U.S. Food and Drug Administration

Food Safety Survey
OMB Control No. 0910-0345

SUPPORTING STATEMENT **Part A: Justification**

Terms of Clearance: *Respondents should be informed that their responses will be kept 'secure to the extent permitted by law' and that 'confidentiality' cannot be assured absent explicit statutory authority. The agency should ensure that the instruments reflect the current wording.*

1. Circumstances Making the Collection of Information Necessary

This information collection supports the Food Safety Survey (FSS), a unique data set on consumer food handling practices, and food safety-related knowledge and attitudes used in support of improving consumer health. These objectives are also included as part of *Healthy People 2020* goals, discussed more fully at www.healthpeople.gov. The survey is administered through telephone interviews using a random sample of approximately 4,000 US adults (2,400 landline and 1,600 cell phone), including at least 400 Hispanic Americans and at least 400 African-Americans. Data from the survey will be used in support of FDA's regulatory policy in diverse areas dealing with food safety and will support consumer education by enabling us to track consumer knowledge, attitudes, and practices concerning food safety. The data will also be used to measure progress on two Healthy People 2020 consumer objectives for food safety: (1) increase the proportion of consumers who follow key food safety practices: clean, cook, separate, and chill, (Objective FS-5); and (2) one objective related to food allergies: reduce severe allergic reactions to food among adults (Objective FS-4) (Ref.1). Data from this survey will also be used to measure progress toward the USDA Food Safety Inspection Service's (FSIS) goal of ensuring that, "*Consumers, including vulnerable and underserved populations, adopt food safety best practices*" (Ref. 2).

While previous versions of the Food Safety Survey included only landline telephone numbers, this version will include cellular telephone numbers. The proposed survey will contain many of the same questions and topics as previous Food Safety Surveys to facilitate measuring trends in food safety knowledge, attitudes, and behaviors over time. The survey will also be updated to explore emerging consumer food safety topics and expand understanding of previously asked topics. For example, recent papers in both the United States (Ref. 3) and Europe (Refs. 4 and 5) have pointed to changing epidemiology of *listeriosis* where adults over 60 years old have the highest rates of the illness. One reason for the increase in *listeriosis* rates among those over 60 years old could be increasing host susceptibility due to widened use of immunocompromising medications. We plan to include questions to document the proportion of those over 60 years old who self-report taking immunocompromising medications. In conjunction with established questions about safe food handling and eating potentially risky foods, additional questions will expand our understanding of *listeriosis* among those over 60. Other new topics planned to be included on the survey include: consumer understanding of mechanically tenderized beef, awareness of foodborne pathogens

such as *Toxoplasma gondii*, and awareness of the risks associated with eating raw sprouts. The questionnaire has been updated to reflect current issues for consumers and food safety.

2. Purpose and Use of the Information Collection

Data will be used by staff in the Division of Public Health Informatics and Analytics of the Center for Food Safety and Applied Nutrition (CFSAN) and staff in FSIS. DPHIA staff will analyze the data in consultation with other units of the Center including the food safety educators, risk assessors and risk communicators. Survey questions on food handling behaviors and food allergies will serve as measures of progress toward two Healthy People 2020 objectives by comparing results to previous surveys. Trend analysis will also be conducted by demographic characteristics to evaluate disparities in practices and attitudes over time.

3. Use of Improved Information Technology and Burden Reduction

The computer-assisted telephone interviewing (CATI) methodology proposed for the survey duplicates the method used for the 1993, 1998, 2001, 2006, and 2010 surveys, with which the data will be compared. CATI is also the most cost-effective approach to acquiring the needed information. Telephone interviews are less intrusive than face-to-face interviews and are considerably less expensive. Self-administered surveys sent by mail are not appropriate for questionnaires with skip patterns such as used here.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. The FSS is a unique survey instrument designed to capture information otherwise unavailable. The value of asking the core FSS questions with the same data collection method as the previous waves of the FSS has increased substantially, now that five data collections have been completed. The collaboration between FDA and FSIS avoids duplication that would result from independent surveys.

5. Impact on Small Businesses or Other Small Entities

Respondents to the collection are randomly selected private individuals.

6. Consequences of Collecting the Information Less Frequently

Without the data collection, national estimates of current knowledge, attitudes, and the safety of consumer food handling practices will not be available. This is important because the 2010 FSS results most likely do not adequately reflect the current state of consumer knowledge, attitudes, and practices in regard to food safety.

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

The collection fully complies with 5 CFR 1320.5(d) (2). There are no special circumstances associated with this information collection. The study will not require respondents to: report the information more often than quarterly; provide a written response in less than 30 days; submit more than one original plus 2 copies of the information; or, retain records for more than 3 years. The design of the statistical survey will not produce results that cannot be generalized to the universe of study. The study will not use statistical data that has not yet been reviewed or approved by OMB. The study will not include a pledge of confidentiality that is (1) not supported by authority established in statute or regulation; (2) not supported by disclosure and data security policies that are consistent with the pledge; or (3) which unnecessarily impedes sharing of data with other agencies for compatible confidential use. Finally, the study does not involve the submission of trade secrets, proprietary information or other confidential 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), FDA published a 60-day notice in the Federal Register of July 3, 2017 (82 FR 30871) soliciting public comment on the information collection. While two comments were received, they were beyond the scope of the information topics solicited. After evaluating the comments we did not revise the information collection.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts will be offered to respondents. If cell phone respondents request money to offset the cost to them of paying for the phone minutes needed to take the survey, a ten dollar incentive will be offered.

10. Assurance of Confidentiality Provided to Respondents

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). Identifying information will not be included in the data files delivered by contractors to the agency. Information will be kept private to the extent permitted by law.

All 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 be maintained in consistency 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 study does not include any questions that are of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

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

12a. Annualized Hourly Burden

Table 1 – Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
Cognitive interview screener	75	1	75	0.083 (5 min.)	6
Cognitive interview	9	1	9	1 (60 min.)	9
Pretest screener	45	1	45	0.0167 (1 min.)	1
Pretest	18	1	18	0.33 (20 min.)	6
Survey screener	10,000	1	10,000	0.0167 (1 min.)	167
Survey	4,000	1	4,000	0.33 (20 min.)	1,320
Non-response survey screener	125	1	125	0.0167 (1 min.)	2
Non-response survey	50	1	50	0.167 (10 min.)	8
Total					1519

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA plans to conduct cognitive interviews by screening 75 potential respondents in order to obtain 9 respondents in the interviews. Each screening is expected to take 5 minutes (0.083 hour) and each cognitive interview is expected to take one hour. The total for cognitive interview activities is 15 hours (6 hours + 9 hours). Subsequently, we plan to conduct pretests of the questionnaire before it is administered in the study. We expect that 45 adults will need to be screened, each taking 1 minute (0.0167 hours), in order to get 18 of them to complete a 20-minute (0.33 hours) pretest. The total for the pretest activities is 7 hours (1 hour + 6 hours). For the survey, we estimate that 10,000 adults will need to be screened, each taking 1 minutes (0.0167 hours), to have 4,000 of them complete a 20-minute (0.33 hours) questionnaire. The total for the survey activities is 1,487 hours (167 hours + 1,320 hours). Additionally, for the survey non-response analysis, we estimate that 125 adults will need to be screened, each taking 1 minute (0.0167), to have 50 of them complete a 10 minute (0.167 hours) non-response survey. The total time for the non-response survey is 10 hours (2 hours + 8 hours). Thus, the total estimated burden is 1,519 hours.

12b. Annualized Cost Burden Estimate

The annualized cost to all respondents for the hour burden for the collection of information is $30,380 (1,519 x $20) at the 2017 median wage rate for Clinical Processing Clerks, in the United States (rounded from $19.61).

The annualized cost to all respondents for the hour burden for the collection of information is $27,053.39 (1,519 x $20.00) at the 2017 median wage rate in the United States.[1]

Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Responding to Survey	1,519	$20.00	$30,380.00

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

There are no capital, operating, or maintenance costs associated with this data collection.

14. Annualized Cost to the Federal Government

Costs for the information collection are estimated at $650,000 and include costs paid to the contractor to draw the sample, collect the survey data, create a database of the data, tabulate and summarize the survey data, and prepare a final report. This estimate also includes FDA staff time to manage the study.

15. Explanation for Program Changes or Adjustments

There is no change in the estimated burden for this collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Activities associated with the outcomes of this research will primarily consist of a top-line report summarizing the survey findings posted on the FDA Web site, articles published in peer reviewed journals, and presentations at national conferences on food safety and public health. The planned schedule for project activities is shown in Table 3.

Table 3. Project Schedule

Date	**Activity**	**Audience**
Within 3 days after receipt of OMB approval of collection of information	Notification to the contractor to proceed with data collection activities	Not applicable
Within 150 days after notification to contractor	Completion of data collection	Not applicable
Within 180 days after notification to contractor	Delivery by the contractor of final data files	Not applicable
Within 6 months after receipt of final data files	Posting of top-line report to FDA Web site.	FDA

[1] http://www.bls.gov/oes/current/oes_nat.htm, accessed October, 2017.

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

Display of OMB Expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

REFERENCES:

1. U.S. Department of Health and Human Services, "*Health People 2020 - Improving the Lives of Americans*," July 30, 2013. Available http://www.healthypeople.gov/2020/default.aspx.
2. U.S. Department of Agriculture, Food Safety Inspection Service, "*Strategic Plan FY 2011-2016*," April 6, 2012. Available at http://www.fsis.usda.gov/wps/portal/informational/aboutfsis/strategic-planning/fy-2011-2016-strategic-plan/ct_index.
3. Pouillot, R., Hoelzer, K., Jackson, K.A., Henao, O.L. and Silk, B.J. "*Relative Risk of Listeriosis in Foodborne Diseases Active Surveillance Network (FoodNet) Sites According to Age, Pregnancy, and Ethnicity*," Clinical Infectious Diseases, 54(S5): S401-410, 2012.
4. Goulet, V., Hedberg, C., Le Monnier A. and de Valk, H. "*Increasing Incidence of Listeriosis in France and other European Countries*," Emerging Infectious Diseases, 14(5): 734-740, 2008.
5. Muñoz, P., Rojas, L., Bunsow, E., Saez, E., Sánchez-Cambronero, L., Alcalá, L., Rogríguez-Creixems, M. and Bouza, E. "*Listeriosis: An Emerging Public Health Problem Especially Among the Elderly*," Journal of Infection, 64: 19-33, 2012.