



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Proposed Collection; 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) 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 invites comments on the Health and Diet Survey as used by FDA to gauge and to track consumer attitudes, awareness, knowledge, and behavior regarding various topics related to health, nutrition, physical activity, and product labeling.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, [PRAStaff@fda.hhs.gov](mailto: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, we are publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, we invite 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 as Used by the Food and Drug Administration (OMB Control Number  
0910-0545--Revision)

We are seeking OMB approval to revise 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. Currently this collection is approved as a traditional collection, however, the Agency wishes to employ future collections under the generic collection process. 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)).

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 the survey 2 to 3 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.

We estimate 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	0.083 (5 minutes)	8
Cognitive interview	18	1	18	1	18
Pretest screener	2,000	1	2,000	0.033 (2 minutes)	66
Pretest	200	1	200	0.25 (15 minutes)	50
Survey screener	30,000	1	30,000	0.033 (2 minutes)	990
Survey	3,000	1	3,000	0.25 (15 minutes)	750
Total					1,882

<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. 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 (0.083 hours) to complete the cognitive interview screener, for a total of 8 hours, rounded down from 8.3 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 30,000 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 990 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. Thus, the total estimated burden is 1,882 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: July 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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