TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Capital Costs
65	1	65	16	1,042	$32,571

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

In determining the estimated annual recordkeeping burden, FDA estimated that at least 90 percent of firms maintain documentation, such as packing codes, batch records, and inventory records, as part of their basic food production or import operations. Therefore, the recordkeeping burden was calculated as the time required for the 10 percent of firms that may not currently be maintaining this documentation to develop and maintain documentation, such as batch records and inventory records. For firms that do not maintain documentation, such as batch records and inventory records, as part of their normal manufacturing operations, it was estimated that with $500 or less, the necessary software and hardcopy filing systems could be obtained to implement a system.

Dated: October 9, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–27120 Filed 10–27–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1994N–0418]

Medical Devices; Reclassification of Automated External Defibrillators

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of intent.

SUMMARY: The Food and Drug Administration (FDA) announces an opportunity to submit information and comments concerning FDA's intent to initiate a proceeding to reclassify automated external defibrillators (AEDs) from class III (premarket approval) to class II (special controls). AEDs are devices that deliver an electric shock to correct an arrhythmia.

DATES: Submit written or electronic information or comments by January 26, 2004.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Megan Moynahan, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517, ext. 180.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 14, 1995 (60 FR 41984 and 41986), FDA published two orders for certain class III devices requiring the submission of safety and effectiveness information in accordance with the preamendments class III strategy for implementing section 515(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(i)) (FDA published two updated orders in the **Federal Register** of June 13, 1997 (62 FR 32352 and 32355)). The orders describe in detail the format for submitting the type of information required by section 515(i) of the act so that the information submitted would either support reclassification or indicate that a device should be retained in class III. The orders also scheduled the required submissions in groups, at 6-month intervals, beginning on August 14, 1996. Arrhythmia detectors and alarms, which included AEDs, were among the devices for which information was to be submitted.

In response to this document, FDA received three petitions to reclassify arrhythmia detectors and alarms from the following petitioners: (1) Health Industry Manufacturers Association (HIMA) (now known as Advamed), (2) Quinton Instrument Co., and (3) Zymed Medical Instrumentation. The Advamed petition also requested reclassification of AEDs. Additionally, Datascope Corp., Hogan and Hartson L.L.P., Life Sensing Instrument Co., Medical Data Electronics, Inc., Mennen Medical Ltd., Mortara Instrument, Inc., and Olsson, Frank, and Weeda, P.C. submitted safety and effectiveness information (515(i) submissions).

In the **Federal Register** of December 13, 2002 (67 FR 76706), FDA proposed to reclassify arrhythmia detector and alarm devices from class III to class II. These devices are used to monitor an electrocardiogram and to produce a visible or audible signal or alarm when an atrial or ventricular arrhythmia exists. FDA also proposed to separate AEDs from the identification of the arrhythmia detector and alarm. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule reclassifying arrhythmia detector and alarm devices into class II with a special controls guidance document. The final rule also establishes a separate classification regulation for AEDs.

AEDs, primarily designed for an intended use (i.e., to correct an arrhythmia) different from arrhythmia detector and alarm devices, have a shock advisory algorithm, automatically detect a shockable cardiac rhythm, and automatically deliver an electric shock (fully automated device) or deliver a shock when activated by the operator (semiautomated device). FDA regulates AEDs as class III devices. In response to Advamed's petition (Ref. 1), FDA stated that it would publish a notice of a panel meeting that would discuss the possible reclassification of AEDs. In the December 13, 2002, proposed rule (67 FR 76706), FDA stated that it intended to propose the reclassification of the AED at a later time.

FDA is publishing this document to provide interested persons with an opportunity to submit any new information concerning the safety and effectiveness of AEDs. After FDA reviews any information that it receives in response to this notice, FDA will determine whether it should go forward with the reclassification of AEDs and whether a panel meeting is necessary before taking any action.

II. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**). Interested persons may view this reference between 9 a.m. and 4 p.m., Monday through Friday.

1. HIMA (Health Industry Manufacturers Association) (now known as Advamed), reclassification petition, Docket No. 1994N–0418, vol. 1–7, Washington, DC, August 14, 1996.

Dated: October 2, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–27116 Filed 10–27–03; 8:45 am]

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