Food Safety Survey

OMB Control No. 0910-0345—Reinstatement

SUPPORTING STATEMENT Part A

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food Safety Survey (FSS) is widely accepted as a unique data base on consumer food handling practices, food safety-related knowledge and attitudes and is used as the definitive source of this information by both Healthy People 2010 and Healthy People 2020.

Telephone interviews are planned with 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 the Agency's regulatory policy in diverse areas dealing with food safety and will support consumer education by enabling the Agency 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) FY2011-FY2016 Strategic Plan goal of ensuring that, "Consumers, including vulnerable and underserved populations, adopt food safety best practices" (Ref. 2).

The methods for the proposed Food Safety Survey will be largely the same as those used with the previous Food Safety Surveys. One major difference is that, unlike the data collection mode for previous Food Safety Surveys that only included landline telephone numbers, the proposed survey will include cell phones in addition to landlines.

The proposed Food Safety 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 proposed 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 on the proposed survey to document the proportion of those over 60 years old who self-report taking immunocompromising medications. In conjunction with our established questions about

safe food handling and eating potentially risky foods, the 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 collected using independently drawn and randomized samples of telephone numbers (one for landlines and one for cell phones) with an over-sample of Hispanics and African Americans. The samples will be drawn, and data collected, by IPSOS, a large marketing firm.

The primary users of the data will be 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.

Staff in FDA and FSIS will use the data to track, and to better understand, consumers' food handling and preparation practices, food consumption practices related to food safety (such as consumption of raw or undercooked foods of animal origin) and related attitudes, concerns, knowledge, and sources of information. Because many of the questions were asked in the 1988, 1993, 1998, 2001, 2006, and 2010 FSSs, staff will compare the results over time to estimate extent and nature of changes that occurred in any of these areas. 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 proposed data collection effort will involve telephone surveys – both landline and cell phone. 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

The FSS is a unique survey instrument. 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. No other consumer survey of consumer food handling practices can satisfy the criteria needed to provide current national estimates of consumer food handling practices, knowledge and attitudes or to enable a comparison with the previous FSS results. The collaboration between FDA and FSIS avoids duplication that would result from independent surveys.

5. Impact on Small Businesses or Other Small Entities

No small businesses would be involved in this information collection.

6. Consequences of Collecting the Information Less Frequently

Without this 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.

A data collection in 2014 will also serve the data needs of Healthy People 2020. Data from the 2014 Food Safety Survey will serve as the mid-point for the objectives on consumer food preparation and consumer allergen experiences.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320

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), in the Federal Register of November 1, 2013 (78 FR 65661), FDA published a 60-day notice requesting public comment on the proposed information collection. FDA received two letters in response to the notice, each containing one comment. The comments, and the agency's responses, are discussed in the following

paragraphs. For ease of reading, we preface each comment with a numbered "Comment;" and each response by a corresponding numbered "Response." We have numbered each comment to help distinguish between different topics. The number assigned to each comment is for organizational purposes only and does not signify the comment's value, or importance, or the order in which it was received.

(Comment 1) One comment asked if a sample size of 4,000 was sufficient for this study, and suggested that FDA work with the Centers for Disease Control (CDC) on questions related to *Toxoplasma gondii*.

(Response 1) FDA believes that a sample size of 4,000 adults is sufficient for this study since this study evaluates consumer knowledge, attitudes, and perceptions related to food safety. It is not a clinical study looking at the effects of *Toxoplasma gondii* in the U.S. population. FDA consults with its Federal partners, including the CDC and the U.S. Department of Agriculture (USDA) to make sure this survey meets their needs.

(Comment 2) One comment suggested that FDA add questions to the survey about preparing offals at home, washing raw poultry and meat, and cooking turkeys in the oven overnight.

(Response 2) FDA agrees that these are interesting additional topics and has added questions about washing raw poultry and cooking turkeys to the survey. Due to space constraints, FDA is unable to add questions about preparing offals at home to the survey questionnaire. This topic will be considered for future research.

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

All data will be collected with an assurance that the respondents' answers will remain confidential. The survey questionnaire and screener contain a statement that responses will be kept confidential. 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.

Prior to starting data collection, FDA's Institutional Review Board (IRB) will review the survey protocol to ensure that human subjects are protected and that confidentiality procedures are adequate. An independent contractor for FDA, IPSOS, will collect the data and will not provide FDA with identifying information on the respondents. Respondents will be promised that their data will be treated as confidential and released to the public only in the form of aggregate statistics that cannot be associated with any individual or

household. Interviewing staff are required to sign a pledge of confidentiality that reinforces confidentiality requirements of the study and states that any procedural violation that jeopardizes a respondent's privacy will be grounds for immediate termination and possible legal action. Once response editing and interview validation are completed for the survey data, respondents' names and other identifying information will be permanently dissociated from interview data.

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

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	Avg. Burden per Response	Total Hours
Cognitive interview screener	75	1	75	0.083 (5 minutes)	6
Cognitive interview	9	1	9	1 (60 minutes)	9
Pretest screener	45	1	45	0.0167 (1 minute)	1
Pretest	18	1	18	0.33 (20 minutes)	6
Survey screener	10,000	1	10,000	0.0167 (1 minute)	167
Survey	4,000	1	4,000	0.33 (20 minutes)	1,320
Non-response survey screener	125	1	125	0.0167 (1 minute)	2
Non-response survey	50	1	50	0.167 (10 minutes)	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 $25,823 (1,519 x $17) at the 2013 median wage rate in the United States.[1]

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

The estimated cost to the federal government is $650,000. This cost includes 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 cost also includes FDA staff time to manage the study.

15. Explanation for Program Changes or Adjustments

This request seeks to reinstate an expired collection. We have revised the individual information collections as discussed below. We have also added three new information requests believing this better shows the burden associated with the individual collection elements.

IC#1 (Cognitive Interview Screener): We estimate the number of respondents to be 75 where previously the number of respondents to IC #1 was 20; thus there is an increase of 55 respondents with a corresponding increase in burden hours.

IC#2 (Pretest): We estimate the number of respondents to be 18 where previously the number of respondents to IC #2 was 27; thus there is a decrease of 9 respondents. Estimating a half hour per response, this results in a corresponding decrease in 8 burden hours.

IC#3 (Survey Screener) and IC#4 (Survey) are unchanged.

[1] http://www.bls.gov/oes/current/oes_nat.htm, accessed September, 2014.

IC#5 (Non-response survey screener): We estimate the number of respondents to be 125 where previously the number of respondents to IC#5 was 200; thus there is a decrease of respondents by 75. Estimating a minute per response, this results in a corresponding decrease in 18 burden hours.

IC#6 (Cognitive Interview) is a new collection, but a companion to IC#1.

IC#7 (Pretest Screener) is a new collection, but a companion to IC#2.

IC#8 (Non-response survey) is a new collection, but a companion to IC#5.

Overall, the number of respondents to this collection has **increased from 14,247 to 14,322, a total of 75**; while the burden hours have **decreased from 1,541 to 1,519, a total of 22**.

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

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

No exemption is requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions requested.

REFERENCES:

1. U.S. Department of Health and Human Services, "Health People 2020 - Improving the Lives of Americans," July 30, 2013. Available at *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.

List of Appendices:

A Study Questionnaire
B Initial Respondent Letter
C Refusal Conversion Letter
D Non-Response Questionnaire