* * * * *

3. In § 354.3, paragraph (c)(3)(i) would be amended by removing the words '', *except*, that through September 30, 1997, the amount to be paid is $40.00''.

Done in Washington, DC, this 30th day of July 1999.

Bobby R. Acord,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 99–20113 Filed 8–6–99; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 207, 607, and 807

[Docket No. 98N–1215]

Foreign Establishment Registration and Listing; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening for 60 days the comment period for the proposed rule that appeared in the **Federal Register** of May 14, 1999 (64 FR 26330). The proposed rule would require foreign establishments whose products are imported or offered for import into the United States to register with FDA and to identify a U.S. agent. The proposal would also describe some of the agent's responsibilities. FDA is taking this action in response to a request from the Canadian Embassy.

DATES: Written comments by October 8, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy, Planning, and Legislation (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 14, 1999 (64 FR 26330), FDA published a proposed rule that would require foreign establishments whose products are imported or offered for import into the United States to register with FDA. The proposal would also require foreign establishments to identify a U.S. agent and would describe some of the agent's responsibilities. FDA issued the proposed rule in order to implement section 417 of the Food and Drug Administration Modernization Act of 1997. Interested persons were given until July 28, 1999, to comment on the proposed rule.

On July 23, 1999, the Government of Canada requested an extension of the comment period, stating that the proposed requirement could present significant cost and compliance burdens to small and medium-sized Canadian establishments. The Canadian Government requested the extension so that it could: (1) Ensure that affected Canadian establishments are aware of the proposal and (2) prepare informed comments. The requested extension was 60 days.

The agency considered the Canadian Government's request and because the request was submitted too late to permit an extension of the comment period the agency is reopening the comment period until October 8, 1999.

Interested persons may submit to the Dockets Management Branch (address above) written comments on the proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the proposed rule and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 1, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–20363 Filed 8–6–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 870, 888, and 890

[Docket No. 99N–2210]

Cardiovascular, Orthopedic, and Physical Medicine Diagnostic Devices; Reclassification of the Cardiopulmonary Bypass Accessory Equipment, Goniometer Device, and the Electrode Cable Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the cardiopulmonary bypass accessory equipment device that involves an electrical connection to the patient, the goniometer device, and the electrode cable from class I into class II. FDA is also proposing to exempt these devices from the premarket notification requirements. This classification is being proposed on FDA's own initiative based on new information. This action is being taken to establish sufficient regulatory controls that will provide reasonable assurance of the safety and effectiveness of these devices.

DATES: Written comments by November 8, 1999. See section IX of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration,9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory Authorities)

The act (21 U.S.C. 301 *et seq.*), as amended by the 1976 amendments (Public Law 94–295), the SMDA (Public Law 101–629), and the FDAMA (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments devices, are classified automatically by statute (section 513(f) of the act (21 U.S.C. 360c(f)) into class III without any FDA rulemaking process. Those devices

remain in class III and require premarket approval, unless and until: (1) The device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act, as amended by the FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and part 807 of the regulations (21 CFR part 807).

A preamendments device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Reclassification of classified preamendments devices is governed by section 513(e) of the act (21 U.S.C. 360c(e)). This section provides that FDA may, by rulemaking, reclassify a device (in a proceeding that parallels the initial classification proceeding) based upon ''new information.'' The reclassification can be initiated by FDA or by the petition of an interested person. The term ''new information,'' as used in section 513(e) of the act, includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, e.g., *Holland Rantos* v. *United States Department of Health, Education, and Welfare*, 587 F. 2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell v. Goddard*, 366 F.2d 177 (7th Cir. 1966).).

Reevaluation of the data previously before the agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell* v. *Goddard*, supra, 366 F.2d at 181; *Ethicon, Inc.* v. *FDA*, 762 F. Supp. 382, 389–91 (D.D.C. 1991)), or in light of changes in ''medical science.'' (See *Upjohn* v. *Finch*, supra, 422 F.2d at 951.) Regardless of whether data before the agency are past or new data, the ''new information'' upon which reclassification under section 513(e) of the act is based must consist of ''valid scientific evidence,'' as defined in section 513(a)(3) of the act (21 U.S.C. 360c(a)(3)) and 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co.* v. *FDA*, 770 F.2d 214 (D.C.Cir. 1985); *Contact Lens Assoc.* v. *FDA*, 766 F.2d 592 (D.C. Cir.), *cert. denied*, 474 U.S. 1062 (1985)). FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. For the purpose of reclassification, the valid scientific evidence upon which the agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending premarket approval application. (See section 520 of the act (21 U.S.C. 360j(c)).

II. Regulatory History of Devices

In accordance with section 513(e) of the act and 21 CFR 860.130(a)(1), based on new information with respect to the devices, FDA, on its own initiative, is proposing to reclassify the following devices from class I, to class II: (1) Cardiopulmonary bypass accessory equipment, when intended to be used in the cardiopulmonary bypass circuit to support, adjoin, or connect components, or to aid in the setup of the extracorporeal line; (2) the goniometer device, which is an ac-powered device, when intended to evaluate joint function by measuring and recording ranges of motion, acceleration, or forces exerted by a joint; and (3) the electrode cable device, which is a electrode cable device composed of strands of insulated electrical conductors laid together around a central core and intended for medical purposes to connect an electrode from a patient to a diagnostic machine.

III. Device Description

FDA is maintaining the following device descriptions and intended uses:

(1) The cardiopulmonary bypass accessory equipment are devices that have no contact with blood and are intended in the cardiopulmonary bypass circuit to support, adjoin, or connect components or to aid in the setup of the extracorporeal line, e.g., an oxygenator mounting bracket or system-priming equipment. FDA is reclassifying into class II only cardiopulmonary bypass accessory equipment that involves an electrical connection to the patient. Other accessory equipment remains in class I.

(2) The goniometer is an ac-powered device intended to evaluate joint function by measuring and recording ranges of motion, acceleration, or forces exerted by a joint.

(3) The electrode cable device is a device composed of strands of insulated electrical conductors laid together around a central core and intended for medical purposes to connect an electrode from a patient to a diagnostic machine.

IV. Risk to Health

After several incidents were reported to FDA, pertaining to the risk of patient exposure to macro shock or electrocution, FDA took action to address the problem. A summary of the incidences was published in a final rule that established a performance standard for electrode lead wires and patient cables (62 FR 25477, May 9, 1997). Industry also took steps to prevent electrode lead wires from being connected to electrical power sources; a public conference sponsored by Health Industry Manufacturers Association and the American Hospital Association, held on July 15, 1994, provided a forum for device users, manufacturers, and other health care professionals to offer and hear comments for FDA's consideration during the rulemaking process.

V. Summary of Reasons for Reclassification

Based on new information with respect to the devices and in accordance with section 513 (e) of the act and 21 CFR 860.130(a)(1), FDA, on its own initiative, is proposing to reclassify the cardiopulmonary bypass accessory equipment devices that involve an electrical connection to the patient, the goniometer ac-powered device, and the electrode cable device from class I into class II. The agency is taking this action because the new information shows that these products present a degree of health risk to the patient that cannot be addressed by class I general controls. The agency established a performance standard for electrode lead wires and patient cables to prevent electrical connections between patients and electrical power sources. FDA believes the cardiopulmonary bypass accessory equipment, the ac-powered goniometer, and the electrode cable should be reclassified into class II because special controls in addition to general controls, provide reasonable assurance of safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance.

VI. Summary of Data Upon Which the Reclassification is Based

FDA believes that, in order to eliminate the risk of macro shock and electrocution in the future, a mandatory performance standard must apply to all electrode lead wires and patient cables intended for use with medical devices.

Based on the available information, FDA believes that the special controls discussed below are capable of providing reasonable assurance of the safety and effectiveness of the cardiopulmonary bypass accessory equipment that involves an electrical connection to the patient, the goniometer device, and the electrode cable with regard to the identified risks to health of these devices.

VII. Special Controls

In addition to general controls, FDA believes that the special controls identified in this document are adequate to control the risks to health described for these devices. (1) On May 9, 1997, FDA issued a final rule establishing a performance standard for electrode lead wires and patient cables. The agency determined that the performance standard is needed to prevent electrical connections between patients and electrical power sources. (2) Based on the available information, FDA also identified a guidance document entitled, ''Guidance on the Performance Standard for Electrode Lead Wires and Patient Cables.'' The guidance provides information on electrocution hazards posed by unprotected patient electrical connectors. The guidance is intended to help affected parties understand the steps needed to achieve compliance with the performance standard for electrode lead wires and patient cables.

Since May 11, 1998, electrode lead wires or patient cables have been required to comply with the ECG Cables and Lead Wires, ANSI/AAMI EC 53–1995 standard if they are intended for use with any of the following devices:

(1) Breathing frequency monitors,

(2) Ventilatory effort monitors (Apnea detectors),

(3) Electrocardiographs (ECG's),

(4) Radio frequency physiological signal transmitters and receivers,

(5) Cardiac monitors,

(6) Electrocardiograph electrodes (including pre-wired ECG electrodes),

(7) Patient transducer and electrode cables (including connectors),

(8) Medical magnetic tape recorders (e.g. Holter monitors),

(9) Arrhythmia detectors and alarms,

(10) Telephone Electrocardiograph transmitters and receivers.

Manufacturers and users had an additional 2 years to prepare for the second phase of implementation of the standard. Beginning on May 9, 2000, any electrode lead wire or patient cable lead intended for use with any medical device must comply with the standard.

The performance standard incorporates the specific requirements of international standard, IEC–60601, clause 56.3(c), which requires leads to be constructed in such a manner as to preclude patient contact with hazardous voltages or, for certain devices, contact with electrical ground. Design changes and labeling changes need to be considered by manufacturers and importers of these devices.

Adapters can be used to convert devices already in the marketplace so they can accept electrode wires and patient cables that comply with the new performance standard.

VIII. Exemption from Premarket Notification

A. FDA is proposing to exempt these devices from premarket notification.

On November 21, 1997, the President signed into law FDAMA (Public Law 105–115). Section 206 of FDAMA, in part, added a new section 510(m) to the act (21 U.S.C. 360(m). Section 510(m)(1) of the act requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each type of class II device that does not require a report under section 510(k) of the act (21 U.S.C. 360(k)) to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published that list in the Federal Register of January 21, 1998 (63 FR 3142).

Section 510(m)(2) of the act provides that 1 day after the date of publication of the list under section 510(m)(1) of the act, FDA may exempt a device on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device.

FDA has determined that, for the devices proposed for class II in this rule, the special controls along with general controls other than premarket notification will provide reasonable assurance of the safety and effectiveness of these devices. Therefore, FDA is proposing to exempt these devices from the premarket notification requirements subject to the applicable limitations on exemptions.

B. Certain cardiopulmonary bypass equipment will remain in class I

FDAMA also added a new section 510(l) to the act which provides that a class I device is exempt from the premarket notification requirements under section 510(k) of the act, unless the device is intended for a use which is of substantial importance in preventing impairment of human health or it presents a potential unreasonable risk of illness or injury. FDA refers to the devices that meet these criteria as ''reserved.''

In the **Federal Register** of February 2, 1998 (63 FR 5387), FDA published a list of devices it considered reserved and that require premarket notification and a list of devices it believed met the exemption criteria in FDAMA. FDA invited comments on the February 2, 1998, notice.

In the **Federal Register** of November 12, 1998 (63 FR 63222), after reviewing the comments submitted on the February 2, 1998, **Federal Register** notice, FDA proposed to designate which devices require premarket notification, and which are exempt, subject to limitations, under notice and comment rulemaking proceedings under new section 510(l). One comment on the proposed rule stated that, for cardiopulmonary bypass accessory equipment, the ''reserved'' designation should be limited to accessory equipment that involves an electrical connection to the patient. FDA agrees with this comment and intends to change the final rule on exemptions from premarket notification to adopt this comment. In this proposed rule, FDA is stating that cardiopulmonary bypass accessory equipment that does not involve electrical connection to the patient is a class I device and is exempt from the premarket notification requirements.

IX. Effective Date

FDA proposes that any final rule that may issue based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

X. Environmental Impact

The agency has determined under 21 CFR 25.34(b) 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.

XI. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). 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 proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Based on the May 9, 1997 (62 FR 25477), **Federal Register**, a final rule was issued establishing a performance standard for electrode lead wires and patient cables, which included and applied to the cardiopulmonary bypass accessory equipment that involves an electrical connection to the patient, the goniometer, and the electrode cable. The FDA's analysis determined that the imposition of the performance standard would not have a significant economic impact on a substantial number of small entities. This reclassification, if finalized, will have no economic effect other than the imposition of this standard. In addition, the proposed rule, if finalized, will not impose costs of $100 million or more on either the private sector or state, local, and tribal governments in the aggregate, and therefore a summary statement or analysis under section 202 (a) of the Unfunded Mandates Reform Act of 1995 is not required.

XII. Paperwork Reduction Act of 1995

FDA has tentatively determined that this proposed rule contains no collections of information. Therefore, clearance from the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

XIII. Submission of Comments

Interested persons may, on or before November 8 1999, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Parts 870, 888, and 890

Medical Devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 870, 888, and 890 be amended as follows:

PART 870—CARDIOVASCULAR DEVICES

1. The authority citation for 21 CFR part 870 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 870.4200 is revised to read as follows:

§ 870.4200 Cardiopulmonary bypass accessory equipment

(a) *Identification*. Cardiopulmonary bypass accessory equipment is a device that has no contact with blood and that is used in the cardiopulmonary bypass circuit to support, adjoin, or connect components, or to aid in the setup of the extracorporeal line, e.g., an oxygenator mounting bracket or system-priming equipment.

(b) *Classification*. (1) Class I. The device is classified as class I if it does not involve an electrical connection to the patient. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 870.9.

(2) Class II (special controls). The device is classified as class II if it involves an electrical connection to the patient. The special controls are as follows:

(1) The performance standard under part 898 of this chapter and

(2) The guidance document entitled, ''Guidance on the Performance Standard for Electrode Lead Wires and Patient Cables.'' The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 870.9.

PART 888—ORTHOPEDIC DIAGNOSTIC DEVICES

3. The authority citation for 21 CFR part 888 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

4. Section 888.1500 is amended by revising paragraph (b) to read as follows:

§ 888.1500 Goniometer.

* * * * *

(b) Classification. Class II (special controls). The special controls consist of:

(1) The performance standard under part 898 of this chapter and

(2) The guidance entitled, ''Guidance on the Performance Standard for Electrode Lead Wires and Patient Cables.'' This device is exempt from the premarket notification procedures of subpart E of part 807 of this chapter subject to § 888.9.

PART 890—PHYSICAL MEDICINE PROSTHETIC DEVICES

5. The authority citation for 21 CFR part 890 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

6. Section 890.1175 is amended by revising paragraph (b) to read as follows:

§ 890.1175 Electrode cable.

* * * * *

(b) Classification. Class II (special controls). The special controls consist of:

(1) The performance standard under part 898 of this chapter and

(2) The guidance document entitled, ''Guidance on the Performance Standard for Electrode Lead Wires and Patient Cables.'' This device is exempt from the premarket notification procedures of subpart E of part 807 of this chapter subject to § 890.9.

Dated: July 25, 1999.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 99–20357 Filed 8–6–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–106527–98]

RIN 1545–AW22

Capital Gains, Partnership, Subchapter S, and Trust Provisions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations relating to sales or exchanges of interests in partnerships, S corporations, and trusts. The proposed regulations interpret the look-through provisions of section 1(h), added by section 311 of the Taxpayer Relief Act of 1997 and amended by sections 5001 and 6005(d) of the Internal Revenue Service Restructuring and Reform Act of 1998, and explain the rules relating to the division of the holding period of a