

will provide the better understanding of target audiences that FDA needs to design effective communication strategies, messages, and labels. These communications will aim to improve public understanding of the risks and benefits of using medical devices and radiation-emitting products by providing users with a better context in which to place risk information more completely.

Second, as initial testing, it will allow FDA to assess the potential effectiveness of messages and materials in reaching and successfully communicating with their intended audiences. Testing messages with a sample of the target

audience will allow FDA to refine messages while still in the developmental stage. Respondents will be asked to give their reaction to the messages in either individual or group settings.

Third, as evaluative research, it will allow FDA to ascertain the effectiveness of the messages and the distribution method of these messages in achieving the objectives of the message campaign. Evaluation of campaigns is a vital link in continuous improvement of communications at FDA.

Annually, FDA projects about 30 studies using a variety of research methods and lasting an average of 0.17 hours each (varying from 0.08 to 1.5

hours). FDA estimates the burden of this collection of information based on prior recent experience with the various types of data collection methods described earlier. FDA is requesting this burden so as not to restrict the Agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

In the **Federal Register** of October 28, 2016 (81 FR 75134), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Individual in-depth interviews	360	1	360	.75 (45 minutes)	270
General public focus group interviews	144	1	144	1.5	216
Intercept interviews: Central location	200	1	200	.25 (15 minutes)	50
Intercept interviews: Telephone	4,000	1	4,000	.08 (5 minutes)	320
Self-administered surveys	2,400	1	2,400	.25 (15 minutes)	600
Gatekeeper reviews	400	1	400	.5 (30 minutes)	200
Omnibus surveys	1,200	1	1,200	.17 (10 minutes)	204
Total (general public)	8,704	1,860
Physician focus group interviews	144	1	144	1.5	216
Total (physician)	144	216
Total (overall)	8,848	2,076

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

Dated: March 9, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-1089]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; 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

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 April 14, 2017.

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 oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0553. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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 to avoid misbranding. 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 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.

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 help to ensure that IVD users 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.

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

In the **Federal Register** of December 5, 2016 (81 FR 87570), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	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.

Dated: March 9, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0360]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration Safety Communication Readership Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 Safety Communication Readership Survey.

DATES: Submit either electronic or written comments on the collection of information by May 15, 2017.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the

manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2009–N–0360 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Food and Drug Administration Safety Communication Readership Survey.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your