

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0383]

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Certifier D. Hawkins

Guidance for Industry and Food and Drug Administration 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 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 from international standards already recognized by FDA 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.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the 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 one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-

443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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.

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 Directive on In Vitro Diagnostic Medical Devices (Directive 98/79/EC) (IVD Directive). The EU’s IVD Directive went into full effect on 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 that, in place of text, IVDs use symbols from harmonized standards to convey the required information. 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 (21 U.S.C. 360d(c)), in the **Federal Register** of April 28, 2003 (68 FR 22391), corrected by 68 FR 61448 (October 28, 2003), FDA recognized for use on the labels and labeling of IVDs intended for professional use 25 symbols from the 2 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.

The guidance document entitled “Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use” provides guidance on the use of those recognized symbols.

FDA announced the availability of the level 1 draft guidance document in the **Federal Register** of October 28, 2003 (68 FR 61449). While comments on guidances may be submitted at any time, FDA invited interested persons to submit written or electronic comments on the draft guidance by November 28, 2003, to ensure adequate consideration of the comments. The comment period for the proposed information collection provisions closed on December 29, 2003. FDA received seven comments from manufacturers on the draft guidance. However, many of the comments addressed issues beyond the scope of the use of the 25 FDA recognized symbols on IVD for professional use. FDA will continue to study these comments to determine what other actions may be appropriate. One comment suggested that the glossary of symbols recommended by the guidance be permitted to be provided as a separate labeling piece, rather than being incorporated into the package insert. In the guidance document, FDA continues to express its preference for the inclusion of the glossary as part of the package insert, although it recognizes that while package inserts are being revised, manufacturers may prefer to provide the glossary as a separate labeling piece. As with all aspects of the guidance, this position represents FDA’s recommendation, and manufacturers may select an alternative approach if that approach satisfies the requirements of the applicable statute and regulations.

In addition, in the guidance document, FDA has decided to remove the statement in section III where FDA had proposed to exercise enforcement

discretion if a company used the symbol that represents “Manufacturer” to satisfy § 610.64. Upon reflection, that symbol does not appear applicable to § 610.64.

II. Significance of Guidance

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance, when finalized, will represent 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, 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 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 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 (44 U.S.C. 3501–3520) (the PRA). The collections of information described in sections VII and VIII of the guidance regarding a glossary of terms and educational outreach were approved by OMB in accordance with the PRA under OMB control number 0910–0553 which expires on October 31, 2007. The 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 the 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. 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) were approved under OMB control number 0910–0527. The collections of information described in section X of the guidance, regarding annual reports, were approved under OMB control numbers 0910–0231 and 0910–0338. 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 a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 11-9-04

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November 9, 2004.

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