

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Submit written comments concerning the draft guidance and the proposed information collections provisions to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061,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 Submit electronic comments on the draft guidance and the proposed information collection provisions to 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:

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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,