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

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Under section 502(c) of the Federal Food, Drug, and Cosmetic Act (FD&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 "Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use" recommends that a glossary of terms accompany each in vitro diagnostic (IVD) device 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 FD&C Act and section 351 of the Public Health Service Act (PHS Act).

Section 502 of the FD&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 (http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterVDrugsandDevices/ucm108061.htm). Section 351 of 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 (http://www.fda.gov/RegulatoryInformation/Legislation/ucm149278.htm).

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 FD&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 FD&C 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.

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 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

   There are no special circumstances for this collection of information.

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 60 day notice for public comment in the FEDERAL REGISTER of September 11, 2013 (78 FR 55724). We received one comment.

   The comment is critical of the "premise of the regulation" and the practical utility of the information collection. The comment suggests that the glossary of terms defining the symbols used on the device label is unnecessary "given the many years of successful rest-of-world experience with such symbolic labeling."

   We disagree that information collection lacks practical utility and we note that the comment did not include supporting data or information regarding device users'

understanding of the symbols, especially data that addresses the U.S. intended user population. The information collection is related to a guidance document, not a regulation, which recommends that a glossary of terms accompany each IVD to define the symbols used on that device's labels and/or labeling. It is essential that the symbol convey the substance of the deleted text and be widely understood. The glossary helps to ensure that IVD users will have enough general familiarity with the symbols used, as well as provides a quick reference for available materials, thereby further ensuring that such labeling satisfies the labeling requirements under section 502(c) of the FD&C Act and section 351 of the PHS Act. An alternative approach can be used if the approach satisfies the requirements of the applicable statutes and regulations. Given that the IVD label space to communicate information is limited, FDA issued 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. For these reasons, we decline to modify the information collection at this time.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts are provided to respondents to this information collection.

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 include questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, or other matters that are commonly considered private.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

The glossary activity is inclusive of both domestic and foreign IVD manufacturers. FDA receives submissions from approximately 689 IVD manufacturers annually. The 4-hour burden 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.

Table 1.--Estimated Annual Third-Party Disclosure Burden

Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Glossary	689	1	689	4	2,756

12b. Annualized Cost Burden Estimate

We expect that the information collection will be satisfied by Scientists and Managers. For each 4-hour response, we estimate that 3.75 hours of work will be performed by a Scientist and 0.25 hours by a Manager.

We have updated the hourly wage rate estimates for both Scientists (previously estimated as $75) and Managers (previously estimated as $75). This resulted in a reduction of the estimated respondent costs.

The estimated wage rates for Scientists and Managers are based on the Bureau of Labor and Statistics May 2012 National Occupational Employment and Wage Estimates data for Biological Scientists (Occupation Code #19-1020, http://www.bls.gov/oes/current/oes_nat.htm#19-0000) and Managers, All Other (Occupation Code #11-9199, http://www.bls.gov/oes/current/oes_nat.htm#11-0000), respectively.

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Scientist	3.75	$36.84	$138.15
Manager	0.25	$50.79	$12.70
Total			$150.85

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

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

FDA estimates that a total of 198 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 $209,632* per FTE (which is the agency's average cost of an FTE including the employee's salary and any overhead which accompanies that employee), the estimated annual cost to the Federal government is $41,507,136.

*Based on the FY 2012 President's Budget Request All Purpose Table – Total Program Level table.

15. Explanation for Program Changes or Adjustments

This is a request for extension without change. There are no program changes or adjustments.

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 not to display the expiration date of OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.