associated with unsafe electrode lead wires and patient cables involving medical devices other than apnea monitors (Ref. 3). In 1986, for example, a death occurred when the electrocardiogram (ECG) lead wires were inserted into a pulse oximeter power cord. FDA has received additional reports of similar events that resulted in electrical shocks, burns, and possible brain damage to patients.

In response to the death and electrical burns that occurred in 1985, FDA issued an alert to home-use apnea monitor manufacturers, home user support organizations, and apnea monitor users, announcing, among other things, the agency's intent to embark on a cooperative effort with industry and the medical profession to resolve the problem of users making a hazardous electrical connection between the patient and an electrical power source. FDA also requested each home-use apnea monitor manufacturer to assess its device for potential electrode lead wire and patient cable connection hazards and, when necessary, to consider design changes to preclude insertion of electrode lead wire connectors into AC power cords and outlets. In addition to issuing the alert, FDA's Center for Devices and Radiological Health's (CDRH's) July 1985 ''Medical Devices Bulletin'' was devoted primarily to publicizing the unprotected electrode lead wire and patient cable connection hazard.

Since 1985, FDA has not cleared for marketing any home-use apnea monitor that features an unprotected electrode lead wire and patient cable configuration. For all apnea monitors cleared for marketing since 1989, FDA has required a protected electrode lead wire and patient cable design, whether or not the device was intended for home use. Despite these efforts, some hospitals continue to use older units, or electrode lead wires and patient cables from other devices, which do not have the protected cable and electrode lead wire design. Even with the new protected models, as evidenced by the 1993 incident, it may be possible to switch to use of an unprotected electrode lead wire and patient cable configuration, thereby recreating the hazard.

On September 3, 1993, FDA issued a safety alert to hospital administrators, risk managers, and pediatric department directors, warning them that the use of unprotected electrode lead wires and patient cables 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. 4). FDA included in the alert a number of recommendations to help prevent these accidents. FDA also sent all apnea monitor manufacturers a notification letter under section 518(a) of the act (Ref. 5).

Section 518(a) of the act authorizes the agency to issue an order to ensure that adequate notification is provided in an appropriate form, by the means best suited under the circumstances involved, to all health care professionals who prescribe or use a particular device and to any other person who should properly receive such notification, in

order to eliminate an unreasonable and substantial harm to the public health when no other practicable means is available under the act to eliminate such risk. FDA stated that, for these devices, notification should include replacement of unprotected apnea monitor electrode lead wires and patient cables, and that a warning label should be permanently affixed to all apnea monitors stating that unprotected electrode 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 electrode lead wires and patient cables. On September 20, 1993, FDA issued a similar letter to all known third-party manufacturers of electrode lead wires and patient cables (Ref. 6).

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. 7). In the Public Health Advisory, FDA expanded the scope of its September 3, 1993, apnea monitor safety alert to include all devices using unprotected electrode lead wires and patient cables. FDA noted that, even though many 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 to unprotected patient cables and lead wires, thus recreating the hazard. FDA recommended various precautions be taken to prevent the use of unprotected electrode lead wires and patient cables.

Manufacturers of devices other than apnea monitors that utilize patient-connected electrode lead wires, e.g., ECG monitors, have been encouraged by various organizations to modify their electrode lead wires and patient cables so that they cannot be inserted into AC power cords or outlets. For example, in February 1987 and May 1993, ECRI issued hazard reports concerning electrical shock hazards from unprotected electrode lead wires and patient cables. Further, standards-setting bodies have developed various standards, both in draft and final form, that have the same goal in mind—safety requirements for electrode lead wires and patient cables.

In March 1995, the International Electrotechnical Commission (IEC) published a second amendment to IEC 601–1 (1988), the safety standard for electromedical equipment, which includes a requirement that electrode lead wires be unable to make contact with hazardous voltages.

The Underwriters Laboratories (UL) adopted a modified version of IEC 601–1 by issuing its standard 2601–1, which became effective on August 31, 1994. This standard superseded UL 544 (referenced in the ANPRM). In adopting the IEC standard, UL included a deviation requiring that patient-connected electrodes be designed to avoid connection to electrical power sources. (See UL 2601–1, Medical Electrical Equipment Part 1: General Requirements for Safety.) The UL standard states in the rationale section that ''this is a basic safety concern prompted by recent accidents involving patient injury, including infant deaths. Patients were being accidently connected to hazardous circuits while being connected to applied parts of medical equipment, such as an apnea monitor.'' FDA has been advised that it is possible that UL will modify its requirement to be equivalent to the one included in the second amendment to IEC 601–1 (1988).

There is also a German DIN standard for touch proof connectors for electromedical applications. This design standard was also referenced in the ANPRM and states that it was developed because of the accidents that occurred with infants in 1985 and 1986.

The National Fire Protection Agency (NFPA) is also proposing a standard for patient electrode lead wire connectors. FDA has received information that, even though it is voluntary, this NFPA standard will be adopted by many States and municipalities as a mandatory standard for health care facilities. Further, this standard is referenced by the hospital accrediting body, the Joint Commission on Accreditation of Health Care Organizations.

Finally, the Association for the Advancement of Medical Instrumentation (AAMI) has developed a standard that covers electrode lead wires and patient cables for surface electrocardiographic monitoring in cardiac monitor applications (ECG cables and lead wires, ANSI/AAMI EC53–1995). This design standard addresses safety and performance of electrode lead wires and patient cables with the added purpose of discouraging the availability of unprotected patient cable and lead wire configurations for ECG monitoring applications. The standard defines a safe (no exposed metal pins) common interface at the cable yoke and electrode lead wire connector. The standard was approved by ANSI on December 7, 1995.

FDA believes that industry also recognizes the importance of addressing this hazard. In response to FDA's alert letter in June 1985, manufacturers voluntarily began to redesign their electrode lead wires and patient cables for home apnea monitors. More recently, many firms have taken voluntary action to recall electrode lead wires and patient cables with unprotected exposed metal pins. Apnea monitor firms are replacing their male pin lead wires and associated cables with safety cable systems, usually free of charge, while other device manufacturers are making adapters and warning labels available. Some device manufacturers have ceased supplying unprotected electrode lead wires and patient cables altogether.

II. The Proposed Rule

Despite repeated efforts to reduce the risk associated with the use of unprotected electrode lead wires and patient cables, these products are still available and in use in homes and in various health care settings.

In the **Federal Register** of June 21, 1995 (60 FR 32406), FDA issued a proposed rule designed to allow the orderly removal of unprotected electrode lead wires and patient cables from the marketplace. The proposal set forth a phased-in approach for removing unprotected lead wires and patient cables while seeking to minimize the economic impact to manufacturers and user facilities during the transition to a protected cabling configuration.

Under FDA's proposed phased-in approach, unprotected lead wires and patient cables would be subject to a proposed performance standard, developed by FDA. The effective date for any final regulation based on the proposal was to be phased-in over 1 or 3 years, depending on the device type. Under the proposed rule, any devices that did not meet the standard on its effective date would be banned.

Devices that were to be subject to the 1-year effective date were those devices believed to present the greatest potential risk of harm as demonstrated by use in environments where accidental inappropriate connections could reasonably be anticipated, and by frequent use of the devices and frequent connections of electrode lead wires. Devices subject to the 1-year effective date included all devices that had been the subject of reported adverse events, as well as other devices believed to present the greatest potential risk of

harm. Devices that were proposed to be subject to the 3-year effective date were those devices that did not satisfy the criteria for the 1-year effective date but also utilized unprotected electrode lead wires. As stated earlier, the agency proposed to ban those devices that did not meet the standard on its effective date.

FDA received comments on various aspects of the proposed rule, including: (1) The cost of conversion for manufacturers and user facilities; (2) the placement of a given device on the 1-year or the 3-year list; (3) the appropriate list for devices that were not specifically mentioned on either list, as well as for future devices; and (4) whether the agency might adopt one of the consensus performance standards mentioned in the proposed rule instead of issuing a new one. This final rule addresses these concerns and others in providing a cost effective remedy to eliminate an inappropriate, but preventable occurrence of macro shock or electrocution due to the accidental connection of an electrode lead wire or patient cable to an AC power source.

III. Highlights of the Final Rule

In response to comments, the agency has revised and clarified certain provisions of the final regulation. The final rule establishes a performance standard that FDA believes will eliminate the risk, to the extent possible, of unprotected electrode lead wires and patient cables being inadvertently inserted or manipulated so as to make contact with live parts of an AC power cord or electrical outlet. This standard applies to all electrode lead wires and patient cables. The revisions in the final rule are based on focusing the regulation on the most cost-effective mechanism of accomplishing its important public health goal. The most significant changes from the proposed rule follow:

1. The performance standard being established applies directly to electrode lead wires and patient cables, rather than to the medical equipment to which they are attached. This revision focuses the standard on the actual products that could create a patient hazard.

2. In issuing this standard, the agency is adopting the relevant portion of a recently updated international standard (IEC 601–1). This standard contains all the necessary provisions for patient protection. Moreover, by adopting an existing and widely followed international standard, the cost to industry in complying with this standard is minimized.

3. The agency is revising the effective date so that only the electrode lead wires and patient cables used with those devices presenting the greatest potential risk will be required to conform to the standard within 1 year. Specifically, the 1-year category has been limited to 10 devices that, if unprotected, present the greatest potential risk of harm as demonstrated by past incidents, their use in environments where accidental inappropriate connections could most likely be anticipated, or by the frequency with which the devices are used and the frequency of connections of the patient-connected electrode lead wires. Electrode lead wires and patient cables that are intended for use with those 10 devices will be required to conform to the standard within 1 year. FDA has placed all remaining devices in the 3-year category. Electrode lead wires and patient cables that are subject to the 3-year effective date are those used with, or intended for use with devices that are not subject to the 1-year effective date.

4. The agency has deleted the provision banning devices that do not meet the standard because such a provision is unnecessary. Under section 501(e) of the act (21 U.S.C. 351(e)) electrode lead wires and patient cables not meeting the performance standard on or following the effective date are adulterated.

5. This rule constitutes the first mandatory performance standard established by FDA under section 514 of the act (21 U.S.C. 360d).

IV. The Framework

In order to eliminate the risk of macro shock and electrocution in the future, the agency is establishing a performance standard for all electrode lead wires and patient cables. In reaching this decision, the agency reviewed several standards that are in various stages of development before deciding to adopt a provision of the international performance standard of IEC 601–1 on lead wires for medical devices.

Firms whose electrode lead wire and patient cable systems are subject to this performance standard should begin to adapt existing products to meet the standard, if they have not already done so, before the effective date of the standard. These efforts are consistent with Congress' admonition that ''stockpiling of nonconforming devices is discouraged, since standards will apply to all devices in commercial channels on their effective date.'' (See H. Rept. 853, 94th Cong., 2d sess. 30; see also 45 FR 7474, February 1, 1980, final standards regulation.)

Later in this document, FDA is publishing a list of the 10 devices at highest risk of a user inadvertently connecting the device's electrode lead wire(s) or patient cable to an AC power source. One year from the publication date of this rule, unprotected electrode lead wires and patient cables intended for use with, or used with, any of these 10 devices will be subject to FDA's performance standard. Three years after the publication date of this rule, unprotected patient cable and lead wire systems intended for use with any other medical device, absent an FDA waiver or exemption, will be subject to FDA's performance standard. FDA reserves the right, upon proper notification to interested parties, to amend the list of devices in the future. FDA believes the effective dates are reasonable and consistent with the congressional intent in enacting section 514 of the act, as well as with comments received at the public conference and written comments on the proposed rule.

The agency anticipates a smooth, but rapid, transition for the vast majority of existing devices to a protected electrode lead wire and patient cable configuration following publication of the final rule.

V. Performance Standard

The Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629) prescribes changes to the act (21 U.S.C. 321–394), as amended, that improve the regulation of medical devices and strengthen the Medical Device Amendments of 1976, which established a comprehensive framework for the regulation of medical devices.

The SMDA amended section 513 of the act (21 U.S.C. 360c) to redefine class II as the class of devices that is or will be subject to special controls, and amended section 514 of the act to simplify the requirements for establishing performance standards. Section 513 of the act states that the ''special controls * * * shall include performance standards for a class II device if the Secretary determines that a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device.'' The legislative history of the SMDA states that:

> by simplifying the process for establishing performance standards, and by allowing the Secretary discretion to employ such standards as one of a variety of additional controls to assure the safety and effectiveness of Class II devices, performance standards will become valuable tools to regulate those devices for which they are most needed.

(S. Rept. 513, 101st Cong., 2d sess. 19 (1990))

Under this rule, the mandatory performance standard applies to all electrode lead wires and patient cables intended for use with medical devices and is phased-in over a period of 1 or

3 years. New § 898.12(a) and (b) identifies the devices that are subject to the performance standard, with the applicable effective dates of the standard.

A. The Standard

FDA is issuing the following standard for electrode lead wires or patient cables:

Electrode lead wires and patient cables shall comply with the International Electrotechnical Commission (IEC) standard 601–1 subclause 56.3, paragraph c (1995).

Compliance with this standard shall be determined by inspection and by applying the test requirements also found in IEC 601–1, subclause 56.3(c). This standard is available from the American National Standards Institute (ANSI), 11 West 42nd Street, New York, NY 10036.

B. The Effective Date for Compliance

21 CFR 861.36 states that:

A regulation establishing * * * a performance standard will set forth the date upon which it will take effect. To the extent practical, consistent with the public health and safety, such effective date will be established so as to minimize economic loss to, and disruption or dislocation of, domestic and international trade.

(See also section 514(b)(3)(B) of the act)

FDA has determined that the cost of converting or adapting unsafe electrode lead wire configurations in order to comply with the performance standard being established minimizes economic loss to, and disruption or dislocation of, domestic and international trade because the standard is to be phased in over a 1- or 3-year period, depending on the device(s) with which the electrode lead wire or patient cable is intended to be used, and the vast majority of devices fall under the 3-year rule. Furthermore, FDA believes that this cost is justifiable given the severity of the adverse events that have occurred and the fact that such adverse events are entirely preventable.

VI. The Banning Action

FDA proposed to ban devices under section 516 of the act (21 U.S.C. 360f) that did not meet the standard on the applicable effective date. Upon reconsideration, FDA has determined that a ban is unnecessary. Under section 501(e) of the act, devices not meeting the performance standard on its effective date are adulterated. Furthermore, original equipment manufacturers (OEM's) and third-party suppliers will not be permitted to supply replacement cables and lead systems that fail to meet the standard, absent an FDA waiver or exemption.

VII. Summary and Analysis of Comments and FDA's Response

The agency received 27 written comments from manufacturers, distributors, user facilities, and trade associations in response to the proposed rule. A summary of the written comments is provided below.

1. In general, several comments supported FDA's efforts to resolve the problem of macro shock or electrocution due to an improper connection of a patient-connected electrode lead wire to an AC power source. However, a few comments expressed concern that the proposed banning action would apply to the devices that utilize unprotected electrode lead wires and patient cables instead of the lead wire systems themselves.

FDA has shifted the applicability of the performance standard from the device utilizing the electrode lead wires and patient cables onto the electrode lead wires and patient cables themselves. Moreover, FDA has withdrawn the banning action from the final rule, because it was determined not to be necessary.

2. FDA received several comments questioning which devices should be subject to the 1-year effective date and which should be subject to the 3-year effective date. One comment suggested that the two lists of devices in the proposed rule be eliminated from the final rule and that the ban simply be made effective for all devices 1 year from the publication date of the final rule. Other comments questioned whether particular devices should be placed on the 1-year list and, thus, subjected to the ban and performance standard after 1 year or whether the devices should properly be included in the 3-year list and thus be given additional time to meet the standard.

In response to the comments, FDA has limited the devices on the 1-year list to the 10-device types that the agency believes to be most likely to expose persons to macro shock or electrocution based on the reported adverse events and the environments in which the devices are used. Electrode lead wires or patient cables intended for use with any other device will be subject to the performance standard 3 years from the date of publication.

3. One comment suggested replacing the word ''protected'' in the proposed performance standard (§ 898.11) with the word ''designed'' to allow greater flexibility for electrode lead wire designers.

FDA advises that, although the standard that the agency is issuing in this final rule has been modified from the proposed standard, the word ''protected'' in the proposed rule was intended to encompass creative design changes to devices as well as the development of adapters for use with existing devices in order to achieve a safe electrode lead wire and patient cable configuration. The agency believes that the mandatory performance standard being established in this final rule accomplishes the goal of providing manufacturers flexibility in achieving the desired protected configuration. It is anticipated that the marketplace will determine one or more suitable design standards for the manufacture of new equipment and adapters which will provide safe and effective protected electrode lead wire and patient cable configurations.

4. One comment suggested that, instead of instituting a ban on unprotected electrode lead wires and patient cables and establishing a mandatory performance standard, it would be easier to simply fire the hospital employee who plugs a patient into a receptacle.

FDA disagrees with this comment. The agency believes that proactive measures are appropriate to address the risk of harm presented by unprotected electrode lead wires and patient cables, particularly when it is reasonably foreseeable that risk of misuse of a device will result in serious adverse health consequences or death. Imposing sanctions after adverse incidents would not necessarily reduce the risk presented by those devices, nor would it address the risks presented by them when used in a home environment. The agency has determined that a change in the design of electrode lead wires and patient cables to a protected configuration is both technologically and economically feasible, if given a reasonable time for implementation.

5. One comment questioned whether devices that utilize unprotected patient cables and/or electrode lead wires which simply contact the patient during operation, as opposed to being directly attached to him or her, are included in this rule.

FDA has determined that, because the electrical contact between a patient and an unprotected cable or electrode lead wire that is plugged into an AC power source need only be momentary to produce disastrous results, devices that simply contact the patient during operation are also hazardous and, consequently, are included within the scope of the performance standard.

6. One comment suggested that a company should be allowed to label its conforming product as registered and approved by FDA so that physicians

could buy from an FDA approved manufacturer.

The act specifically prohibits a manufacturer from representing its medical device as having been approved. (See section 301(l) of the act (21 U.S.C. 331(l)); and see also 21 CFR 807.97, regarding premarket notifications.) In addition, compliance with a mandatory performance standard is different from FDA approval of a device.

7. Several comments expressed concern over the ability of their health care facilities to absorb the cost of either adapting old equipment to the protected configuration or purchasing new equipment to meet the performance standard in a 1-year timeframe. These comments requested that a particular device be moved from the proposed 1-year list to the 3-year list in order to have an adequate opportunity for compliance.

It is not the intent of the agency to create undue economic hardship on facilities in its efforts to minimize the risk of injury or death from an improper connection of a patient cable or electrode lead wire to an AC power source. The agency is interested in balancing the cost of implementing this rule with the demonstrated risk. The agency has addressed the issue of cost to facilities in the following two ways. First, in the final rule, FDA has significantly reduced the number of devices subject to the performance standard in the 1-year timeframe. Due to the higher level of risk they present, unprotected electrode lead wires and patient cables cannot be used with the 10-device types that remain in this category 1 year after the publication date of this rule. However, 3 years from the date of publication of this rule, unprotected electrode lead wires and patient cables cannot be manufactured, distributed, sold, resold, or used on patients unless they meet the performance standard. On the effective date of the performance standard, electrode lead wire and patient cable manufacturers can no longer produce or supply unprotected electrode lead wires and patient cables as replacements for use with these existing devices.

FDA encourages the entrepreneurial development of suitable adapters that can be used with existing equipment to speed the creation of a safer environment for patients.

8. Several comments have cited the professionalism of their health care staff as evidence of the improbability that an adverse event such as a macro shock or electrocution would occur in their facility. These comments believe that their devices should not be subject to the ban or performance standard.

FDA disagrees with these statements. Since 1985, when the first incident occurred, various groups have made the argument that such events do not, have not, and would not happen at their facility. After the first death in 1985 in a patient's home, it was argued that these events could only happen outside of a health care facility, away from the watchful eye of a professional. However, since that time, at least 23 additional cases of macro shock or electrocution have occurred, including 3 electrocutions by nurses. FDA believes that, while some areas of a health care setting are more stressful than others, human error can and does occur. A patient should not needlessly be exposed to a known and preventable risk simply because it has not happened yet in a particular area of a facility. However, in an effort to address the cost considerations for health care facilities, the agency has moved most devices to the 3-year effective date.

9. One comment suggested that FDA simply encourage manufacturers to comply with one of the existing voluntary standards (e.g., IEC 601–1), rather than issuing its own mandatory standard. Other comments suggested that enforcement of a voluntary standard could be achieved through manufacturer ''self-certification'' of compliance with IEC 601–1. It was further suggested that compliance with a voluntary standard could be monitored through the 510(k) review process.

FDA disagrees with a voluntary approach. The agency has determined that a mandatory performance standard is necessary to address the significant risk of harm presented by unprotected electrode lead wires and patient cables. However, FDA has taken the suggestion that the agency adopt an existing consensus standard rather than develop its own and possibly conflicting standard.

10. Two comments questioned the need for a protected electrode lead wire performance standard to apply to battery-powered devices, such as a transcutaneous electrical nerve stimulator (TENS) device. The comments indicated that TENS devices use a lead wire with a 2.5 millimeters (mm) coaxial pin connection that is not universally interchangeable with apnea monitors and ECG lead systems.

FDA disagrees with these comments. Two electrocutions occurred when one child plugged his own attached lead wire into a wall socket and when a second child plugged a sibling's attached lead wire into a power cord. These incidents happened with a 2.0 mm exposed pin, but could easily have happened with a 2.5 mm plug. The point that these devices are battery-powered is not relevant because it is the dangling patient-connected cable or electrode lead wire that is dangerous, not the battery-powered device.

11. Several comments suggested that each electrode lead wire or cable simply be labeled with specific warnings about exposed pins and the potential hazard of electrocution when connected to an AC power source.

FDA is aware that, in response to the section 518(a) of the act letters that the agency issued in 1993 (Ref. 7), many firms conducted voluntary recalls of unprotected electrode lead wires to correct the labeling on these devices. However, FDA has determined that the continued marketing of unprotected electrode lead wires and patient cables, no matter how they are labeled, presents an unreasonable and substantial risk of illness or injury to individuals, and provides no benefit to the public health that is not provided by protected electrode lead wires and patient cables. Use of unprotected electrode lead wire and patient cable configurations have resulted in, and can be expected to continue to result in, serious adverse health consequences or death because these devices are inherently dangerous when used in a reasonably foreseeable, albeit inappropriate, manner. There are no labeling requirements that can reliably prevent inappropriate connections of unprotected electrode lead wires and patient cables and, thus, unprotected electrode lead wire configurations cannot be safely marketed for their intended purpose.

Accordingly, FDA determined that a change in labeling will not suffice. Indeed, labeling warnings are meaningless when unprotected electrode lead wires and patient cables are available to preschool children or individuals with limitations such as vision problems or cognitive impairments. Further, labeling is often an inadequate solution in certain hospital settings when health care professionals find themselves in busy, stressful situations in which they may not be provided with, or could inadvertently overlook, instructions.

12. Two comments questioned whether 2.5 mm coaxial pin electrode lead wires should be subject to the performance standard because these lead wires may not produce the same potentially damaging result. These comments cited a 1994 class II recall and labeling action by CDRH's Office of Compliance in which the agency did not call for user notification and labeling of

2.5 mm coaxial plugs. In addition, one comment stated that there is no reasonable possibility of substitution of a 2.5 mm coaxial plug for use with an apnea monitor patient cable designed to accept individually exposed 2.0 mm pins.

FDA disagrees. The August 1993 incident in which a protected 2.0 mm electrode lead wire and patient cable system for an apnea monitor had been replaced by an unprotected 2.0 mm cable and lead wire configuration had disastrous results. In this incident, an infant was electrocuted when the replacement unprotected electrode lead wire was directly connected to an AC power cord. CDRH's Office of Compliance required contraindication labeling of exposed 2.0 mm pin lead wires which, in short, warned users not to use unprotected 2.0 mm pin lead wires with apnea monitors. Older apnea monitor designs use electrode lead wires with individual 2.0 mm pins and a patient cable with 2.0 mm sockets. Unprotected electrode lead wires having a 2.5 mm pin (such as those used with TENS devices) were exempted from the labeling requirement because it was believed to be physically impossible to fit a 2.5 mm plug into a 2.0 mm patient cable socket. FDA accepted the firm's argument against labeling an unprotected lead wire with a 2.5 mm pin to warn against its use with an apnea monitor.

In view of the information available to the agency at the time, on March 8, 1994, the agency informed a contract leads manufacturer that, ''It is our understanding from discussions with other manufacturers that a 2.5 mm pin plug is too large to fit into an electrical power cord or wall outlet, and therefore would not need to be labeled.'' However, that assessment was subsequently changed following test results submitted by two TENS/national medical equipment supplies manufacturers, both of whom confirmed that the 2.5 mm coaxial pin could be inserted into power cords and wall outlets. One manufacturer also showed the same results for flexible 2.75 mm ''banana'' plugs. One test showed no electrical current flow for the 2.5 mm pins, while a second test showed that an electrical connection was made.

Because it is physically possible to insert a 2.5 mm pin into an AC power source, these devices are subject to the performance standard established in this rule.

13. One comment sought clarification of FDA's assertion in the proposal that, ''if an adapter is used, it should prevent removal by the user.'' The comment suggested that ''like the patient cable, an adapter can trap blood and other contaminants during use. A reusable adapter must be easily and thoroughly cleaned and sterilized. The adapter should be submersible, capable of being abrasively scrubbed, and autoclavable.''

FDA agrees that, in some applications, it may be necessary to have an adapter that is capable of being removed from the device for cleaning purposes. However, because reported adverse events have shown a propensity for individuals to simply remove a protected configuration from a device and replace it with an unprotected configuration for the sake of convenience, the agency recommends use of adapters that are not easily removed by the user (e.g., only detachable with the use of a tool). The agency believes that, for those applications where device contamination is of concern, the adapter should be disposable, if possible, and that the device should not be suited to accept and function with an unprotected electrode lead wire and patient cable configuration.

14. One comment sought to clarify whether only electrodes with preattached lead wires were unprotected or whether the ''snap-on'' electrodes without the lead wires are also considered unprotected. Another comment questioned whether patient-connected electrodes with exposed wires were covered under the standard or only those having a pin attached at the end distal to the patient.

FDA considers any patient cable or electrode lead wire having a distal end that is capable of making conductive contact with an AC power source (e.g., a power cord, or wall outlet) to be unprotected and, therefore, subject to the performance standard. The standard applies to the lead wires themselves, and not to detachable ''snap-on'' electrodes with which they may be used.

15. One comment questioned who would be responsible for product inventory once the banning action becomes effective. Another comment expressed opposition to manufacturers having to recover product from the field. Yet another comment sought clarification of the responsibility of the manufacturer for a device that was introduced into the marketplace prior to the effective date of the standard but the user returns the device for repair or maintenance under a maintenance agreement and the device has not yet been modified in accordance with the standard.

As mentioned in section VI. of this document, FDA has eliminated the proposed banning action in this final rule. FDA believes that the manufacturer, distributor, seller, and user should share in the responsibility for removing adulterated goods under their control from the marketplace. Because many of the devices that are affected by the performance standard may be retrofitted in the field, or perhaps equipped with a suitable adapter, the agency has not determined that a device recall is warranted at this time. The agency believes that each participant in the chain of commerce has a role to play in ensuring that the devices under their control meet the performance standard by the effective date. The responsibility for equipping a device that is returned to the manufacturer under a maintenance agreement such that it conforms to the standard would likely depend upon the specific terms of the agreement. As both users and manufacturers are equally concerned for the safety and welfare of the patients that they serve, FDA anticipates that they will work cooperatively to ensure that these devices are in compliance with the performance standard. FDA reiterates that the performance standard in the final rule applies to the lead wire and patient cable, not to the medical equipment to which they are attached.

16. One comment suggested that the agency adopt the comparable IEC 601–1 standard (i.e., IEC 601–1, subclause 56.3(c)) as the performance standard because it addresses test methods that were not included in FDA's proposed performance standard. The comment believed that adoption of this international standard would also promote global harmonization of standards.

FDA agrees with this comment. Prior to drafting the proposed standard, FDA evaluated the voluntary standards that were then in existence to determine whether any of these standards might be adopted to address the concerns of the agency with unprotected electrode lead wires. At the time of publication of the proposed rule, IEC 601–1 was being amended and it could not be determined whether the amended standard would be adopted by the membership and, if so, when it would be published. However, in March 1995, IEC published the second amendment to IEC 601–1, including subclause 56.3(c), which prohibits electrode lead wires and patient cables from having the capacity to make conductive contact with hazardous voltages. After examination of this ratified amendment, the agency has determined that adherence to the IEC 601–1 as amended would provide acceptable protection of patients from connections to hazardous

voltages. In addition, FDA's adoption of this requirement of the IEC standard demonstrates the agency's continued interest in promoting the adoption of international voluntary standards, where feasible, to satisfy safety and effectiveness requirements for medical devices.

17. One comment asked whether, for a preamendment device, FDA would accept a letter of notification of a change to a protected configuration. The comment believed that it would be unreasonable to subject a preamendment device, that has been modified to incorporate a protected configuration, to additional regulatory requirements while those devices under a 510(k) require only an addendum.

FDA is establishing the following procedures for notifying the agency of device modifications in compliance with the following performance standard:

For a device reviewed through the premarket notification (510(k)) process or for a preamendment device, information regarding modification of the device from an unprotected electrode lead wire and patient cable configuration to a protected configuration, and information demonstrating compliance with the performance standard, should be documented in the manufacturer's device master records in accordance with the current good manufacturing practice regulation. FDA recognizes that a change from the unprotected to the protected configuration is a change that under 21 CFR 807.81(a)(3) could affect safety and effectiveness. However, in the interest of public health, and due to the straightforward nature of the device modification and demonstration of compliance with the performance standard, the agency is not requiring prior clearance for this specific device modification. FDA recognizes that this procedure differs from the agency's previous recommendation that manufacturers who were voluntarily making changes from the unprotected to the protected configuration submit documentation of the changes as an addendum to their existing premarket notification (510(k)) files. Because compliance with the performance standard will no longer be voluntary, but will be mandatory, placement of documentation of the device modification from an unprotected configuration to a protected configuration and of documentation demonstrating compliance with the performance standard into the device master records will be sufficient.

For devices reviewed through the premarket approval process, modifications from an unprotected electrode lead wire and patient cable configuration to a protected configuration also may be implemented without prior approval by FDA. FDA has determined under 21 CFR 814.39(e) that an alternate submission, a periodic report, is appropriate. Thus, in the interest of public health, and due to the straightforward nature of the device modification, information regarding modifications to the protected configuration and information demonstrating compliance with the performance standard should be provided in the next annual report to the applicable premarket approval application (PMA). The modification can be made prior to submission of the annual report.

The information provided in the manufacturer's device master record or the PMA annual report should include engineering drawings and a description of the change(s), an explanation of how the change(s) prevents connection to a power source, and documentation demonstrating compliance with the performance standard. If an adapter design is implemented, an explanation of how the signal acquisition and processing is not compromised by the addition of the adapter, and how the design of the adapter prevents removal by the user, should also be provided.

18. One comment sought clarification of the manner in which the agency would identify those devices that would be subject to this rule, but have not yet been classified (e.g., electrode lead wires and patient cables intended for use with dental TENS units).

All devices that meet the applicability section of the standard (§ 898.11) are subject to the requirements under the rule, whether or not they have been formally classified.

19. One comment wrote that implementation of the ban and performance standard in 1 year might not provide the time needed for design changes, validation, and manufacturing, and for production of a device inventory sufficient to meet global demand. The comment believed that difficulties in meeting the 1-year timeline may cause some manufacturers to abandon businesses associated with the affected devices, which potentially could affect supply.

The agency believes that changes made to the final rule adequately balance public health concerns with the economic impact of making this transition. Under the final rule, the devices for which the performance standard will become effective in 1 year are only those electrode lead wires and patient cables associated with the 10 devices presenting the highest risk of a user inappropriately connecting the electrode lead wire or patient cable to an AC power source. Of these 10 devices, electrode lead wires and patient cables intended for use with apnea monitors are largely in compliance with the standard. Because of their early involvement with electrocution and macro shock incidents, new apnea monitor devices without a protected electrode lead wire configuration have not received agency clearance for marketing since 1989. ECG manufacturers have also been encouraged by the agency to provide protected electrode lead wire and patient cable systems with their devices. In addition, the agency published the ANPRM in the **Federal Register** of May 19, 1994, held a public conference on the issue in July 1994, and advised the manufacturing and medical user community of efforts to address this problem through wide dissemination of public health advisories, direct mailings to the users and the manufacturing communities, and published its proposal to establish a performance standard and a ban in the June 21, 1995, proposed rule. The agency believes that both manufacturers and the medical user community have had ample time to begin modifying these 10-device types, and electrode lead wires and patient cables intended for use with them, to avoid this potential problem. The agency is establishing the effective date of the performance standard for electrode lead wire and patient cables for use with these 10 devices at 1 year from the date of publication of the final rule to provide further time for a steady transition to a safe electrode lead wire and patient cable configuration. Finally, for exceptional circumstances that are not adequately addressed in the 1-year timeframe, the agency has established a variance procedure in which affected parties may request an exemption or additional time in which to meet the standard.

20. One comment stated that the marginal replacement costs mentioned in section IX. of the proposed rule (60 FR 32406 at 32414) assume an appropriate replacement accessory is available through the manufacturer at costs comparable to the original lead system. According to the comment, because lead wire manufacturers do not have to produce replacement leads, but rather must cease producing unprotected patient cables and leads, the costs of unplanned replacement of even a small fraction of expensive diagnostic devices as a result of the unavailability of the protected style

accessories is exponentially greater than the lead-for-lead replacement costs alluded to section IX. of the proposed rule.

FDA disagrees with this statement. Several lead wire manufacturers have already informed the agency that they are now, or soon will be, producing protected electrode lead wire and patient cable configurations. The agency does not have any evidence to show that manufacturers will simply cease manufacturing unprotected electrode lead wires and patient cables and fail to produce a protected electrode lead wire configuration as a replacement.

21. One comment suggested that in cases where the electrode lead wires are permanently attached to incontinence electrodes, the leads could not migrate to other uses or environments and, therefore, the lead wire cannot be detached from the uniquely shaped electrodes.

Sections 898.11 and 898.13 specify the applicability of the performance standard. If a device meets the applicability requirements under § 898.11 and an interested party believes, due to the unique circumstances of the device, its intended use, or its reasonably foreseeable misuse, that no electrical hazard is presented to a patient, the party may petition the agency under the variance procedure for review of these unique circumstances.

22. One comment expressed concern about not having a sufficient manufacturing staff to retrofit its devices. Concern was also expressed that hospital staffs lack qualifications to perform and validate changes to installed medical devices. The comment contended that making these changes increases the risk of device failure due to unapproved or improperly tested device adaptations, and increases legal liability for the institution.

FDA disagrees with this comment. It is imperative that the manufacturer of a device that utilizes electrode lead wires and patient cables provide a connection arrangement from the patient to the monitoring or treatment device which cannot be conductively connected to a hazardous voltage. The manufacturer has a choice of modifying the design of the equipment to accept only a protected cable and electrode lead wire, of providing an adapter for the equipment interface to receive only a protected electrode lead wire configuration, or of directing the user of its medical device to a third-party manufacturer of protected electrode lead wires and patient cables or suitable adapters. Hospital staff with ability to make an unprotected patient cable and lead wire connection from the patient to the device are equally capable of making a protected connection. It is up to the manufacturer to ensure that the device change is in conformity with its specifications and labeling.

23. One comment noted that lead wires are not always class II devices and, therefore, it is not clear that FDA has the authority to regulate all electrode lead wires with a mandatory standard.

FDA agrees that a few unprotected cable and electrode lead wire systems are class I devices, and, as such, are not subject to a mandatory performance standard. Specifically, these devices include:

TABLE 1.

Phase	Product code	21 CFR section	Class	Device name
2	89 IKD	890.1175	I	Cable, Electrode (for Use With Diagnostic Physical Medicine Devices).
2	74 KARI	870.4200	I	Accessory Equipment, Cardiopulmonary Bypass.
2	87 KQX	888.1500	I	Goniometer, AC-Powered.

Because of the degree of the health risk, the agency plans to initiate procedures to reclassify these devices into class II so that all electrode lead wires and patient cables will be subject to the mandatory performance standard.

24. Another comment questioned whether a manufacturer would be in violation of the banning action for repairing a user's banned device.

As stated above, FDA is not banning these devices. Therefore, this comment is now moot.

25. One comment suggested that there may be cases where the OEM is out of business and protected replacement cables and electrode lead wires cannot be obtained.

FDA has no evidence to suggest that the absence of the OEM would pose a significant obstacle to obtaining suitable lead wire replacements. Replacement cables and electrode lead wires may often be obtained from third-party manufacturers, or an adapter set may be used to convert the unprotected pin configuration to a protected one. In rare cases, where a user finds that the OEM is unwilling or unable to supply a protected electrode lead wire and patient cable system, and that there exists no thirdparty equivalent, the user has the option of petitioning the agency under the variance procedure by documenting the special circumstances that warrant an exception to the standard.

VIII. Enforcement

FDA's statutory authority to issue performance standards is derived from section 514 of the act. Section 701(a) of the act (21 U.S.C. 371(a)) authorizes FDA to issue binding regulations for the efficient enforcement of the act. (*Weinberger* v. *Hynson, Westcott & Dunning, Inc.,* 412 U.S. 609 (1973); see also *Weinberger* v. *Bentex Pharmaceuticals Inc.,* 412 U.S. 645, 653 (1973); *National Assn. of Pharmaceutical Manufacturer* v. *FDA,* 637 F.2d 877 (2d Cir.), *cert. denied,* 423 U.S. 827 (1975).) Section 519(a) of the act (21 U.S.C. 360i(a)) also authorizes the agency to issue regulations requiring manufacturers of devices to maintain and provide records to ensure that devices are not adulterated, misbranded, unsafe, or ineffective. FDA's performance standards for medical devices are substantive regulations with the force and effect of law. (See *United States* v. *Undetermined Quantities of Various Articles of Device* * * * *Proplast II,* 800 F. Supp. 499, 502 (S.D. Tex. 1992); *United States* v. *789 Cases* * * * *Latex Surgeons' Gloves,* 799 F. Supp. 1275, 1287 (D.P.R. 1982).)

Section 501(e) of the act deems a device to be adulterated, and thus prohibited from commerce, if it is a device subject to a performance standard established under section 514 of the act, unless such device is in all respects in conformity with such standard. Introduction into interstate commerce of a device that fails to comply with the requirements established by section 514 of the act is a prohibited act under section 301(a) of the act (21 U.S.C. 331(a)), and the agency will use its enforcement powers to deter noncompliance. Persons who violate section 301 of the act may be subject to injunction under section 302(a) of the act (21 U.S.C. 332(a)). In addition, any person responsible for

violating section 301 of the act may be subject to civil penalties under section 303(f) of the act (21 U.S.C. 333(f)) and criminal prosecution under section 303(a).

IX. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(3) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Unfunded Mandates Reform Act of 1995

Under the Unfunded Mandates Reform Act, FDA concludes that the substantial benefits of this regulation will greatly exceed the compliance costs that it imposes on the U.S. economy. In addition, the agency has considered other alternatives and determined that the final rule is the least burdensome and the most cost effective alternative that would meet the objectives of this rule. Because FDA anticipates no significant additional costs to State, local, or tribal governments, this regulatory action does not require an assessment under the Unfunded Mandates Reform Act.

XI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this rule is consistent with the regulatory philosophy and principles identified in the Executive Order. The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact on small entities. As a result of its analysis, FDA has determined that this final rule is not a significant regulatory action as defined by Executive Order 12866. In addition, the Commissioner of Food and Drugs certifies that the rule will not have a significant economic impact on a substantial number of small entities.

XII. Introduction to Economic Analysis

FDA believes that the presence of unprotected lead wires in a home, hospital, or other user facility creates an unreasonable risk to patients of hazardous electrical connections from electrical power sources. In the proposed rule of June 21, 1995, FDA proposed to create a performance standard for electrode lead wires, and to ban the use of unprotected leads. Many comments supported the intent of the proposal, and agreed with the phased approach toward eliminating the problem. Other comments, however, expressed the view that the benefits would be outweighed by the costs associated with converting the large number of device types listed in the proposed rule. For example, AHA wrote that ''[when] all costs from all devices are considered, the total cost impact to a facility would be at least $45 per licensed bed * * *. For the over one million hospital beds in the United States, the impact would be greater than $45 million.'' AHA called this a conservative estimate, and requested that a comprehensive impact analysis be performed by FDA, which would include logistical costs, stocking costs, cost for ongoing surveillance, and the capital cost to replace equipment for which protected style lead systems are not available. In this economic analysis, FDA considers those costs and benefits that would be incurred as a direct result of this final regulation.

Due to liability concerns, many of today's manufacturers are already moving toward protected lead and cable pin configurations for select devices. In order to prevent future adverse incidents, however, FDA is issuing a new regulation that will ensure the movement toward protected electrode lead wires and patient cables. Phase I of the regulation applies to unprotected lead wires used with the 10 devices for which there is the highest risk of accidental connection to hazardous voltages. In 1 year from the publication date of this rule, electrode lead wires and patient cables used with or intended for use with the following devices will be subject to a performance standard: Patient cable, apnea/breathing frequency monitor, ECG monitor, cardiac monitor, multi-parameter/vital signs monitor, ECG electrode with attached lead wire, arrhythmia monitor, transmitters and receivers/physiological signal/radiofrequency, recorder/magnetic tape/medical, and transmitters and receivers, electrocardiograph/telephone. Phase II applies to electrode lead wires and patient cables used with or intended for use with all other medical devices. Three years from the effective date of this rule, lead wires and patient cables that do not meet the performance standard may no longer be used or sold. The rule also states that exemptions may be requested for devices that justifiably cannot meet the standard on the date it goes into effect.

A. Regulatory Benefits

Since 1985, there have been at least 24 reported incidents involving the use of unprotected electrode lead wires and patient cables. These incidents occurred with both infants and children who received ''macro-shock'' due to the improper use of these leads and cables. Such occurrences have caused burns to the skin under the electrodes, cardiorespiratory arrest, comas, neurological damage, or other serious injuries. In five of these incidents, children died by electrocution. Less significant incidents are probably underreported as FDA typically receives reports on only a fraction of all events.[1]

FDA believes that this regulation will eliminate, to the extent possible, the hazard associated with unprotected lead wires and patient cables. While most comments acknowledged the unacceptable risk attributable to the unprotected Phase I devices, many denied the need to extend the scope of the rule to the Phase II devices. FDA, however, finds that the interchangeability of electrode lead wires and patient cables among medical equipment establishes the need to encompass such a large number of devices. Regardless of where or what device they are used with, unprotected electrode lead wires themselves can be plugged into a receptacle and become hazardous. Through the implementation of this regulation, FDA expects to prevent another incident of ''macro-shock'' or death.

B. Regulatory Costs

In order to comply with this final rule, unprotected devices will either be replaced or modified to accept only protected leads, and all new devices under development will need to be designed to accept only protected leads. The agency received no comments indicating that incremental cost to manufacturers for the redesign of new devices would be substantial, if adequate time was allowed. Moreover, few existing devices will need to be prematurely replaced because virtually all devices can be made safe through the use of protected lead wires and either adaptors or other modifications of the connecting equipment. Where adaptors or modifications are not feasible, FDA

[1] ''Medical Devices: Early Warning of Problems is Hampered by Severe Underreporting,'' United States General Accounting Office Report to the Chairman, Committee on Governmental Affairs, U.S. Senate, p. 61, December 1986.

will consider individual variance requests. A number of manufacturers have indicated that adaptors are inexpensive and easy to install, and provide no loss of signal integrity. Adaptors are not presently available for all existing devices, because there is inadequate current demand. The regulation, however, will create strong incentives for device manufacturers or other suppliers to develop adequate adaptors, and the extended phase-in periods will provide sufficient time for such conversions to be made. Thus, FDA expects that there will be minimal costs for redesigning the new devices currently under development, and most existing devices will comply by obtaining appropriate adaptors. As derived below, FDA estimates the total cost of bringing all of these devices into compliance to be about $21 million.

1. Phase I

a. *Devices.* For the purpose of this analysis, the lead wires and patient cables used with or intended for use with the 10 previously mentioned Phase I devices have been grouped into two categories. The first category consists solely of the lead wires and patient cables used with the apnea/breathing frequency monitor. In the early 1990's, a Federal performance standard was proposed to phase out the use of unprotected lead wires with apnea monitors. Encouraged by the intense liability concerns among industry, almost all of the lead wires for these monitors are now protected. Therefore, FDA assumes no costs associated with bringing this first category of lead wires into compliance.

The second category consists of the lead wires used with the remaining nine devices (hereinafter referred to as ECG-type devices). The useful life for these devices reportedly ranges from 7 to 10 years. Using an average useful life of 8 years 6 months, the 1-year phase-in period implies that about 88 percent of these devices will have to be converted. According to a survey by AHA conducted in early 1994,[2] approximately 78 percent of their responding members indicated that steps have already been taken to replace the unprotected lead wires on their ECG devices. In this cost analysis, therefore, FDA only counts the costs associated with bringing into compliance the lead wires on the remaining 22 percent of those devices that would still have some remaining useful life by the conclusion of the 1-year timeframe following publication of this rule.

b. *Lead wires.* All of the ECG-type devices have three lead wires except for the arrhythmia monitors and the Holter monitors (classified under transmitters and receivers/physiological signal/radiofrequency, recorder/magnetic tape/medical, and transmitters and receivers, electrocardiograph/telephone). The number of lead wires on an arrhythmia monitor could range from 5 to 12. For analysis, FDA estimates the mean number of lead wires on an arrhythmia monitor to be 8.5. The number of lead wires on a Holter monitor generally ranges from three to five. Thus, FDA estimates the mean number of lead wires on a Holter monitor to be four.

Lead wires are generally sold in pairs, sets, or bulk quantities. For this analysis, FDA uses an average price of $7 for a set of three lead wires, or $2.33 per unit. This estimate may be too high as some user facilities may purchase lead wires in bulk at less expensive per unit prices.

There is only an incidental price difference between the protected lead wires and those that are not protected. Therefore, no incremental costs have been added for the purchase of the protected leads as compared to the unprotected leads. As costs are counted only for leads that need to be replaced while they still have some useful life, FDA charges only half the cost of the purchase of these lead wires to the regulation. Because the lead wires for ECG-type devices have a useful life of approximately 2 years, 50 percent of these lead wires will be replaced on average within the 1-year timeframe after the publication date of this final rule.

c. *Adaptors.* For all ECG-type devices, FDA assumes that adaptors will be available to connect the cables and lead wires. Only one cable is used per ECG-type device, with the exception of the Holter monitor. These cables cost between $50 to $100 to be replaced. Because it is less costly to purchase adaptors than to purchase new cables to fit the protected lead wires, FDA assumes that user facilities would purchase adaptors to use for the remaining useful life of the cables. For Holter monitors, FDA assumes that adaptors will be used between the lead wires and the device itself. The costs of purchasing adaptors is approximately $5 each. One adaptor is needed for each lead wire used with or intended for use with the device. Therefore, most ECG-type devices would require three adaptors, the arrhythmia monitor would use 8.5 adaptors, and the Holter monitor would use four adaptors on average. A block of adaptors may be purchased, however, FDA assumes the unit price will remain unchanged. After discussions with various manufacturers, FDA finds that the distal ends of most cables are either already protected or too large to be forced into contact with a hazardous voltage. Thus, no costs were assigned for attaching adaptors to the distal end of the cables.

Because the useful life of cables for ECG-type devices is approximately from 2 to 3 years, FDA estimates that 40 percent of these original cables will need to be replaced with cables that accept the protected lead wires within 1 year after the publication date of this final rule. As redesigned cables are sold at about the same price as the older cables, no added cost is attributable to these cables. Therefore, only about 60 percent of these devices will require an adaptor due to the regulation. Some facilities whose cables have little remaining useful life may opt to replace their cables earlier, even though the price of new cables are significantly higher than that of adaptors. Nevertheless, this analysis assumes that users would purchase new cables only if they were a less costly option.

d. *Adaptor installation.* FDA uses the 1995 median weekly earnings of $598[3] for engineering and related technologists and technicians as the base for the costs associated with affixing the adaptors onto the unprotected cables. Adding 40 percent for benefits, total hourly earnings are estimated at $20.93. The following tables show a per minute salary rate of $0.35. Based on discussions with industry representatives, FDA estimates that it will take a total of about 5 minutes to thoroughly clean the connector area on the cable or device itself, and then to affix the adaptor to the cable or device. For those instances where the adaptor is to be affixed onto a cable, FDA allots 5 minutes per device, regardless of the number of lead wires utilized by the device. This time should be adequate because one block of adaptors could be used to convert the entire device. For those instances where the adaptors are to be affixed onto the device itself, FDA allots 5 minutes per lead wire. FDA also added a one-time cost for each facility to capture the amount of time they would need to familiarize themselves with the conversion process and to locate the affected devices.

e. *User facilities.* The user facilities examined are hospitals, nursing homes,

[2] "Electrode Leadwire Survey," distributed by the American Society for Hospital Engineering of AHA, early 1994.

[3] *Employment and Earnings,* U.S. Department of Labor Bureau of Labor Statistics, Table 39, p. 206, January 1996.

ambulances, and doctor's offices, and clinics. It is in these facilities that the majority of ECG-type devices are found. ECG-type devices found in Free-Standing Ambulatory Care Centers and in Cardiac Labs of Hospital Outpatient Centers are accounted for under costs to doctor's offices and clinics.

(i). *Cost to hospitals.* In 1993, 6,467 hospitals were accepted for registration by AHA, with an average number of 179 beds in each of these hospitals.[4] According to several clinical engineers and bioengineering directors at various hospitals, one ECG-type device is found at approximately 30 percent of these beds. Therefore, FDA calculates that approximately 347,278 ECG-type devices are used in hospitals across the United States. Because the arrhythmia monitors were estimated to make up about 10 to 20 percent of the ECG-type devices used in the average hospital, FDA assumes that 15 percent of ECG-type devices in all hospitals are arrhythmia monitors. Holter monitors were estimated to make up another 15 percent of the ECG-type devices used in the average hospital. In addition, assuming that it might take roughly 1 minute to scan the devices in each room, FDA adds 3 hours per facility to account for the time it will take an average hospital to locate the appropriate devices. As shown in the table below, the total cost of this rule to hospitals comes to about $1.6 million.

TABLE 2.—COST OF PROTECTED LEAD WIRES TO HOSPITALS

Hospitals	Number of ECG's per hospital	Percent (%) of ECG's not protected	Percent (%) of leads to be replaced	Percent (%) of ECG's with useful life	Cost per lead	Number of leads	Percent (%) of useful lead life remaining	Total cost
ECG-Type Devices Except the Arrhythmia Monitor and the Holter Monitor								
6,467	38	22%	50%	88%	$2.33	3	50%	$82,581
The Arrhythmia Monitor								
6,467	8	22%	50%	88%	$2.33	8.5	50%	$50,138
The Holter Monitor								
6,467	8	22%	50%	88%	$2.33	4	50%	$23,594

TABLE 3.—COST OF ADAPTORS TO HOSPITALS

Hospitals	Number of ECG's per hospital	Percent (%) of ECG's not protected	Percent (%) of cables to be converted	Percent (%) of ECG's with useful life	Cost per adaptor	Number of adaptors	Total cost
ECG-Type Devices Except the Arrhythmia Monitor and the Holter Monitor							
6,467	38	22%	60%	88%	$5.00	3	$424,700
The Arrhythmia Monitor							
6,467	8	22%	60%	88%	$5.00	8.5	$257,854
The Holter Monitor							
6,467	8	22%	N/A	88%	$5.00	4	$202,238

[4] *The Statistical Abstract of the United States,* U.S. Department of Commerce Economics and Statistics Administration, Bureau of Census, No. 183, p. 125, 1995.

TABLE 4.—COST TO INSTALL ADAPTORS TO HOSPITALS

Hospitals	Number of ECG's per hospital	Percent (%) of ECG's not protected	Percent (%) of cables to be converted	Percent (%) of ECG's with useful life	Salary per minute	Installation time (in minutes)	Learning cost per hospital	Total cost
ECG-Type Devices Except the Holter Monitor								
6,467	46	22%	60%	88%	$0.35	5	N/A	$59,965
The Holter Monitor								
6,467	8	22%	N/A	88%	$0.35	20	N/A	$70,547
Learning Time								
6,467	N/A	N/A	N/A	N/A	N/A	N/A	$62.79	$406,063
Total Cost to Hospitals (Tables 1 through 3) =								**$1,577,680**

(ii). *Cost to nursing homes.* In 1993, there were approximately 11,309 skilled nursing facilities[5] in the United States. FDA estimates that there are approximately one to two ECG-type devices per nursing home (assuming no arrhythmia monitors or Holter monitors). FDA adds one-half hour to account for the time it would take each individual facility to learn how to convert their devices. As shown below, the total cost of this rule to the nursing homes amounts to about $157,000.

TABLE 5.—COST OF PROTECTED LEAD WIRES TO NURSING HOMES

Skilled nursing facilities	Number of ECG's per nursing home	Percent (%) of ECG's not protected	Percent (%) of leads to be replaced	Percent (%) of ECG's with useful life	Cost per lead	Number of leads per device	Percent (%) of useful lead life remaining	Total cost
11,309	1.5	22%	50%	88%	$2.33	3	50%	$5,763

TABLE 6.—COST OF ADAPTORS TO NURSING HOMES

Skilled nursing facilities	Number of ECG's per nursing home	Percent (%) of ECG's not protected	Percent (%) of cables to be converted	Percent (%) of ECG's with useful life	Cost per adaptor	Number of adaptors	Total cost
11,309	1.5	22%	60%	88%	$5.00	3	$29,636

TABLE 7.—COST TO INSTALL ADAPTORS TO NURSING HOMES

Skilled nursing facilities	Number of ECG's per nursing home	Percent (%) of ECG's not protected	Percent (%) of cables to be converted	Percent (%) of ECG's with useful life	Salary per minute	Installation time (in minutes)	Learning cost per facility	Total cost
11,309	1.5	22%	60%	88%	$0.35	5	N/A	$3,446
				Learning Time				
11,309	N/A	N/A	N/A	N/A	N/A	N/A	$10.47	$118,349
Total Cost to Nursing Homes (Tables 4 through 6) =								**$157,194**

(iii). *Cost to ambulances and other ground transport vehicles.* In 1995, the United States was reported to have 59,640 active and reserve ground transport vehicles for emergency purposes.[6] This figure does not include emergency vehicles designed to extinguish fires. Of this total number of vehicles, some are classified with advanced life support (ALS) services. These vehicles carry a manual defibrillator with an ECG monitor. These ECG-type devices have three lead wires and a screen with the ability to print a tape. The other vehicles have basic life support (BLS) services. Of these BLS transport vehicles, some have an automated external defibrillator (AED) which fires shocks automatically. These ECG-type devices have two lead wires, but do not have a screen or the capability to print a tape.

According to a survey completed by the National Association of State Emergency Medical Services (EMS) Directors in 1992, 59 percent of all emergency transport vehicles have ALS transport services.[7] Therefore, FDA estimates that 35,188 vehicles are ALS transport systems. Of the reporting organizations in 1995, 48 percent are classified as BLS with AED.[8] To determine the number of BLS vehicles with AED, FDA assumes that all 30,000 organizations with emergency transport vehicles identified in the 1995 survey[9] have two vehicles per organization. If all organizations reporting BLS with AED services have at least one vehicle offering this service, 14,314 BLS transport vehicles have AED. FDA adds one-half hour to account for the time it would take each individual organization to learn to convert its devices. Because FDA assumed two vehicles per organization, the costs associated with one-quarter hour per vehicle are shown in the table below. The total cost of this regulation amounts to approximately $362,000 for ambulances and other ground transport vehicles.

[5] *The Statistical Abstract of the United States,* U.S. Department of Commerce Economics and Statistics Administration, Bureau of Census, No. 200, p. 134, 1995.

[6] ''The United States Emergency Medical Services Market Report,'' based on data gathered from EMS Census 1995, prepared by Emergency Care Information Center and JEMS Communications, p. 40.

[7] ''Transportation Systems, 1994,'' produced by the National Association of State EMS Directors, p. 2, 1994.

[8] ''The United States Emergency Medical Services Market Report,'' based on data gathered from EMS Census 1995, prepared by Emergency Care Information Center and JEMS Communications, p. 17.

[9] ''The United States Emergency Medical Services Market Report,'' based on data gathered from EMS Census 1995, prepared by Emergency Care Information Center and JEMS Communications.

TABLE 8.—COST OF PROTECTED LEAD WIRES TO AMBULANCES

Ground transport vehicles	Number of ECG's per vehicle	Percent (%) of ECG's not protected	Percent (%) of leads to be replaced	Percent (%) of ECG's with useful life	Cost per lead	Number of leads per device	Percent (%) of useful lead life remaining	Total cost
ECG-Type Devices on ALS Transport Vehicles								
35,188	1	22%	50%	88%	$2.33	3	50%	$11,954
ECG-Type Devices on BLS Transport Vehicles								
14,314	1	22%	50%	88%	$2.33	2	50%	$3,242

TABLE 9.—COST OF ADAPTORS TO AMBULANCES

Ground transport vehicles	Number of ECG's per vehicle	Percent (%) of ECG's not protected	Percent (%) of cables to be converted	Percent (%) of ECG's with useful life	Cost per adaptor	Number of adaptors	Total cost
ECG-Type Devices on ALS Transport Vehicles							
35,188	1	22%	60%	88%	$5.00	3	$61,476
ECG-Type Devices on BLS Transport Vehicles							
14,314	1	22%	60%	88%	$5.00	2	$16,671

TABLE 10.—COST TO INSTALL ADAPTORS TO AMBULANCES

Ground transport vehicles	Number of ECG's per vehicle	Percent (%) of ECG's not protected	Percent (%) of cables to be converted	Percent (%) of ECG's with useful life	Salary per minute	Installation time (in minutes)	Learning cost per organization	Total cost
49,502	1	22%	60%	88%	$0.35	5	N/A	$10,056
Learning Time								
49,502	N/A	N/A	N/A	N/A	N/A	N/A	$5.23	$259,019
Total Cost to Ambulances and Other Ground Transport Vehicles (Tables 7 through 9) =								**$362,418**

(iv). *Cost to doctor's offices and clinics.* In 1992, there were approximately 199,500 offices and clinics of medical doctors[10] in the United States. FDA estimates that, on average, there is at most one Holter monitor and/or ECG-type device per office, and one to two ECG-type devices per clinic. For analysis, FDA assumes 1.25 ECG-type devices per doctor's office and clinic. FDA further assumes an equal proportion of Holter monitors and other ECG-type devices would be found in both doctor's offices and clinics. FDA adds one-half hour to account for the time it would take each individual facility to learn how to convert their devices. The total cost of this rule to the doctor's offices and clinics comes to about $3 million.

[10] *The Statistical Abstract of the United States,* U.S. Department of Commerce Economics and Statistics Administration, Bureau of Census, No. 1316, p. 795, 1995.

TABLE 11.—COST OF PROTECTED LEAD WIRES TO OFFICES AND CLINICS

Doctor's offices and clinics	Number of ECG's per office and clinic	Percent (%) of ECG's not protected	Percent (%) of leads to be replaced	Percent (%) of ECG's with useful life	Cost per lead	Number of leads	Percent (%) of useful lead life remaining	Total cost
ECG-Type Devices Except the Arrhythmia Monitor and the Holter Monitor								
199,500	0.6	22%	50%	88%	$2.33	3	50%	$40,605
The Holter Monitor								
199,500	0.6	22%	50%	88%	$2.33	4	50%	$54,140

TABLE 12.—COST OF ADAPTORS TO OFFICES AND CLINICS

Doctor's offices and clinics	Number of ECG's per office and clinic	Percent (%) of ECG's not protected	Percent (%) of cables to be converted	Percent (%) of ECG's with useful life	Cost per adaptor	Number of adaptors	Total cost
ECG-Type Devices Except the Arrhythmia Monitor and the Holter Monitor:							
199,500	0.6	22%	60%	88%	$5.00	3	$209,123
The Holter Monitor							
199,500	0.6	22%	N/A	88%	$5.00	4	$464,718

TABLE 13.—COST TO INSTALL ADAPTORS TO OFFICES AND CLINICS

Doctor's offices and clinics	Number of ECG's per office and clinic	Percent (%) of ECG's not protected	Percent (%) of cables to be replaced	Percent (%) of ECG's with useful life	Salary per minute	Installation time (in minutes)	Learning cost per facility	Total cost
ECG-Type Devices Except the Holter Monitor								
199,500	0.6	22%	60%	88%	$0.35	5	N/A	$24,316
The Holter Monitor								
199,500	0.6	22%	N/A	88%	$0.35	20	N/A	$162,109
Learning Time								
199,500	N/A	N/A	N/A	N/A	N/A	N/A	$10.47	2,087,768
Total Cost to Doctor's Offices and Clinics (Tables 10 through 12) =								**$3,042,779**

2. Phase II

This section examines the cost to user facilities for Phase II of this regulation. Although FDA believes that the use of adaptors will be an effective and available conversion method for most affected devices, facilities are permitted to request a variance for those devices that cannot be modified to accept protected leads. Therefore, the agency has not counted the cost of conversion methods other than adaptors.

For analysis, FDA has grouped most of the devices into the following general categories: Electrosurgery appliances, telemetry transmitters, external pacemakers, supervised diagnostic equipment, stimulators, and patient monitoring devices. While FDA recognizes that a small number of devices may not be represented in these categories, these device categories are based on the categories used in a survey distributed by AHA in 1995.[11] FDA assumes that at the end of 3 years, adaptors will be available for all devices. Therefore, the only costs identified as a direct result of the regulation are the cost of the adaptors, and the costs associated with their installation. FDA continues to assume that the distal ends of these cables have either previously been protected or are too large to be forced into a connection with a hazardous voltage, and therefore, no adaptor will be needed to attach the distal ends of these cables to the face plates of the devices. FDA has not included the costs of purchasing new cables or new lead wires because the 3-year phase-in period allows adequate time for protected models to be purchased through general attrition. The percentage of devices that utilize patient cables are estimated for each category. For example, all machines in the category of patient monitoring devices, typically have cables. As these devices move toward protected lead wire and patient cable designs, they will incur no extra costs as a direct result of this regulation.

[11] ''Electrode Leadwire Survey II,'' distributed by the American Society for Hospital Engineering of AHA, fall 1995.

Because specific data on the number of all affected devices are unavailable, FDA examines the cost to hospitals for Phase II of the rule by again estimating the device quantities as a percentage of hospital beds. As in Phase I, FDA's estimates are based upon the 6,467 hospitals in the United States and the reported average number of 179 beds in each hospital.[12] To determine the total number of devices in each category, FDA relied on estimates from clinical and biomedical engineering directors for the percentage of beds that would have these devices. The estimates are: Six percent for electrosurgery appliances, 15 percent for telemetry transmitters, 5 percent for external pacemakers, 13 percent for supervised diagnostic equipment, and 6 percent for stimulators. FDA assumed that between 90 percent to 100 percent of the devices have not already been converted to protected styles, and that a general useful life ranges from 7 to 10 years. Also, only devices without cables would need modification. These percentages were estimated to be approximately 75 percent for electrosurgery appliances, 100 percent for telemetry transmitters, 60 percent for external pacemakers, 50 percent for supervised diagnostic equipment, and 100 percent for stimulators. As previously noted, FDA uses a $20.93 hourly compensation figure to estimate incremental labor costs, or a per minute salary rate of $0.35.

The agency once more estimates it will take a total of 5 minutes per lead wire to both thoroughly clean the connector area on the device itself and to affix the adaptor to the device. The number of adaptors needed for each of the device categories is based on estimates of the average number of lead wires found on all devices in each category. FDA estimates that the adaptors cost $5 apiece and that it will take each hospital twice as long as for the Phase I devices, or 6 additional hours, to locate all of the Phase II devices. This adds $812,126 to the total cost of Phase II of this regulation. Using an average useful life of 8 years 6 months, the 3-year phase-in period implies that about 65 percent of these devices would have to be converted. The total costs to hospitals are illustrated in the following tables.

TABLE 14.—COST OF ADAPTORS TO HOSPITALS ONLY

	Electrosurgery appliances	Telemetry transmitters	External pacemakers	Supervised diagnostic equipment	Stimulators
Number of hospitals	6,467	6,467	6,467	6,467	6,467
Number of beds	179	179	179	179	179
Percent (%) of beds	6%	15%	5%	13%	6%
Percent (%) not protected	90% to 100%	90% to 100%	90% to 100%	90% to 100%	90% to 100%
Percent (%) without cables	70% to 80%	100%	55% to 65%	50%	100%
Percent (%) to be converted	65%	65%	65%	65%	65%
Cost per adaptor	$5	$5	$5	$5	$5
Number of adaptors (average)	1.5	10.5	3.5	10	3
TOTAL COST	$213,315–$270,877	$5,332,886–$5,925,429	$325,899–$427,948	$2,200,874–$2,445,415	$609,473–$677,192
Total Cost of Adaptors =	$8,682,447–$9,746,861				

[12] *The Statistical Abstract of the United States,* U.S. Department of Commerce Economics and Statistics Administration, Bureau of Census, No. 183, p. 125, 1995.

TABLE 15.—COST OF INSTALL ADAPTORS TO HOSPITALS ONLY

	Electrosurgery appliances	Telemetry transmitters	External pacemakers	Supervised diagnostic equipment	Stimulators
Number of hospitals	6,467	6,467	6,467	6,467	6,467
Number of beds	179	179	179	179	179
Percent (%) of beds	6%	15%	5%	13%	6%
Percent (%) not protected	90% to 100%	90% to 100%	90% to 100%	90% to 100%	90% to 100%
Percent (%) without cables	70% to 80%	100%	55% to 65%	50%	100%
Percent (%) with useful life	65%	65%	65%	65%	65%
Salary per minute	$0.35	$0.35	$0.35	$0.35	$0.35
Installation time per adaptor	5 minutes	5 minutes	5 minutes	5 minutes	5 minutes
Number of adaptors	1.5	10.5	3.5	10	3
TOTAL COST	$14,882–$18,898	$372,058–$413,397	$22,737–$29,856	$153,548–$170,608	$42,520–$47,245
Total Cost to Install Adaptors =	$605,745–$680,008				

Because these numbers account for the cost to hospitals only, FDA uses quantity of shipment data from the 1994 Current Industrial Report for Electromedical and Irradiation Equipment[13] to establish a proportion between the number of the devices found in a hospital setting versus all other user facilities. To make the Current Industrial Report data more applicable, FDA derived some quantity estimates from the value of shipment data, made categorical adjustments, corrected for exports, and consulted additional sources to customize the categorical adjustments, corrected for exports, and consulted additional sources to customize the estimates. In instances where no quantity data was given, FDA used the average price of equipment in the particular device category and the value of shipments data to derive a quantity of shipments. The average prices used are as follows: Electrosurgery appliances, $10,000; telemetry transmitters, $4,000; external pacemakers, $5,000; supervised diagnostic equipment, $35,000; and stimulators, $3,500. To account for the telemetry transmitters, which were not specifically mentioned in the Current Industrial Reports, FDA used worldwide sales data for total cardiac diagnostic equipment and the telemetry monitoring markets.[14] This figure includes sales data on electrocardiographs, long-term electrocardiographs, and cardiac telemetry systems. The agency multiplied this figure by 55 percent to account for U.S. sales in this market.[15] To break out the sales data for the telemetry products, FDA subtracted the U.S. sales data for electrocardiographs in 1994 as given by the Current Industrial Report. To break out data for the external pacemakers covered by this rule, FDA used the sales data for all pacemakers in the Current Industrial Report, and subtracted out the sales for implantable cardiac pacemakers.[16] Since this 1990 sales data for cardiac pacemakers is worldwide, FDA multiplied this data by 43 percent, which represents the percentage of the world medical device market held by the United States in 1990.[17] The following categories were counted under the Supervised Diagnostic Equipment category: Magnetic resonance imaging equipment, electroencephalograph, electromyograph, and respiratory analysis equipment. The value of shipment data for all other medical therapy equipment was used to derive FDA's stimulator estimate. Total quantity data estimates by FDA for 1994 are as follows: Electrosurgery appliances, 24,447; telemetry transmitters, 6,432; external pacemakers, 5,813; supervised diagnostic equipment, 9,325; and stimulators, 132,340. To adjust for exports, FDA multiplied these numbers by 57 percent in accordance with the U.S. Industrial Outlook forecast that 43 percent of U.S. electromedical equipment production would be exported in 1994.[18] The estimated total number of devices sold in the United States per year were then multiplied by the average useful life to make the data comparable to the number of devices found in a hospital setting. An analysis of both data sources indicates that 60 percent of all of the above devices are located in hospitals. Therefore, the hospital cost estimates are assumed to be 60 percent of the total costs of Phase II of this rule, and the total costs are increased to account for the 40 percent of devices found in other user facilities.

The analysis assumes that Phase II costs will be incurred in equal increments for the first 3 years after the regulation is issued. Therefore, annual costs of $6 million will be incurred for 3 years. Using a 7 percent discount rate, the present value of the total costs for Phase II is approximately $16 million.

[13] ''Current Industrial Reports—Electromedical Equipment and Irradiation Equipment (including x-ray)—MA38R,'' U.S. Department of Commerce News, Bureau of the Census, issued September 1995.

[14] ''Forecasts of the Total World Cardiac Diagnostic Equipment and Telemetry Monitoring Market,'' Frost and Sullivan, 1992, April 1995.

[15] Medical and Healthcare Marketplace Guide, MLR Biomedical Information Services, 8th ed., p. 92, 1992.

[16] Medical and Healthcare Marketplace Guide, MLR Biomedical Information Services, 8th ed., p. 75, 1992.

[17] Medical and Healthcare Marketplace Guide, MLR Biomedical Information Services, 8th ed., p. 69, 1992.

[18] U.S. Industrial Outlook, U.S. Department of Commerce, International Trade Administration, pp. 44–113, 1994.

C. Small Business Impact

FDA certifies that the rule will not have a significant economic impact on a substantial number of small entities. To illustrate this result, the agency examined the potential impact of the rule on small entities by using the highest cost scenario for analysis. Hospitals will absorb an approximate total of $11 million over both phases of this regulation. The cost for an average-sized 179 bed hospital would be about $1,723, or less than $10 per bed. According to the Small Business Administration, profit-making hospitals with revenue at $5 million or less per year are considered a small business. Using this criteria and 1993 data from AHA[19], FDA finds that most hospitals with 6 to 24 beds are small businesses. Because the individual cost to hospitals with 6, 24, 50, or 100 beds would be approximately $230, $394, $629, and $1,084 respectively, it would be less than 1 percent of the total net revenue for any of these bed size categories, and far less than 1 percent of gross revenue. Nursing homes would absorb approximately $157,000 of the total costs, or about $14 per nursing home. Ambulances and other ground transport vehicles would incur approximately $362,000 or about $7 per vehicle, and approximately $15 per organization. If doctor's offices and clinics incur the remainder of the costs, they absorb approximately $3 million under Phase I of the rule and approximately $6 million under Phase II. These estimates amount to about $47 per office and clinic. While some user facilities will incur a greater share of these costs than others, all of the above cost figures represent far less than 1 percent of total gross revenue per facility. As a result, FDA finds that the magnitude of the individual costs determined above would not represent a significant impact for a substantial number of small user facilities.

D. Conclusion

FDA estimates the total costs for Phase I of the regulation to be $5 million. The Phase II costs are approximately $6 million per year for 3 years, or a total present value cost of $16 million. All cost estimates are based upon the use of adaptors as a viable conversion method. Adding costs for Phase I and Phase II, total costs for this rule are $21 million.

As shown in section XIII. of this document, the reporting and recordkeeping burden is minimal for user facilities. Using the previously mentioned $20.93 hourly compensation figure, FDA calculates the recordkeeping burden to user facilities and manufacturers for filing an exemption or variance. FDA estimates these reporting costs under § 10.30 to be $10,465 per year. Such a minimal amount does not significantly add to the final costs of this regulation.

XIII. Paperwork Reduction Act 1995

This final rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Exemptions and Variances from the Performance Standard for Electrode Lead Wires and Patient Cables

Description: Section 898.14 provides that any person subject to the standard may submit a petition under § 10.30 (21 CFR 10.30) requesting an exemption or variance from the standard. The petition must demonstrate why compliance with the standard is unnecessary or unfeasible and what alternate means will be used to protect the public health. FDA will use this information to determine whether granting an exemption is in the best interests of the public health. Allowing for exemptions and variances will provide for flexibility while assuring public health protection.

Description of Respondents: Manufacturers, distributors, health care facilities.

TABLE 16—ESTIMATED ADDITIONAL ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10.30	50	1	50	10	500

There are no capital costs or operating and maintenance costs expected as a result of this rule.

The proposed rule did not include a Paperwork Reduction Act burden estimate because it contained no information collection provisions. In the final rule, a new regulation, providing that requests for exemptions and variances from the performance standard may be submitted under § 10.30, has been added. Because of the resulting anticipated additional reporting burden under § 10.30, FDA is providing a burden estimate and an opportunity for public comment, as required by the Paperwork Reduction Act of 1995. Therefore, FDA now invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology. Individuals and organizations may submit comments on the information collection provisions of this final rule by July 8, 1997. Comments should be directed to the Dockets Management Branch (address above).

At the close of the 60-day comment period, FDA will review the comments received, revise the information collection provision as necessary, and submit these provisions to OMB for review. FDA will publish a notice in the **Federal Register** when the information collection provisions are submitted to OMB, and an opportunity for public

[19] ''Hospital Statistics,'' The American Hospital Association Profile of U.S. Hospitals, Table 11, p. 206, 1994.

comment to OMB will be provided at that time. After receiving OMB's decision, FDA will publish a notice in the **Federal Register** of OMB's decision to approve, modify, or disapprove the information collection provisions. The effective date of § 898.14 will be announced in the **Federal Register** after OMB approval has been received. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

XIV. References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Letter to FDA Commissioner David A. Kessler from Ron Wyden, then Chairman, U.S. House of Representatives, Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Technology, dated August 2, 1994.
2. Information from FDA's medical device reporting (MDR) data base, Rockville, MD.
3. Information from FDA's MDR data base, Rockville, MD.
4. ''FDA Safety Alert: Unsafe Patient Lead Wires and Cables,'' FDA's September 3, 1993, Safety Alert.
5. Section 518(a) notification letter to apnea monitor manufacturers, September 3, 1993.
6. Section 518(a) notification letter to patient cable and lead wire manufacturers, September 20, 1993.
7. FDA Public Health Advisory: Unsafe Electrode Lead Wires and Patient Cables Used With Medical Devices, December 28, 1993.
8. Proceedings, Unprotected Patient Cables and Electrode Lead Wires Conference, July 15, 1994.
9. ''Medical Devices: Early Warning of Problems is Hampered by Severe Underreporting,'' United States General Accounting Office Report to the Chairman, Committee on Governmental Affairs, U.S. Senate, p. 61, December 1986.
10. Fran Hos ''Electrode Leadwire Survey,'' distributed by the American Society for Hospital Engineering of AHA, early 1994.
11. Employment and Earnings, U.S. Department of Labor Bureau of Labor Statistics, Table 39, p. 206, January 1996.
12. The Statistical Abstract of the United States, U.S. Department of Commerce Economics and Statistics Administration, Bureau of Census, No. 183, p. 125, 1995.
13. The Statistical Abstract of the United States, U.S. Department of Commerce Economics and Statistics Administration, Bureau of Census, No. 200, p. 134, 1995.
14. ''The United States Emergency Medical Services Market Report,'' based on data gathered from EMS Census 1995, prepared by Emergency Care Information Center and JEMS Communications, p. 40.
15. ''Transportation Systems, 1994,'' produced by the National Association of State EMS Directors, p. 2, 1994.
16. ''The United States Emergency Medical Services Market Report,'' based on data gathered from EMS Census 1995, prepared by Emergency Care Information Center and JEMS Communications, p. 17.
17. ''The United States Emergency Medical Services Market Report,'' based on data gathered from EMS Census 1995, prepared by Emergency Care Information Center and JEMS Communications.
18. ''The Statistical Abstract of the United States,'' U.S. Department of Commerce Economics and Statistics Administration, Bureau of Census, No. 1316. p. 795, 1995.
19. *The Statistical Abstract of the United States*, U.S. Department of Commerce Economics and Statistics Administration, Bureau of Census, No. 183. p. 125, 1995.
20. ''Electrode Leadwire Survey II,'' distributed by the American Society for Hospital Engineering of AHA, fall 1995.
21. *The Statistical Abstract of the United States*, U.S. Department of Commerce Economics and Statistics Administration, Bureau of Census, No. 183, p. 125, 1995.
22. ''Current Industrial Reports—Electromedical Equipment and Irradiation Equipment (including x-ray)—MA38R,'' U.S. Department of Commerce News, Bureau of the Census, issued September 1995.
23. ''Forecasts of the Total World Cardiac Diagnostic Equipment and Telemetry Monitoring Market,'' Frost and Sullivan, April 1995.
24. Medical and Healthcare Marketplace Guide, MLR Biomedical Information Services, 8th edition, p. 92, 1992.
25. Medical and Healthcare Marketplace Guide, MLR Biomedical Information Services, 8th edition, p. 75, 1992.
26. Medical and Healthcare Marketplace Guide, MLR Biomedical Information Services, 8th edition, p. 69, 1992.
27. U.S. Industrial Outlook, U.S. Department of Commerce, International Trade Administration, pp. 44–113, 1994.

List of Subjects in 21 CFR Part 898

Administrative practice and procedure, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

1. Part 898 is added to read as follows:

PART 898–PERFORMANCE STANDARD FOR ELECTRODE LEAD WIRES AND PATIENT CABLES

Sec.
898.11 Applicability.
898.12 Performance standard.
898.13 Compliance dates.
898.14 Exemptions and variances.

Authority: Secs. 501, 502, 513, 514, 530–542, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 352, 360c, 360d, 360gg–360ss, 371, 374); secs. 351, 361 of the Public Health Service Act (42 U.S.C. 262, 264).

§ 898.11 Applicability.

Electrode lead wires and patient cables intended for use with a medical device shall be subject to the performance standard set forth in § 898.12.

§ 898.12 Performance standard.

(a) Any connector in a cable or electrode lead wire having a conductive connection to a patient shall be constructed in such a manner as to comply with subclause 56.3(c) of the following standard:

International Electrotechnical Commission (IEC)

601–1: Medical Electrical Equipment

601–1 (1988) Part 1: General requirements for safety

Amendment No. 1 (1991)

Amendment No. 2 (1995).

(b) Compliance with the standard shall be determined by inspection and by applying the test requirements and test methods of subclause 56.3(c) of the standard set forth in paragraph (a) of this section.

§ 898.13 Compliance dates.

The dates for compliance with the standard set forth in § 898.12(a) shall be as follows:

(a) For electrode lead wires and patient cables used with, or intended for use with, the following devices, the date for which compliance is required is May 11, 1998:

LISTING OF DEVICES FOR WHICH COMPLIANCE IS REQUIRED EFFECTIVE

May 11, 1998

Phase	Product code	21 CFR section	Class	Device name
1	73 BZQ	868.2375	II	Monitor, Breathing Frequency.
1	73 FLS	868.2375	II	Monitor (Apnea Detector), Ventilatory Effort.

LISTING OF DEVICES FOR WHICH COMPLIANCE IS REQUIRED EFFECTIVE—Continued

May 11, 1998

Phase	Product code	21 CFR section	Class	Device name
1	74 DPS	870.2340	II	Electrocardiograph.
1	74 DRG	870.2910	II	Transmitters and Receivers, Physiological Signal, Radio Frequency.
1	74 DRT	870.2300	II	Monitor, Cardiac (including Cardiotachometer and Rate Alarm).
1	74 DRX	870.2360	II	Electrode, Electrocardiograph.
1	74 DSA	870.2900	II	Cable, Transducer and Electrode, Patient (including Connector).
1	74 DSH	870.2800	II	Recorder, Magnetic Tape, Medical.
1	74 DSI	870.1025	III	Detector and Alarm, Arrhythmia.
1	74 DXH	870.2920	II	Transmitters and Receivers, Electrocardiograph, Telephone.

(b) For electrode lead wires and patient cables used with, or intended for use with, any other device, the date for which compliance is required is May 9, 2000.

§ 898.14 Exemptions and variances.

(a) A request for an exemption or variance shall be submitted in the form of a petition under §10.30 of this chapter and shall comply with the requirements set out therein. The petition shall also contain the following:

(1) The name of the device, the class in which the device has been classified, and representative labeling showing the intended uses(s) of the device;

(2) The reasons why compliance with the performance standard is unnecessary or unfeasible;

(3) A complete description of alternative steps that are available, or that the petitioner has already taken, to ensure that a patient will not be inadvertently connected to hazardous voltages via an unprotected patient cable or electrode lead wire for intended use with the device; and

(4) Other information justifying the exemption or variance.

(b) An exemption or variance is not effective until the agency approves the request under § 10.30(e)(2)(i) of this chapter.

Dated: April 28, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 301

[TD 8717]

RIN 1545–AU14

Termination of a Partnership Under Section 708(b)(1)(B)

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the termination of a partnership upon the sale or exchange of 50 percent or more of the total interest in partnership capital and profits within a 12-month period. The final regulations affect all partnerships that terminate under section 708(b)(1)(B).

DATES: These regulations are effective May 9, 1997.

For applicability dates, see Effective Dates under Supplementary Information.

FOR FURTHER INFORMATION CONTACT: Steven R. Schneider, (202) 622–3060 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On May 13, 1996, a notice of proposed rulemaking (PS–5–96) was published in the **Federal Register** (61 FR 21985) containing proposed amendments to the Income Tax Regulations (26 CFR part 1) under section 708 of the Internal Revenue Code (Code). The notice of proposed rulemaking also contained proposed amendments to other sections of the Income Tax Regulations to reflect the amendments to the regulations under section 708. Written comments responding to this notice were received. A public hearing was held on September 5, 1996, pursuant to the notice published in the **Federal Register** on May 13, 1996. After consideration of all comments received, the proposed amendments are adopted as revised by this Treasury decision.

Explanation of Provisions

Section 708(b)(1)(B) provides that, for purposes of section 708(a), a partnership shall be considered terminated if within a 12-month period there is a sale or exchange of 50 percent or more of the total interest in partnership capital and profits. The existing regulations under § 1.708–1(b)(1)(iv) provide that, if a partnership is terminated by a sale or exchange of an interest, the following is deemed to occur: The partnership distributes its properties to the purchaser and the other remaining partners in proportion to their respective interests in the partnership properties; and, immediately thereafter, the purchaser and the other remaining partners contribute the properties to a new partnership, either for the continuation of the business or for its dissolution and winding up. The final regulations adopt the proposed regulations and change the mechanics of a termination under section 708(b)(1)(B) so that the following is deemed to occur on a termination: The partnership contributes all of its assets and liabilities to a new partnership in exchange for an interest in the new partnership; and, immediately thereafter, the partnership liquidates by distributing interests in the new partnership to the purchaser and the other remaining partners, followed by the continuation of the business by the new partnership or its dissolution and winding up. The final regulations also clarify certain aspects of the proposed regulations in response to comments received.

One commentator requested clarification of the section 704(c) consequences of a termination. The proposed regulations provide for a section 704(b) capital account ''book up'' upon the deemed contribution of assets by the terminated partnership to