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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