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more recent technical standards and, in some cases, suggested alternate methods and standards to those FDA cited in the draft guidance.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

or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning the draft guidance and the proposed information collections provisions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments on the draft guidance and the proposed information collection provisions to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Paula G. Silberberg, Center for Devices and Radiological Health (HFZ–230), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–1217; or Sheryl A. Kochman, Center for Biologics Evaluation and Research (HFM–390), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3524.

SUPPLEMENTARY INFORMATION:

I. Background

The market for in vitro diagnostic devices is international. European Union (EU) member countries have attempted to harmonize their national legislation governing IVDs through the EU's IVD Directive. The EU's IVD Directive is in full effect as of December 8, 2003. As of that date, IVD products marketed in the EU must comply with the IVD Directive and bear the CE mark (mark showing that the product is certified for sale in the European community) to indicate compliance.

The EU's IVD Directive and FDA regulations in § 809.10 (21 CFR 809.10) and parts 610 and 660 (21 CFR parts 610 and 660) all require substantial information to appear on the IVD itself and/or in its labeling. The IVD Directive specifically allows each EU member State to require that such information appear in its national language, so that a single IVD could be required to bear labeling in multiple languages in order to be sold in the EU. As an alternative, the IVD Directive encourages the use of symbols from harmonized standards to convey the required information in place of text. Given that the use of national languages may be required by individual member States and that most IVDs and their packaging are quite small, the IVD Directive's symbols provision represents an avenue through which manufacturers can achieve compliance in an international marketplace.

Similarly, the use of symbols helps IVD manufacturers to create uniform labels and labeling for the United States and the EU (and any other countries that may permit use of symbols from these international standards), instead of needing designated labels for each marketplace. Because symbols take up less space than the text for which they may substitute, the use of symbols promotes less crowded and more legible IVD labels. An additional advantage is that there are likely to be fewer labeling errors when using a single label, rather than having one set of labels for use in the United States and another set for use in the EU. Of course, it is essential that the symbol convey the substance of the deleted text and be widely understood.

Therefore, in accordance with the consensus standards recognition process, established by section 514(c) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360d(c)), elsewhere in this issue of the **Federal Register**, FDA recognizes 25 symbols from the two international consensus standards:

- ISO 15223, Medical Devices—Symbols to be Used With Medical Device Labels, Labeling and Information to be Supplied, and
- EN 980, Graphical Symbols for Use in the Labeling of Medical Devices.

This document provides guidance on the use of those recognized symbols.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on the use of symbols on the labels and in labeling only of IVDs intended for professional use, and not for over-the-counter or prescription home-use IVDs. It 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 ''Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use'' 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 (4444) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft 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 from CBER at *http://www.fda.gov/cber/guidelines.htm* or on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Sections VII and VIII of the guidance propose new recommended collections of information. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth below.

With respect to the following collection of information, FDA 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.

Title: Recommended Glossary and Educational Outreach to Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use

Description: This document provides guidance on the voluntary use of selected symbols in place of text to convey some of the information required for IVDs intended for professional use under § 809.10 (FDA's labeling requirements for in vitro diagnostic devices) and parts 610 and 660 (FDA's labeling requirements for biologics (including IVDs)) that are licensed under the Public Health Service (PHS) Act. Use of these symbols will not result in a new collection of information but is a means of fulfilling underlying labeling requirements that are subject to OMB clearance. Under section 502(c) of the act (21 U.S.C. 352), a drug or device is misbranded ''If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.'' This guidance document recommends that a glossary of terms accompany each IVD to define the symbols used on that device's labels and/or labeling. Furthermore, this guidance recommends an educational outreach effort to enhance the understanding of newly introduced symbols. Both the glossary and the educational outreach help to ensure that IVD users will have enough general familiarity with the symbols, as well as quick reference materials available, to be likely to understand the symbols used in IVD labeling, further ensuring that such labeling satisfies the requirements of section 502(c) of the act.

Respondents: The likely respondents are IVD manufacturers who plan to use the selected symbols in place of text on the labels and/or labeling of their IVDs.

FDA estimates the burden of the collection of information in table 1:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Glossary	1,742	1	1,742	4	6,968[2]
Educational outreach	1,742	1	1,742	16	27,872
Total					34,840

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]One-time burden.

The glossary and educational outreach activities would be carried out by domestic and foreign IVD manufacturers. The CDRH Information Retrieval System's Registration and Listing Information database provided the number of IVD manufacturers as 1,742; 1,206 are domestic IVD manufacturers and 536 are foreign manufacturers. Consequently, FDA has based its burden estimate on the maximum possible number of manufacturers choosing to implement the use of symbols in labeling. The number of hours per response for the glossary and educational outreach activities were derived from consultation with a trade association and FDA personnel. The 4-hour estimate for a glossary is based on the average time necessary for a manufacturer to modify the glossary, as shown in the draft guidance, for the specific symbols used in labels or labeling for the IVDs they manufacture. The 16-hour estimate for educational outreach includes activities manufacturers will use to educate the various professional users of IVDs about the meaning of the IVD symbols. This estimate is based on FDA 's expectation that IVD manufacturers will jointly sponsor many educational outreach activities.

This draft guidance document also refers to labeling requirements, annual reporting requirements, and other information collections established under existing regulations. The collections of information described in section III of this guidance that result from § 809.10 were approved under OMB control number 0910–0485. The collections of information described in section III of the guidance that result from §§ 610.60, 610.61, and 610.62 were approved under OMB control number 0910–0338. In accordance with section 3506(c)(2)(A) of the PRA, a 60-day notice soliciting public comment on the collections of information described in section III of the guidance that result from part 660 (§§ 660.2, 660.28, 660.35, 660.45, and 660.55) published in the **Federal Register** on July 22, 2003 (68 FR 43359). The collections of information described in section X of the guidance, regarding annual reports, were approved under OMB control numbers 0910–0231 and 0910–0315. The collections of information described in section X of this guidance, regarding adverse event reporting, were approved under OMB control numbers 0910–0437 and 0910–0291.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit comments on the collection of information. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit two hard 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. 03–27117 Filed 10–27–03; 8:45 am]

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