Explanation of Recordkeeping Burden Estimate. FDA expects that at least some of the manufacturers will be able to satisfy the PS requirement using information or data they already have. For purposes of calculating burden, however, FDA has assumed that each PS order can only be satisfied by a 3-year clinically based surveillance plan, using three investigators. These estimates are based on FDA's knowledge and experience with postmarket surveillance.

Dated: September 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–22013 Filed 9–10–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013-N–1089]

Agency Information Collection Activities; Proposed Collection; 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 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 either electronic or written comments on the collection of information by November 12, 2013.

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@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.

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 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.

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

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

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: September 6, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–22110 Filed 9–10–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0717]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Evaluation of the Food and Drug Administration's General Market Youth Tobacco Prevention Campaigns

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 October 11, 2013.

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–New and title ''Evaluation of FDA's General Market Youth Tobacco Prevention Campaigns''. 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, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *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.

Evaluation of FDA's General Market Youth Tobacco Prevention Campaigns—(OMB Control Number 0910–New)

The 2009 Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to grant FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health and to reduce tobacco use by minors. Section 1003(d)(2)(D) of the FD&C Act (21 U.S.C. 393(d)(2)(D)) supports the development and implementation of FDA public education campaigns related to tobacco use. Accordingly, FDA is currently developing and implementing youth-targeted public education campaigns to help prevent tobacco use among youth and thereby reduce the public health burden of tobacco. The campaigns will feature televised advertisements along with complementary ads on radio, on the Internet, in print, and through other forms of media.

In support of the provisions of the Tobacco Control Act that require FDA to protect the public health and to reduce tobacco use by minors, FDA requests OMB approval to collect information needed to evaluate FDA's general market youth tobacco prevention campaigns. Comprehensive evaluation of FDA's public education campaigns is needed to ensure campaign messages are effectively received, understood, and accepted by those for whom they are intended. Evaluation is an essential organizational practice in public health and a systematic way to account for and improve public health actions.

FDA plans to conduct two studies to evaluate the effectiveness of its youth tobacco prevention campaigns: (1) An outcome evaluation study consisting of a youth experimenter and non-trier initiative and a male only youth rural smokeless initiative and (2) a media tracking survey. The timing of these studies will be designed to follow the multiple, discrete waves of media advertising planned for the campaigns.

- *Outcome Evaluation Study.* The outcome evaluation study consists of an initial baseline survey of youth aged 11 to 16 before the campaigns launch. The baseline will be followed by three longitudinal followup surveys of the same youth, aged 11 to 16, at approximate 8-month intervals after the campaigns launch. As the cohort will be aging over this time period, the data collected throughout the study will reflect information from youth aged 11 to 18. Information will be collected about youth awareness of and exposure to campaign advertisements and about youth knowledge, attitudes, and beliefs related to tobacco use. In addition, the surveys will measure tobacco use susceptibility and current use. Information will also be collected on demographic variables including age, sex, race/ethnicity, grade level, and primary language. Finally, a baseline survey will also be conducted with the parent or legal guardian of each youth baseline survey participant in order to collect data on household characteristics and media use.

- *Media Tracking Survey.* The media tracking survey consists of assessments of youth aged 13 to 17 conducted at 4 months, 12 months, and 20 months post launch. The tracking survey will assess awareness of the campaigns and receptivity to campaign messages. These data will provide critical evaluation feedback to the campaigns and will be conducted with sufficient frequency to match the cyclical patterns of media advertising and variation in exposure to allow for mid-campaign refinements.

All information will be collected through in-person and Web-based questionnaires. Youth respondents will be recruited from two sources: (1) A probability sample drawn from 90 U.S. media markets gathered using an address-based postal mail sampling of U.S. households for the outcome evaluation study and (2) an Internet