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
Supporting Statement For:

A. JUSTIFICATION

1. Circumstances Making the Information Collection Necessary

Abstract

Under section 502(c) of the FFD&C Act, 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."

The 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, the guidance recommends an educational outreach effort to enhance the understanding of newly introduced symbols. Both the glossary and educational outreach information will help to ensure that IVD users will have enough general familiarity with the symbols used, as well as provide a quick reference for available materials, thereby further ensuring that such labeling satisfies the labeling requirements under section 502(c) of the act and section 351 of the PHS Act.

Section 502 of the Federal Food, Drug and Cosmetic Act (FFD&C Act) (21 U.S.C. 352), http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/ucm108061.htm among other things, establishes requirements for the label or labeling of a medical device so that it is not misbranded. Section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262), http://www.fda.gov/RegulatoryInformation/Legislation/ucm149278.htm 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.

In the Federal Register of November 30, 2004 (69 FR 69606), FDA published a notice of availability of the guidance entitled, "Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use," http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085404.htm. The guidance document provides guidance for the voluntary use of selected symbols in place of text in labeling. It provides the labeling guidance required for: (1) In vitro diagnostic devices (IVDs), intended for professional use under 21 CFR 809.10, http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=25e37e791ac395e903ad3626f51de07b&rgn=div8&view=text&node=21:8.0.1.1.7.2.1.1&idno=21, and FDA's labeling requirements for IVDs and (2) FDA's labeling

requirements for biologics, including IVDs under 21 CFR parts 610 and 660. http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=25e37e791ac395e903ad3626f51de07b&c=ecfr&tpl=/ecfrbrowse/Title21/21cfrv7_02.tpl.

Under section 502(c) of the FFD&C Act, 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."

The 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, the guidance recommends an educational outreach effort to enhance the understanding of newly introduced symbols. The glossary will help to ensure that IVD users will have enough general familiarity with the symbols used, as well as provide a quick reference for available materials, thereby further ensuring that such labeling satisfies the labeling requirements under section 502(c) of the act and section 351 of the PHS Act. Given that the symbols are well understood at this time, we do not believe that educational outreach efforts are still being conducted.

This information collection is not related to the American Recovery and Reinvestment Act of 2009. (ARRA).

2. Purpose and use of the Information Collection

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.

The likely respondents for this collection of information are IVD manufacturers who plan to use the selected symbols in place of text on the labels and/or labeling of their IVDs (private sector, business or other for profit).

3. Use of Improved Information Technology and Burden Reduction

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. FDA estimates that 0% of the respondents will use electronic means to fulfill the agency's requirement or request.

4. Efforts to Identify Duplication and Use of Similar Information

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

5. Impact on Small Businesses or Other Small Entities

FDA estimates that 482 respondents are small businesses. The information collection will have a minimal impact on a substantial number of small entities. FDA also aids small business in dealing with the requirements of the regulations by providing guidance and information through the Division of Small Manufacturers, International, and Consumer Assistance (DSMICA), and through the scientific and administrative staff, workshops in which FDA Staff participate, and through the CDRH website at http://www.fda.gov/cdrh . These efforts help to assure that the burden on all manufacturers, including small manufacturers, is minimized.

6. Consequences of Collecting the Information Less Frequently

IVD manufacturers need submit only once as required by the statute; and occasionally, 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 consistent with 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a notice soliciting comments on this information collection on October 5, 2010 (75 FR 61494); no comments were received.

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. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection of information as follows:

Section 502 of the FFD&CAct/Section 351 of the PHS Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Glossary	689	1	689	4	2,756

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

The glossary activity is inclusive of both domestic and foreign IVD manufacturers. FDA receives submissions from approximately 689 IVD manufacturers annually. The number of hours per response for the glossary activity was 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 for the specific symbols used in labels or labeling for the IVDs manufactured. The annualized hour burden reflects an increase of 462 respondents. Previously, the agency determined the burden estimate based on the number of manufacturers, but believes that the number of submissions more accurately reflects the burden associated with the information collection.

12b. Annualized Cost Burden Estimate

FDA estimates that the cost to respondents is $300.25.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Scientist	3.75	$75.00	$281.25
Manager	.25	$75.00	$19
Total			$300.25

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

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 the total cost to the federal government to be $51,342,000. This figure is based upon the cumulative cost of review for both premarket notification submissions and premarket approval applications.

With regard to premarket notification submissions, 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 review and processing. Based on a cost of $129,000 per position (which is the agency's average cost of an FTE including their benefits), the estimated annual Federal cost is $ 24,123,000.

With regard to premarket approval applications, FDA estimates that approximately 211 staff-years are devoted to the activity annually, at a cost of $27.2 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 cost of $27,219,000.

15. Explanation for Program Changes or Adjustments

There is a reduction of 1,784 hours from the last submission. This adjustment is due to the assumption that most manufacturers are not providing educational outreach because the use of symbols is well understood and accepted. There was in increase of 462 in respondents due to the agency re-estimating. Previously, the agency determined the burden estimate based on the number of manufacturers, but believes that the number of submissions more accurately reflects the burden associated with the information collection.

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/RegulatoryInformation/Legislation/ucm149278.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/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085679.pdf

Attachment 4: 21 CFR 809.10

Attachment 5: 21 CFR 610 and 21 CFR 660

Attachment 6: 60 day notice