

estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Pre-Existing Health Insurance Plan and Supporting Regulations; *Use:* On March 23, 2010, the President signed into law H.R. 3590, the Patient Protection and Affordable Care Act (Affordable Care Act), Public Law 111-148. Section 1101 of the law establishes a "temporary high risk health insurance pool program" (which has been named the Pre-Existing Condition Insurance Plan, or PCIP) to provide health insurance coverage to currently uninsured individuals with pre-existing conditions. The law authorizes HHS to carry out the program directly or through contracts with states or private, non-profit entities.

We are requesting an extension of this package because this information is needed to assure that PCIP programs are established timely and effectively. This request is being made based on regulations and guidance that have been issued and contracts which have been executed by HHS with States or an entity on their behalf participating in the PCIP program. PCIP is also referred to as the temporary qualified high risk insurance pool program, as it is called in the Affordable Care Act, but we have adopted the term PCIP to better describe the program and avoid confusion with the existing state high risk pool programs. *Form Number:* CMS-10339 (OMB#: 0938-1100); *Frequency:* Reporting—On occasion; *Affected Public:* State governments; *Number of Respondents:* 51; *Total Annual Responses:* 2,652; *Total Annual Hours:* 36,924. (For policy questions regarding this collection contact Laura Dash at 410-786-8623. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to

[Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by: March 8, 2011.

1. *Electronically.* You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: January 4, 2011.

**Kenneth Cohen,**

*Director, Executive Secretariat & Regulatory Affairs, Office of Consumer Information and Insurance Oversight.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0001]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Health and Diet Survey

**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 FDA's Health and Diet Survey.

**DATES:** Submit either electronic or written comments on the collection of information by March 8, 2011.

**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:** Denver Presley, Jr., Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

**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.

#### Health and Diet Survey (OMB Control Number 0910-0545—Extension)

FDA is seeking extension of OMB approval for the Health and Diet Survey, which is a voluntary consumer survey

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 <sup>1</sup>

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
<i>Dietary Guidelines</i> Supplement: Screener .....	4,000	1	4,000	0.02	80
<i>Dietary Guidelines</i> Supplement: Survey .....	1,200	1	1,200	0.22	264
Total .....					1,301

<sup>1</sup> 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]  
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**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