



4164-01-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. FDA-2014-N-0920]**

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Health and Diet Survey, as Used by the Food and Drug Administration**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) 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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**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 [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov). All comments should be identified with the OMB control number 0910-0545. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, [PRASstaff@fda.hhs.gov](mailto:PRASstaff@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.

Health and Diet Survey as Used by the Food and Drug Administration

OMB Control Number 0910-0545--Extension

We are seeking to renew OMB approval of the Health and Diet Survey, which is a voluntary consumer survey intended to gauge and to track consumer attitudes, awareness, knowledge, and behavior regarding various topics related to health, nutrition, physical activity, and product labeling. OMB approved this collection as a generic collection on December 5, 2014. The authority for FDA to collect the information derives from FDA's Commissioner of Food and Drugs authority provided in section 1003(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)).

We will use the Health and Diet Survey findings to test and refine our ideas, but will generally conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

This survey has been repeated approximately every 3 to 5 years over the course of the past 3 decades for the purpose of tracking changes and trends in public opinions and consumer behavior, with some new questions added or omitted or partially modified in each iteration in response to emerging and current events or issues. In the next 3 years, we plan to field this survey two to three times. We will use the information from the Health and Diet Survey to evaluate and develop strategies and programs to encourage and help consumers adopt healthy diets and lifestyles. The information will also help FDA 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.

In the *Federal Register* of July 18, 2017 (82 FR 32832), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received no comments.

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

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Cognitive interview screener	100	1	100	.08 (5 minutes)	8
Cognitive interview	18	1	18	1	18
Pretest screener	2,000	1	2,000	.033 (2 minutes)	66
Pretest	200	1	200	.25 (15 minutes)	50
Survey screener	40,000	1	40,000	.033 (2 minutes)	1,320
Survey	4,000	1	4,000	.25 (15 minutes)	1,000
Total					2,462

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

We base our estimate of the number of respondents and the average burden per response on our experience with previous Health and Diet Surveys and we estimate that the burden for this information collection has increased by 580 hours (from 1,882 to 2,462 hours) since the last OMB approval. The increase is due to an expected increase in the number of participants completing the survey screener (from 30,000 to 40,000 participants) and number of participants taking the survey (from 3,000 to 4,000). We will use a cognitive interview screener with 100 individuals to recruit prospective interview participants. We estimate that it will take a screener respondent approximately 5 minutes (0.08 hours) to complete the cognitive interview screener, for a total of 8 hours. We will conduct cognitive interviews with 18 participants. We estimate that it will take a participant approximately 1 hour to complete the interview, for a total of 18

hours. Prior to the administration of the Health and Diet Survey, the Agency plans to conduct a pretest to identify and resolve potential survey administration problems. We will use a pretest screener with 2,000 individuals; we estimate that it will take a respondent approximately 2 minutes (0.033 hours) to complete the pretest screener, for a total of 66 hours. The pretest will be conducted with 200 participants; we estimate that it will take a participant 15 minutes (0.25 hours) to complete the pretest, for a total of 50 hours. We will use a survey screener to select an eligible adult respondent in each household reached by landline telephone numbers to participate in the survey. A total of 40,000 individuals in the 50 states and the District of Columbia will be screened by telephone. We estimate that it will take a respondent 2 minutes (0.033 hours) to complete the screening, for a total of 1,320 hours. We estimate that 4,000 eligible adults will participate in the survey, each taking 15 minutes (0.25 hours), for a total of 1,000 hours. Thus, the total estimated burden is 2,462 hours.

We are requesting this burden for unplanned surveys so as not to restrict our ability to gather information on consumer attitudes, awareness, knowledge, and behavior regarding various topics related to health, nutrition, physical activity, and product labeling. This ability will help the Agency identify and respond to emerging issues in a more timely manner.

Dated: November 6, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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