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>
<thead>
<tr>
<th>Activity</th>
<th>Number of respondents</th>
<th>Number of disclosures per respondent</th>
<th>Total annual disclosures</th>
<th>Average burden per disclosure</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glossary</td>
<td>689</td>
<td>1</td>
<td>689</td>
<td>4</td>
<td>2,756</td>
</tr>
</tbody>
</table>

† 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.

[FR Doc. 2017–05106 Filed 3–14–17; 8:45 am]

BILLING CODE 4164–01–P

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, 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, Room 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
Based on the history of the Safety Communication program, it is estimated that an average of three collections will be conducted per year. The total burden of response time is estimated at 10 minutes per survey. This was derived by CDRH staff completing the survey.

**Table 1—Estimated Annual Reporting Burden**

<table>
<thead>
<tr>
<th>Activity</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public Health Notification Readership Survey</td>
<td>300</td>
<td>3</td>
<td>900</td>
<td>0.17 (10 minutes)</td>
<td>153</td>
</tr>
</tbody>
</table>

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