intended to gauge and track consumer attitudes, awareness, knowledge, and behavior regarding various topics related to health, nutrition and physical activity. The authority for FDA to collect the information derives from FDA's Commissioner of Food and Drugs authority provided in section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)).

The survey consists of two independent data collection activities. One collection, entitled "Health and Diet Survey—General Topics," tracks a broad range of consumer attitudes, awareness, knowledge, and self-reported behaviors related to key diet and health issues. The other collection, entitled "Health and Diet Survey—*Dietary Guidelines* Supplement," will provide FDA with updated information about consumer attitudes, awareness, knowledge, and behavior regarding various elements of nutrition and physical activity based on the key recommendations of the *Dietary Guidelines for Americans,* which are jointly issued by the Department of Health and Human Services and the U.S. Department of Agriculture every 5 years.

The information to be collected with the Health and Diet Survey—General Topics will include: (1) Awareness of diet-disease relationships, (2) food and dietary supplement label use, (3) dietary practices including strategies to lose or maintain weight, and (4) awareness and knowledge of dietary fats. This survey has been repeated approximately every 3 years over the course of the past several years for the purpose of tracking changes and trends in public opinions and consumer behavior, with some new questions added or omitted or partially modified each iteration in response to current events. In the next 3 years, FDA plans to field the Health and Diet Survey—General Topics in 2012 and anticipates that it might have the need for additional iterations in 2014. The information to be collected with the Health and Diet Survey—*Dietary Guidelines* Supplement will include: (1) Awareness and sources of information, (2) attitudes toward diet and physical activity, and (3) practice and knowledge related to recommended behaviors. The survey will also ask about perceptions and use of Federal nutrition information, special diet, weight status, health status, and demographics. In the next 3 years, FDA anticipates to field the Health and Diet Survey—*Dietary Guidelines* Supplement in 2011–2012.

FDA and other Federal Agencies will use the information from the Health and Diet Survey to evaluate and develop strategies and programs to encourage and help consumers adopt healthy lifestyles. The information will also help FDA and other Federal Agencies evaluate and track consumer awareness and behavior as outcome measures of their achievement in improving public health.

Description of Respondents: The respondents are adults, age 18 and older, drawn from the 50 States and the District of Columbia. Participation will be voluntary.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
General Topics: Pretest	27	1	27	0.25	7
General Topics: Screener	10,000	1	10,000	0.02	200
General Topics: Survey	3,000	1	3,000	0.25	750
Dietary Guidelines Supplement: Screener	4,000	1	4,000	0.02	80
Dietary Guidelines Supplement: Survey	1,200	1	1,200	0.22	264
Total					1,301

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

FDA bases its estimate of the number of respondents and the hours per response on its experience with previous Health and Diet Surveys. Prior to the administration of the Health and Diet Survey—General Topics, the Agency plans to conduct a pretest to identify and resolve potential problems. The pretest will be conducted with 27 participants; we estimate that it will take a respondent 15 minutes (0.25 hours) to complete the pretest, for a total of 6.75 hours, rounded to 7. The Agency will use a screener to select an eligible adult respondent in each household to participate in the survey. For the Health and Diet Survey—General Topics data collection activity, a total of 10,000 individuals in the 50 States and the District of Columbia will be screened by telephone. We estimate that it will take a respondent 1.2 minutes (0.02 hours) to complete the screening, for a total of 200 hours. We estimate that 3,000 eligible adults will participate in the survey, each taking 15 minutes (0.25 hours), for a total of 750 hours. For the Health and Diet Survey—Dietary Guidelines Supplement data collection activity, 4,000 individuals in the 50 States and the District of Columbia will be screened by telephone. We estimate that it will take a respondent 1.2 minutes (0.02 hours) to complete the screening questions, for a total of 80 hours. Of these respondents, 1,200 will complete the survey. We estimate that it will take a respondent 13 minutes (0.22 hours) to complete the entire survey, for a total of 264 hours. Thus, the total estimated burden is 1,301 hours.

Dated: January 3, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–85 Filed 1–6–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0492]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 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 February 7, 2011.

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 e-mailed 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: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, e-mail: *Daniel.Gittleson@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.

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.

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.

In the **Federal Register** of October 5, 2010 (75 FR 61494), 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]

Section 502 of the FD&C Act/Section 351 of the PHS Act	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	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: January 3, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–74 Filed 1–6–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0610]

Draft Guidance for Industry on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic." The draft guidance discusses FDA's intended approach to enforcement of adverse event reporting requirements for drugs, biologics, medical devices, and dietary supplements during an influenza pandemic. The agency makes recommendations to industry for focusing limited resources on reports