United States Food and Drug Administration

Food Safety and Nutrition Survey

OMB Control No. 0910-0345

SUPPORTING STATEMENT

Part A: Justification:

1. <u>Circumstances Making the Collection of Information Necessary</u>

- 1. Under section 1003(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b) (2)), we are authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the nation's food supply. This voluntary survey is being completed to measure consumers' knowledge, attitudes, beliefs, and reported behavior about food safety and nutrition. It provides FDA with information about:
 - 1. Food labeling policies: FSANS data on consumer understanding and use of food labels may have informed updates to nutrition labeling requirements.
 - 2. Food safety education initiatives: Consumer knowledge gaps identified through FSANS could have led to targeted food safety education campaigns.
 - 3. Risk communication strategies: Understanding consumer perceptions of food risks through FSANS may have shaped how the FDA communicates about food safety issues.
 - 4. Dietary guidance: FSANS data on consumer dietary practices and nutritional knowledge may have contributed to updates in dietary recommendations.

In the past, FDA has conducted two separate surveys, a Food Safety Survey and a Health and Diet Survey, to measure consumers' knowledge, attitudes, and beliefs about food safety and nutrition issues. These surveys have been conducted every three to five years since the 1980's. In the *Federal Register* of August 14, 2018 (83 FR 40293), we announced our intention to combine these two surveys into the Food Safety and Nutrition Survey (FSANS). Data from FDA's food and nutrition surveys have been used to support rulemaking related to the Nutrition Facts label, and educational campaigns related to food safety, and to measure progress toward Healthy People 2010, 2020, and 2030 food safety consumer handling goals. The proposed 2025 FSANS will contain many of the same questions and topics as the previous surveys to facilitate measuring trends in food safety and diet knowledge, attitudes, and behaviors over time. The proposed survey will also be updated to explore emerging consumer food safety and nutrition topics and to expand understanding of previously asked topics.

The 2025 FSANS will be both a paper-and-pencil and web-based survey. Respondents will be contacted by postal mail, using an addressed-based sampling frame. Once contacted, respondents will be encouraged to take the survey online. A paper-and-pencil version of the survey will be mailed to those who do not initially take the web-based version of the survey. One randomly selected adult from each sampled household will be invited to participate in the survey using the Hagen-Collier method.¹ A total of 5,000 respondents will be surveyed. We will sample approximately 25,000 households to offset nonresponding households and ineligible addresses to

¹ In this method, we randomly select a category based on sex and age (based on the sex-age composition of the household), and then take the adult in that selected category.

achieve 5,000 adult respondents. Participation in the survey will be voluntary. Cognitive interviews and a pre-test will be conducted prior to fielding the survey.

We therefore request OMB to reinstate this collection of information as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

This voluntary survey is being completed to measure consumers' knowledge, attitudes, beliefs, and reported behavior about food safety in regard to various topics related to health, nutrition, and physical activity.

The Centers for Disease Control and Prevention (CDC) estimates 48 million people get sick, 128,000 are hospitalized, and 3,000 die from foodborne diseases each year in the United States. Consumers play an important role in the safety of the food they eat and are the last line of defense for preventing foodborne disease. Safe in-home food preparation practices can reduce the risk of illness. Since the late 1990s, most consumer food safety education has focused on one or more behaviors that consumers can practice at home to reduce foodborne illness. Although each food safety education campaign is unique, many include information encouraging consumers to wash their hands often while cooking and to think about and take preventive actions to mitigate the transfer of pathogens from raw foods onto hands and food contact surfaces such as cutting boards, and to use food thermometers.

Improving safe consumer food handling practices in the home continues to be an important goal for improving human health. To help achieve this goal, the Partnership for Food Safety Education (PFSE) was created in 1997 as a not-for-profit organization that unites industry associations, professional societies in food science, nutrition and health, consumer groups, and the U.S. government to educate the public about safe food handling. PFSE works with an active network of 13,000 health and food safety educators (BAC Fighters) and supports them by making their work more visible, collaborative, and effective. These BAC Fighters are connecting each year with an estimated 7.5 million consumers – helping them to protect their health through safe food handling and hand hygiene.

Data from previous Food Safety Surveys and the FSANS has been used to measure progress towards the nation's health via the Healthy People Initiative. Healthy People is a national health promotion and disease prevention initiative led by the U.S. Department of Health and Human Services (HHS). It provides science-based, 10-year national objectives for improving the health of all Americans. The program establishes benchmarks and monitors progress over time to:

- 1. Encourage collaborations across communities and sectors
- 2. Empower individuals to make informed health decisions
- 3. Measure the impact of prevention activities.

Data from FSANS was used for five Healthy People 2020 objectives related to consumer food handling (Clean, Cook, Separate, and Chill) and one related to food allergy experiences, and data from the upcoming survey are being proposed as a baseline for measuring the same four consumer food handling objectives for Healthy People 2030. The goal of these objectives for both Healthy People 2020 and Healthy People 2030 is to measure what consumers are doing in their homes when they prepare food. To measure progress on these goals, the survey has detailed questions asking consumers if and how they: 1) wash their hands before and during the cooking process (CLEAN); 2) use a food thermometer to determine the doneness of meat, poultry, and seafood

(COOK); 3) wash cooking surfaces such as cutting boards (SEPARATE); 4) and refrigerate foods within two hours of preparing (CHILL).

The information collected is expected to help evaluate and develop strategies and programs to encourage and help consumers adopt healthy lifestyles. The information will also help FDA and other federal agencies evaluate and track consumer awareness and behavior as outcome measures of their achievement in improving public health, especially as it relates to helping consumers use the Nutrition Facts label and menu labeling information. Data from FSANS about Nutrition Facts label use was cited in the proposed rules, such as Food Labeling: Front of Package Nutrition Information rule ((FDA-2024-N-2910) Additionally, survey data will be used to measure trends in consumers' attitudes and risk perceptions toward food safety.

The 2025 FSANS will contain many of the same questions and topics as the surveys previously collected under OMB control no. 0910-0345 to facilitate measuring trends in food safety, diet knowledge, attitudes, and reported behaviors over time. The survey is designed around three major themes relative to consumers' experience with food: Eat, Shop, and Prepare. "Eat" is comprised of questions related to eating at restaurants, including the frequency of eating at restaurants, awareness of menu labeling, and use of restaurant inspection scores. "Eat" will also include questions about consumers' overall dietary patterns, consumption of potentially risky foods, and perceptions of food safety risks.

"Shop" is comprised of questions about use of the Nutrition Facts label and claims made on the front of food packages.

Finally, "Prepare" is comprised of questions about food handling practices related to cleaning hands and kitchen surfaces, separating meat and other foods to be eaten raw, using food thermometers, preparing ready- and non-ready-to eat foods, and properly chilling foods.

This survey is directed towards individual consumers or households.

Description of Respondents: Respondents to this collection of information are individuals who are adults, age 18 and older, drawn from the 50 states and the District of Columbia.

3. <u>Use of Improved Information Technology and Burden Reduction</u>

The address-based, mail-push-to-web survey methodology is designed to encourage respondents to fill out the survey via an online web survey. Respondents are contacted via mail with an initial notification letter asking them to go to the web to complete the survey. After follow-up mailings, non-responding households will be mailed a paper questionnaire they can complete as an alternative to the web survey. We expect that over half of the respondents will complete the survey electronically via the web.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. The FSANS is a unique survey instrument. Many of the topics are of special interest to FDA and are not addressed by any other public- or privately- sponsored national surveys. There are no other consumer surveys of consumer food handling and diet practices that can satisfy the criteria needed to provide current national estimates and that would enable a comparison with the previous FSANS results. FDA collaborated with other federal agencies when developing the survey. The collaboration avoids duplication that would result from each agency conducting independent surveys. FDA met with experts across

FDA as well as from USDA/FSIS, USDA/CNPP, HHS/ODPHP, and CDC. Each of these entities contributed questions, suggested edits to existing questions, or provided comments that helped to improve the survey.

5. <u>Impact on Small Businesses or Other Small Entities</u>

No small businesses will be involved in this information collection.

6. <u>Consequences of Collecting the Information Less Frequently</u>

Without this data collection, current national estimates of knowledge, attitudes, beliefs, and reported behavior related to food safety, health, and diet will not be available. A new collection is important because data from the most recent FSANS are over 5 years old and do not adequately reflect the current state of consumer knowledge, attitudes, beliefs, and practices regarding food safety, health, and diet. FDA needs up-to-date data to make informed policy decisions.

A data collection in 2025 will also serve the data needs of Healthy People 2030. At a minimum, three data points are needed for Healthy People 2030. These FSANS data will serve as the midpoint data to show improvement in consumer home food safety practices over the 10 year period.

Not conducting this new, updated data collection will severely limit FDA's ability to promote and protect the public health.

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.

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 for public comment in the *Federal Register* of July 31, 2024 (89 FR 61457). One comment was received which did not relate to the PRA and will not be discussed.

FDA has also collaborated with other Federal agencies when developing the survey and met with experts across FDA as well as from USDA/FSIS, USDA/CNPP, HHS/ODPHP, and CDC to discuss additional questions, edit existing questions, or provide comments to help improve the survey and avoid duplication of information.

Results from previous surveys were posted on FDA's website and available with the FDA data Explorer tool (https://fsans-explorer.fda.gov/)

Additionally, the following peer reviewed journal articles were based on the 2019 FSANS:

- O Lando, A.M., Ferguson, M.S., Verrill, L., Wu F, Jones-Dominic, O.E., Punzalan, C., Wolpert, B.J. Health Disparities in Calorie Knowledge and Confidence Among the U.S. Adult Population, *Journal of Primary Care & Community Health*. 2021;12:19. doi: https://dio.org/10.1177/21501327211002416
- O Verrill, L., Lando, A., Wu, F., Tatavarthy, A., Obenhuber, D. Consumption of Raw Flour in the United States: Results from the 2019 FDA Food Safety and Nutrition

Survey. *Journal of Food Protection*. 2021;85(1), 31-35. https://doi.org/10.4315/JFP-21-256

- O Lando, A.M., Bazaco, M.C., Chen Parker, C., Ferguson, M., Characteristics of U.S. Consumers Reporting Past Year Intake of Raw (Unpasteurized) Milk: Results from the 2016 Food Safety Survey and 2019 Food Safety and Nutrition Survey. *J Food Prot.* 2022; 85 (7): 1036–1043. doi: https://doi.org/10.4315/JFP-21-407
- O Ferguson, M.S., Lando, A.M., Wu, F., Verrill, L. Transitioning the FDA Food Safety and Nutrition Survey from RDD to ABS. *Survey Practice*. 2022; 15(1): https://www.surveypractice.org/article/34118-transitioning-the-fda-food-safety-and-nutrition-survey-from-rdd-to-abs
- O Wu F, Ferguson M, Lando AM, Verrill L. Self-Efficacy: the Key to Nutrition Facts Label Use – Theory-Based Findings from the 2019 FDA Food Safety and Nutrition Survey (FSANS). *Journal of the Academy of Nutrition and Dietetics*. (Accepted)

9. Explanation of Any Payment or Gift to Respondents

Two \$1 bills (\$2 total per sampled respondent) will be included in the invitation letter for the address-based sample. Studies have shown that small pre-paid incentives are effective at increasing survey response.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

Privacy Act

This ICR does not collect personally identifiable information (PII) or information of a personal nature. This information collection supports FDA's food research and educational and public information programs relating to the safety of the nation's food supply. The FSANS measures consumers' knowledge, attitudes, and beliefs about food safety and nutritional issues. The subject information collection does not utilize any FDA forms and does not involve solicitation or collection of PII by or on behalf of FDA. An independent contractor for FDA will collect survey responses using respondent contact information already maintained by the contractor (not collected de novo in performance of the contract). All data provided to FDA will be sent in aggregate and will not contain any PII. Because neither FDA nor any party acting on behalf of the agency collects PII, the ICR is not subject to the Privacy Act of 1974 and the requirements of the Privacy Act such as displaying a Privacy Act Statement on a collection form do not apply.

Freedom of Information Act

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

Although respondents are asked about their height, weight, and perception of their risk of chronic illnesses these questions are not of a sensitive nature. The agency's experience with these questions suggests that the overwhelming majority of respondents feel comfortable providing this information.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

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

Table 1.--Estimated Annual Reporting Burden¹

Activity	Number of Respondent	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
	S	rr.	F	r	
Cognitive interview	75	1	75	0.083	6
screener				(5 minutes)	
Cognitive interview	18	1	18	1	18
				(60 minutes)	
Pretest	100	1	100	0.33	33
				(20 minutes)	
Mail survey	5,000	1	5,000	0.33	1,650
				(20 minutes)	
Total			5,193		1,707

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

FDA's burden estimate is based on the Agency's prior experience with the FSANS. We will use a cognitive interview screener with 75 individuals to recruit prospective interview participants for a total of 18 individuals. 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 6 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 surveys, the Agency plans to conduct a pretest to identify and resolve potential survey administration problems. The pretest will be conducted with 100 participants; we estimate that it will take a participant 20 minutes (0.33 hours) for the pretest for a total of 33 hours. We estimate that 5,000 eligible adults will participate in the survey taking 20 minutes (0.33 hours), for a total of 1,650 hours. Thus, the total estimated burden is 1,707 hours.

12b. Annualized Cost Burden Estimate

The annualized cost to all respondents for the hour burden for the collection of information is $39,449 (1,707 \times 23.11)$ at the May 2023 median wage rate in the United States.² To account for overhead, this figure is doubled to 78,898.

Table 2Estimated Annual Cost Burden						
Activity	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs			
Responding to Survey	1,707	\$46.22	\$78,898			

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

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

² http://www.bls.gov/oes/current/oes_nat.htm, accessed January, 2025.

14. Annualized Cost to the Federal Government

The estimated cost to the Federal government is \$900,000. This cost includes costs paid to the contractor to draw the samples, 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 develop and manage the study.

15. Explanation for Program Changes or Adjustments

This is a reinstatement of a previously discontinued collection of information and reflects an estimated overall increase of 1,707 hours and a corresponding increase of 5,193 responses. We attribute this estimated increase of hours and responses to the reinstatement of this collection of information.

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 Website, 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

Tuble 5. Troject benedute					
Date	Activity	Audience			
Within 3 days after receipt	Notification to the contractor to proceed	Not applicable			
of OMB approval of	with data collection activities				
collection of information					
Within 150 days after	Completion of data collection	Not applicable			
notification to contractor					
Within 180 days after	Delivery by the contractor of final data files	FDA			
notification to contractor					
Within 6 months after	Posting of top-line report to FDA Website	Public			
receipt of final data files					

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

Display of the OMB Expiration Date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.