

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 BURDEN¹

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

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

²One-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]

BILLING CODE 4160-01-S