II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cdrh/pmapage.html.*

Dated: October 6, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–27119 Filed 10–27–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0077]

FDA Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 008; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of April 28, 2003 (68 FR 22391). The document announced a publication entitled ''FDA Modernization Act of 1997; Modifications to the List of Recognized Standards, Recognition List Number: 008.'' The publication contains modifications the agency is making to the list of standards FDA recognizes for use in the premarket reviews. The document was published with inadvertent errors. This document corrects those errors and provides clarification.

FOR FURTHER INFORMATION CONTACT: Carol L. Herman, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4766, ext. 156.

SUPPLEMENTARY INFORMATION: FDA also intended to note that it is limiting its recognition of standards 31 and 32 to the use of 25 symbols for labeling of in vitro diagnostic (IVD) devices used by professional IVD users. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of a draft guidance document concerning the use of these symbols in labeling of IVDs.

In FR Doc. 03–10417, appearing on page 22391 in the **Federal Register** of Monday, April 28, 2003, the following corrections are made:

1. On page 22398, under ''*B. General*'', correct the table to read:

Item No.	Title of Standard	Reference No. and Date
30	Medical Electrical Equipment—Part 1–2: General Requirements for Safety—Collateral Standard: Electromagnetic Compatability—Requirements and Tests	ANSI/AAMI/IEC 60601–1–2:2001
31	Symbols to be Used With Medical Device Labels, Labeling and Information to be Supplied	ISO 15223:2000
32	Graphical Symbols for Use in the Labeling of Medical Devices	EN 980:1996+A1:1999+A2:2001

2. On page 22399, in the first table, the entries for item nos. 30, 31, and 32 are removed.

Dated: October 2, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–27118 Filed 10–27–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0421]

Guidance for Industry and FDA Staff on Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance document entitled ''Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm.'' This guidance document describes a means by which arrhythmia detector and alarm devices may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to reclassify these devices from class III into class II (special controls).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818.

Submit written comments concerning this guidance 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.* Identify comments with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Elias Mallis, CDRH (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8517, ext 177.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 13, 2002 (67 FR 76749), FDA announced the availability of a draft of this guidance document and invited interested persons to comment on it by

March 13, 2003. FDA received one comment. The comment suggested that FDA rely on more recent technical standards and, in some cases, suggested alternate methods and standards to those FDA cited in the draft guidance. FDA revised the guidance to reflect the updated technical standards, but declined to incorporate the alternate standards and methods suggested. As discussed next, however, a firm may meet the recommendations of the guidance or in some other way provide equivalent assurances.

The guidance document describes a means by which arrhythmia detector and alarm (including ST-segment measurement and alarm) devices may comply with the requirement of special controls for class II devices. Following the effective date of the final classification rule, any firm submitting a 510(k) premarket notification for the device will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

Also in the **Federal Register** of December 13, 2002 (67 FR 76706), FDA proposed to reclassify the arrhythmia detector and alarm into class II with this guidance document as the special control. FDA did not receive any comments on the proposed rule. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to reclassify the arrhythmia detector and alarm from class III (premarket approval) to class II (special controls).

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the FDA's current thinking on arrhythmia detector and alarm devices. The guidance does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive ''Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm'' by fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1363) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information, including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 USC 3501–3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under the PRA under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document at any time. Submit a single copy of electronic comments or two paper copies of any mailed comments, 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. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 2, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03–27114 Filed 10–27–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0383]

Draft Guidance for Industry and FDA Staff; Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use.'' This document provides guidance on the use of selected symbols in place of text to convey some of the information required for in vitro diagnostic devices (IVDs) intended for professional use by FDA's labeling requirements for IVDs. This draft guidance is not final nor is it in effect at this time.

DATES: Submit written or electronic comments on this draft guidance by November 28, 2003, to ensure adequate consideration of the comments in the preparation of a final guidance. However, you may submit comments at any time. Submit written or electronic comments on the proposed information collection provisions by December 29, 2003.

ADDRESSES: Submit written requests for single copies on a 3.5'' diskette of the draft guidance document entitled ''Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. You may also submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research , Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709