

effectiveness review prevented marketing of the product. The length of the patent term extension is generally limited to a maximum of 5 years, and is calculated by PTO based on a statutory formula. When a patent holder submits an application for patent term extension to PTO, PTO requests information from FDA, including the length of the regulatory review period for the patented product. If PTO concludes that the product is eligible for patent term extension, FDA publishes a notice that describes the length of the regulatory review period and the dates used to calculate that period. Interested parties may request, under § 60.24 (21 CFR 60.24), revision of the length of the regulatory review period, or may petition under § 60.30 (21 CFR 60.30) to reduce the regulatory review period by any time where marketing approval was not pursued with “due diligence.” The statute defines due diligence as “that degree of attention, continuous directed

effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period.” As provided in § 60.30(c), a due diligence petition “shall set forth sufficient facts, including dates if possible, to merit an investigation by FDA of whether the applicant acted with due diligence.” Upon receipt of a due diligence petition, FDA reviews the petition and evaluates whether any change in the regulatory review period is necessary. If so, the corrected regulatory review period is published in the **Federal Register**. A due diligence petitioner not satisfied with FDA’s decision regarding the petition may, under § 60.40 (21 CFR 60.40), request an informal hearing for reconsideration of the due diligence determination. Petitioners are likely to include persons or organizations having knowledge that FDA’s marketing permission for that product was not actively pursued throughout the

regulatory review period. The information collection for which an extension of approval is being sought is the use of the statutorily created due diligence petition.

Since 1992, 12 requests for revision of the regulatory review period have been submitted under § 60.24. For 2007, 2008, and 2009, a total of three, or one per year, have been submitted under § 60.24. Two regulatory review periods have been altered. During that same time period, two due diligence petitions were submitted to FDA under § 60.30, for an average of fewer than one per year. There have been no requests for hearings under § 60.40 regarding the decisions on such petitions; however, for purposes of this information collection approval, we are estimating that we may receive one submission annually.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
60.24(a)	1	100	1	100	100
60.30	1	50	1	50	50
60.40	1	100	1	10	10
Total					160

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

Dated: September 30, 2010.  
**Leslie Kux**,  
*Acting Assistant Commissioner for Policy*.  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**  
 [Docket No. FDA-2010-N-0492]

**Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices: Recommended Glossary and Educational Outreach to Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use**

**AGENCY:** Food and Drug Administration, HHS.  
**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the

proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements for the collection “Recommended Glossary and Educational Outreach to Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use.”

**DATES:** Submit written or electronic comments on the collection of information by December 6, 2010.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm.

1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [Daniel.Gittleson@fda.hhs.gov](mailto:Daniel.Gittleson@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an

existing collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Medical Devices: Recommended Glossary and Educational Outreach to Support Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use (OMB Control Number 0910-0553)—Extension**

Section 502 of the Federal Food, Drug and Cosmetic Act (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. Section 351 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.

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." 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, FDA's labeling requirements for IVDs and (2) FDA's labeling requirements for biologics, including IVDs under 21 CFR parts 610 and 660. 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. 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 PHS Act.

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.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Section 502 of the FD&C Act/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

<sup>1</sup> 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 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 for the specific symbols used in labels or labeling for the IVDs manufactured.

Dated: September 30, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2010-N-0161]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Export of Food and Drug Administration Regulated Products: Export Certificates**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget

(OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by November 4, 2010.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0498. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Jenna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-