Health and Diet Survey

OMB Control No. 0910-0545

SUPPORTING STATEMENT Part A

Terms of Clearance: None, however at OMB's suggestion we are requesting that this collection be revised as a generic collection, as emerging events or issues may trigger periodic question modifications to the survey instrument.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Health and Diet Survey is a voluntary consumer survey intended to gauge and 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, FDA 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)).

2. Purpose and Use of the Information Collection

The information to be collected with the Health and Diet Survey will include, but is not limited to: (1) awareness of diet-disease relationships, including topics such as dietary fats; (2) awareness, understanding, and use of food and dietary supplement labels; (3) dietary practices including strategies to lose or maintain weight; and, (4) dietary practices related to other topics such as energy drinks and sodium reduction. We have repeated this survey every three 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 and our needs. At this time we plan to administer the survey more frequently, approximately 2-3 times, over the next three years to meet the increasing need for consumer information. Each survey will contain a set of core questions while certain question modules will be revised to target topics that might be particularly relevant to current public health issues. Additionally, we plan to use the same sampling and interview approaches each time the survey is administered. Being able to conduct a timely survey with both repeated and targeted questions will be very useful to us. Within the broad context of our public health mission, information gained from the survey will provide a basis with which we can test and refine ideas to encourage and help consumers adopt and maintain healthy lifestyles.

Description of Respondents: The respondents are adults, age 18 and older, drawn from the 50 states and the District of Columbia.

3. Use of Improved Information Technology and Burden Reduction

The telephone interviewing methodology proposed for this collection of information is the most cost-effective approach to acquiring the needed information. Given the rise in cell phone usage, we will include cell phone users, in addition to landline telephone users, to our future surveys. The survey will be administered using a Computer Assisted Telephone Interviewing (CATI) system, since this methodology will minimize possible errors of administration and expedite the timeliness of data processing. Compared to face-to-face interviews, telephone interviews are less intrusive and less costly. Mail surveys are not appropriate for a questionnaire with complicated skip patterns as used in this collection of information. In addition, mail surveys generally have a much lower response rate than telephone surveys. We will also consider using other modes of data collection, such as multi-mode (telephone and web), when appropriate.

4. Efforts to Identify Duplication and Use of Similar Information

There is no duplicative collection of this information. Many of the topics included in the Survey, particularly product labeling, are of special interest to us, but are not covered by any other public- or private-sponsored national surveys.

5. Impact on Small Businesses or Other Small Entities

The collection of information does not involve small businesses. None of the respondents are small businesses.

6. Consequences of Collecting the Information Less Frequently

We plan to field the survey 2 to 3 times in the next three years. If this information is collected less frequently, current, essential, and national data of consumer knowledge, perceptions, attitudes, and practices pertinent to current and emerging public health issues will not be available to the FDA. The lack of information will severely limit our capabilities in performing its functions properly to promote and protect the public health.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), in the *Federal Register* of July 14, 2014 (79 FR 40760), we published a 60-day notice requesting public comment on the proposed collection of information. We received two comments in response to the notice that we were unable to address in our 30 day publication, however we do address them here.

(Comment 1) One comment stated that the information collected will not benefit the public. The comment questioned whether the proposed survey would provide any meaningful data and said it was wasteful spending.

(Response) We respectfully disagree. This survey is intended to gauge and to track consumer attitudes, awareness, knowledge, and behavior regarding various topics related to health, nutrition, physical activity, and product labeling. An example of the survey's utility is FDA's use of the Nutrition Facts label reading questions in its deliberations of proposed changes to the Nutrition Facts label to enhance the label's usefulness. We believe consumers benefit from this information.

(Comment 2) One comment suggests that the Health and Diet Survey should include demographic questions to identify lesbian, gay, bisexual, and transgender (LGBT) individuals so LGBT health disparities may be addressed. The comment continued that the demographic questions should differentiate between sexual orientation and gender identity.

(Response) We appreciate the comment. We will take this suggestion under consideration for future surveys. We want to collect data for all populations. As mentioned in the comment, sexual orientation and gender identity questions are sensitive and potentially stigmatizing. We would need to research this topic further before fielding this line of questions and only when the subject matters warrant attention to potential disparities between individuals with different gender identities or sexual orientations.

9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive any type of payment or gift for participation in this collection of information.

10. Assurance of Confidentiality Provided to Respondents

All data will be collected with an assurance that the respondents' answers will remain confidential. The study instrument will contain a statement that responses will be kept confidential. Identifying information will not be included in the data files delivered by contractors to the agency. FDA will keep the study data confidential to the extent permitted by law.

Confidentiality will be assured by using an independent contractor to collect the information, by enacting procedures to prevent unauthorized access to respondent data, and by preventing the public disclosure of the responses of individual participants. The contractors will only share data and/or information with the agency in an aggregated form or format, which does not permit the agency to identify individual respondents.

All electronic data will be maintained in a manner that is consistent with the Department of Health and Human Services ADP Systems Security Policy as described in DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35. All data will also be maintained in accordance with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

11. Justification for Sensitive Questions

The Health and Diet Survey proposes to ask respondents their height, weight, and self assessment of weight status, and risk perception of chronic illnesses. The agency's experience with these questions suggests that the overwhelming majority of respondents feel comfortable in providing this information. For example, in the last Health and Diet Survey (2008) , the item non-response rates due to refusal were lower than 3% among these questions.

To mitigate potential privacy concerns, the following sentence is read immediately prior to the group of questions concerning health status: "The next few questions may seem a bit personal. But we need this information because this survey is about nutrition and health." It is likely that the low item non-response rates mentioned above were attributable to this sentence.

12. Estimates of Annualized Burden Hours and Costs

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.

12 a. Annualized Hour Burden Estimate

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

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

[1] 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.

12 b. Annualized Cost Burden Estimate

We estimate that the average hourly wage of the respondents is $17 per hour. The overall estimated cost incurred by the respondents is $31,994. (1,882 burden hours X $17/hr = $31,994).

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating, or maintenance costs associated with this collection.

14. Annualized Cost to the Federal Government

The estimated total cost to the Federal government for this information collection $460,000. This estimate consists of (1) $160,000 for 1.5 FTE of FDA professional staff to manage the project, develop the survey, analyze the data, and prepare reports and other informational products to be described in A.16, and (2) $300,000 for data collection. These costs would increase in the event that the agency has a need for additional follow-up surveys in 2016 and 2017.

15. Explanation for Program Changes or Adjustments

This collection is being revised. The burden hours have been increased by 581 and the annual responses by 17,091. Although questions related to the *Dietary Guidelines for Americans* have been removed from this iteration of the survey, a cognitive interview and screeners for the pretest and cognitive interview have been added. We have also increased the number of respondents to allow for more than one survey deployment during the approval period as we will utilize this as a generic collection.

16. Plans for Tabulation and Publication and Project Time Schedule

For the Health and Diet Survey, the planned schedule for the project activities is shown in Table 2.

Table 2. Project Schedule

Date	Activity	Audience
Within 3 days after receipt of OMB approval of collection of information	Notification to contractor to proceed with data collection activities	Not applicable
Within 135 days after notification to contractor	Completion of data collection	Not applicable
Within 180 days after notification to contractor	Delivery by contractor of final data files	Not applicable
Within 6 months after receipt of final data files	Delivery of oral and written preliminary summaries	FDA
Within 18 months after receipt of final data files	Delivery of written summaries and analytical findings	FDA
Within 18 months after receipt of final data files	Response to information requests	FDA and public
Within 24 months after receipt of final data files	Dissemination of findings through submissions of journal manuscript(s) and conference presentations	Public

Following OMB approval, the data collection contractor will draw the sample, conduct the survey, and prepare the deliverables in accordance with the Quick Turnaround Research Services contract. The duration of information collection is estimated to be approximately 135 days to allow (1) a 15-day lead time to prepare for pretests, advance letters, and field operations, and (2) a 120-day field period to conduct interviews and to send conversion letters to initial refusals to encourage participation. Data files and all other deliverables will be delivered to the FDA within 180 days of written notification to the contractor that OMB approval has been granted.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

No exemption is requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.