Health and Diet Survey

0910-0545

SUPPORTING STATEMENT

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 and physical activity. The authority for FDA to collect the information derives from the FDA Commissioner's 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 (HHS) and Department of Agriculture every five years.

2. Purpose and Use of the Information Collection

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 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. In the next three years, FDA plans to field the Health and Diet Survey -- General Topics survey in 2011 and anticipates that it might have the need for additional follow-up surveys in 2014. For example, in developing possible changes to the current Nutrition Facts label, the agency will need information on consumer views and understanding of some of the items listed on the label and this information may not be available anywhere. Being able to field a timely survey with targeted questions would be very useful to us, especially within the context of the broader understanding gained with the Health and Diet Survey -- General Topics survey questionnaire. The information to be collected with the Health and Diet Survey—*Dietary Guidelines* Supplement will include: (1) opinions about the nutrition information provided by the government; (2) awareness and familiarity with government nutrition programs and publications such as the Food Guide Pyramid and the *Dietary Guidelines for Americans*; (3) knowledge of the relationships between food choices, exercise habits, weight loss, and health; (4) choices surrounding exercise, calorie intake, saturated and trans fats, fruits and vegetables, whole grains, dairy, fish, meat, cholesterol, carbohydrates, salt, and sugar. The survey will also ask about use of Federal nutrition information, special diet, weight status, health status, and demographics.

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 the 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. Respondents are individuals.

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. 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. The agency estimates that one hundred percent (100%) of the submissions will be submitted electronically.

4. Efforts to Identify Duplication and Use of Similar Information

There is no duplicative collection of this information. No comparable data are collected by any other means. The Health and Diet Survey is periodically repeated to track changes in consumer awareness and practices. The survey provides valuable consumer information specific to the Congressionally-mandated review of nutrition science every five years by the Federal government in the form of the *Dietary Guidelines for Americans*. The survey information has been used to shape reference measures with resulting data accumulated with cross tabs by specific populations (over sample of Hispanic and African Americans) and other factors (age, gender, education, health status, etc.) Since the 2004 data was obtained before the release of the *Dietary Guidelines*, the survey has a pre-intervention reference point, allowing for the tracking of changes in attitudes, knowledge, and behaviors as a result of the *Dietary Guidelines* (2010) and into future iterations. The Department of Health and Human Services (HHS) collaborated with FDA to use the Health and Diet survey as an evaluation mechanism at OMB's recommendation.

The Health and Diet Survey-General Topics questionnaire is fielded once every three years and, if events warrant, may be fielded once annually during each year of the three-year approval period, with appropriate modifications to specific portions of the questionnaire (addition and/or removal of questions). If changed, the questionnaire would be submitted to OMB for review and approval.

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

Data collection occurs occasionally. If this information is collected less frequently, current, essential, and national data of consumer knowledge, perceptions, attitudes, and practices pertinent to foods and dietary supplements will not be available to the FDA. The lack of information will severely limit the agency's capabilities in performing its functions properly to promote and protect the public health.

The information from the *Dietary Guidelines* provides a blueprint for action; however, putting knowledge into practice can be challenging and changing behavior is usually a long-term proposition. Fielding of this survey provides an on-going, consistent mechanism to monitor American eating habits and lifestyle choices over time, recognizing that adopting more healthy, active lifestyles will take a concerted effort— from the Federal government, health experts, the food and agriculture sectors, business leaders, state and local governments, scientists and researchers, and teachers and parents and individuals. The survey demonstrates that HHS is committed to monitoring American's progress overtime with an on-going evaluation mechanism in place. Without the survey, we lose a tracking mechanism designed specific to the *Dietary Guidelines* information released every five years and used as the benchmark for Federal nutrition policy in this nation.

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

Assurance of confidentiality of information will be provided to all respondents. The information collection provisions of the Health and Diet Survey do not involve more than quarterly submission of information to the agency, written responses to the agency in less than 30 days, submission of more than an original and 2 copies, retention of records for more than three years, the use of statistical methods, pledges of confidentiality by FDA not supported by authority established in statute or regulation, or require the disclosure of trade secrets or other confidential information. The collection fully complies with 5 CFR 1320.5(d)(2).

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 January 7, 2011 (76 FR 1168), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received two comment letters in response to the notice. The letters contained comments outside the scope of the four collection of information topics on which the notice solicits comments and, thus, will not be addressed here.

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

Assurance of confidentiality of information will be provided to all respondents. A statement that "the information will be kept confidential" will be read before each interview. 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.

Identifying information will not be included on the data files delivered to the agency. The data collection contractor has standard procedures for assuring the confidentiality of survey respondents. All of the contractor's employees sign a statement agreeing to maintain confidentiality of data. The data will be collected by a computer-assisted telephone interviewing system (CATI) and will be maintained in an automated information system. Access to the CATI files can only be gained through the use of a password which will be specific to this project. Telephone numbers will be retained only until validation and editing are complete; they will be stripped from the database before the data files are sent to the agency.

All electronic data will be maintained in a manner which 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 consistency with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

Confidential information is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)), and by part 20 of the agency's regulations (21 CFR part 20).

11. Justification for Sensitive Questions

The Health and Diet Survey proposes to ask respondents their height, weight, self assessment of weight status, special diets, and 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 Health and Diet Survey ─ 2004 Supplement, the item non-response rates due to refusal are 1% on height, 2% on weight, 0% on self-assessed weight status, and 0.1% on diet restrictions. That survey asked about awareness of chronic illnesses and risk perceptions as a group ("Have you ever been told by a doctor or other healthcare professional that you have any of the following health conditions. I don't need to know which condition, just whether you have any of them."). Only 0.2% of respondents refused to answer the awareness of chronic illness question and 0.3% the risk perception question, respectively.

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." This sentence appeared in the Health and Diet Survey ─ 2004 Supplement and subsequent surveys at the same location in the questionnaire and before the health status questions. 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

FDA estimates 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 (in Hours)[2]	Total Hours
General Topics: Pretest	27	1	27	15/60	7
General Topics: Screener	10,000	1	10,000	1.2/60	200
General Topics: Survey	3,000	1	3,000	15/60	750
Dietary Guidelines Supplement: Screener	4,000	1	4,000	1.2/60	80
Dietary Guidelines Supplement: Survey	1,200	1	1,200	13/60	264
Total					1,301

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

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.

12 b. Annualized Cost Burden Estimate

FDA estimates that the average hourly wage of the respondents is $16 per hour. The overall estimated cost incurred by the respondents is $20,816. (1,301 burden hours X $16/hr = $20,816).

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 $343,000. This estimate consists of (1) $43,000 for 2 FTE of FDA professional staff to manage the project, 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 2013 and 2014.

15. Explanation for Program Changes or Adjustments

This is a revision request in which the burden hours for a small methodological experiment are being removed from the information collection. The experiment was conducted in 2008 with the approval of OMB. It compared the results from the telephone Health and Diet Survey with the results from a protocol that used the Internet to collect the same information. We estimated 33 burden hours for this experiment. Due to the removal of the experiment, the annual number of responses decreased by 1,000 and the burden hours decreased by 33 hours. Thus, we are characterizing this revision as a program change due to agency discretion. CFSAN would be pleased to discuss the results of this experiment with OMB.

16. Plans for Tabulation and Publication and Project Time Schedule

For the Health and Diet Survey- General Topics, 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 a written final report of 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	• Submission of manuscript(s) of journal article(s) to disseminate information and analytical findings	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.

As stated above, the goal of the collection of information is to (1) enhance the agency's understanding of consumer knowledge, perceptions, attitudes, and practices, (2) enrich deliberations of the agency's regulatory and educational initiatives, (3) help the agency track trends in consumer knowledge, perceptions, attitudes, and practices related to dietary supplements and food, and (4) help the agency evaluate the effectiveness of the Nutrition Labeling and Education Act (NLEA) of 1990 in promoting public health. Hence, the priority of project activities after the agency's receipt of final data files is to meet the agency's information needs. These activities will primarily consist of written and oral presentations of preliminary summaries as well as a written final report of summaries and analytical findings. In addition, journal manuscripts and oral and/or poster presentations will be planned to disseminate the information to the public, including professionals, academics, and industry and consumer organizations. These activities are aimed to create value-added products to share and exchange information on current consumer knowledge, perceptions, attitudes, and practices related to dietary supplements and food and to encourage dialogues between the agency and the public on issues related to these matters. The dialogues will help improve the effectiveness of the agency's regulatory and education initiatives in promoting and protecting the public health.

For the Health and Diet Survey – *Dietary Guidelines* Supplement, a survey report will be produced and made available to the Department and other Federal agencies as appropriate and needed. The survey provides valuable information related to the *Dietary Guidelines for Americans* that the Department will want to reference and, over time, the research will demonstrate insight into American attitudes, awareness and behaviors on healthy eating and physical activity. The survey will only become increasing more valuable over the coming years, as the connections between the measurements are followed, and the increase in trend data helps to shed light on the impact of the *Dietary Guidelines*

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.