Supporting Statement For:

Recommended Glossary and Educational Outreach to Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use
0910-0553

A. JUSTIFICATION

1. Circumstances Necessitating Information Collection

Section 502 (Attachment 1) of the Federal Food, Drug and Cosmetic Act (FFD&C Act) (21 U.S.C. 352), among other things, establishes requirements for the label or labeling of a medical device so that it is not misbranded. Section 351 (Attachment 2) of the Public Health Service Act (the PHS Act) (42 U.S.C. 262), establishes requirements that manufacturers of biological products must submit a license application for FDA review and approval prior to marketing a biological product for introduction into interstate commerce.

The Food and Drug Administration (FDA) issued a guidance document, "Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use", http://www.fda.gov/cdrh/ocd/guidance/444.html, that 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 21 CFR 809.10, FDA's labeling requirements for in vitro diagnostic devices (IVDs) (4) , and 21 CFR parts 610 and 660 (Attachment 5), FDA's labeling requirements for biologics (including IVDs) that are licensed under the Public Health Service (PHS) Act. These recommendations apply to 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. The Center of Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER) issued this guidance to help manufacturers create uniform labels and labeling for the United States and European Union (and any other countries that may permit use of symbols from these international standards), in keeping with the European Union's Directive on In Vitro Diagnostic Medical Devices, (Directive 98/79EC), which went into full effect as of December 8, 2003.

2. Purpose and use of Information

The purpose of this guidance is to allow the use of selected symbols in place of text. Manufacturers will be able to use 25 symbols for IVD devices for professional use recognized by FDA taken from the following two international consensus standards:

- ISO 15223, Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied

- EN 980, Graphical symbols for use in the labeling of medical devices

This guidance helps IVD manufacturers to create uniform labels and labeling for the United States and European Union (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 European Union. Of course, it is essential that the symbol convey the substance of the deleted text and be widely understood.

Given that the IVD label space to communicate information is limited, FDA issued this guidance to recognize the use of selected symbols in place of text for IVDs intended for professional use as a way of meeting the challenge created by multilingual requirements and limited product space.

3. **Consideration of Information Technology**

There are no obvious means to apply information technology to reduce the reporting burden. 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.

4. **Identify of Duplication and Similar Information Already Available**

FDA is the only Federal Agency responsible for the collection of this information.

5. **Impact on Small Businesses or Other Small Entities**

The information collection will not have a significant impact on a substantial number of small entities.

6. **Consequences of Collecting the Information Less Frequently**

IVD manufacturers need submit only one time as required by the statute and additional times only when they make significant changes that may affect the safety and effectiveness of the device.

7. **Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

This information is entirely consistent with 5 CFR 1320.5

8. **Consultation Outside the Agency**

On Friday, August 31, 2007, (72 FR 50373), FDA published a notice soliciting comments on this information collection (Attachment 6). FDA received one comment from a distributor. (Attachment 7). This comment stated, "The time and cost associated with including a glossary of symbols within the product's package insert will vary depending upon the product and the customer. Products that are CE marked require multiple languages and would require additional translations of symbols used within the glossary. Package inserts are very large, and will need to become larger due to the need of increased space required within the insert. Therefore there will be time as well as increased packaging costs associated with the glossary."

FDA disagrees with this comment. The use of symbols allows manufacturers to create uniform labels and labeling for the United States and European Union. Therefore, there is less cost associated with creating multiple labels and labeling for each marketplace. User comprehension studies indicated that providing a glossary was an acceptable means of ensuring and enhancing the user's understanding of the symbols

9. **Explanation of Any Payment or Gift to Respondents**

No payments or gifts shall be provided to respondents under this regulation.

10. **Assurance of confidentiality Provided to Respondents**

Under the Freedom of Information Act (FOIA) (5 U.S.C. 522), the public has broad access to government documents. Information provided under this collection is handled in a manner to comply with the FDA regulations on public information in 21 CFR Part 20.

11. **Justification for Sensitive Questions**

This information collection does not concern questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs or other matters considered private.

12. **Estimate of Hour Burden Including Annualized Hourly Costs**

FDA estimates the burden of this information collection as follows:

TABLE 1. ESTIMATED ANNUAL REPORTING BURDEN[1]

21 U.S.C. 352 and 42 U.S.C. 262	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Glossary	227	1	227	4	908
Educational Outreach	227	1	227	16	3,632
Total					4,540

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

Explanation of Reporting Burden Estimate

FDA based these estimates on conversations with industry, trade association representatives, and internal FDA estimates. The CDRH Information Retrieval System's Registration and Listing Information database provided the number of IVD manufacturers as 2,424. However, of the 2,424 registered and listed manufacturers, only 682 of those manufacturers are newly registered since. FDA has based its burden estimate on the annual number, 227, of new manufacturers registered and listed with the agency since the implementation of 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 hours 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 hours 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.

Cost to Respondents

FDA estimates that the cost to respondents is $1,000.00. This cost is based on an estimated salary cost of $50 per hour multiplied by 20 hours per respondent.

13. Estimate of Other Total Annual Cost to Respondents or Recordkeepers

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

14. Annualized Cost to the Federal Government

FDA estimates that a total of 187 full time equivalent (FTE) positions consisting of a combination of medical officers, dental officers, scientific, and engineering professionals and support staff are required for premarket notification review and processing. Based on a cost of $107,000 per position (which is the agency's average cost of an FTE including their benefits), the estimated annual Federal cost is $20,009,000.

FDA estimates that approximately 211 staff-years are devoted to the activity annually, at a cost of $22.6 million. The average time modules for the activity are 1.2 staff-years for a PMA review and 0.1 staff-years for a supplemental PMA. The cost estimate includes FDA staff effort and advisory panel costs for those PMA's requiring panel review under the law, as changed by the Safe Medical Devices Act of 1990, with a total cost of 22,577,000.

15. Explanation for Program Changes or Adjustments.

The reduction in the burden is due to a recalculation of the burden estimates.

16. Plans for Tabulation and Publication and Project Time Schedule

No publication of information for statistical use is planned.

17. Reason(s) Display of OMB Expiration Date Is Inappropriate

FDA is not seeking approval to prevent the display of expiration date or OMB approval of this request.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

FDA is not requesting any exemption from the certification statement identified in Item 19 of OMB Form 83-I.

ATTACHMENTS

Attachment 1: US Code Authority Citation 21 U.S.C. 352
21 U.S.C. 352; http://www.fda.gov/opacom/laws/fdcact/fdcact5a.htm

Attachment 2: Public Health Service Act 42 PHS 262
http://www.fda.gov/opacom/laws/phsvcact/sec262.htm

Attachment 3: Guidance for Industry and FDA Staff Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use
http://www.fda.gov/cdrh/ocd/guidance/4444.html

Attachment 4: 21 CFR 809.10

Attachment 5: 21 CFR parts 610 and 660

Attachment 6: 60 day notice

Attachment 7: Comment