U.S. Food and Drug Administration
Survey on the Occurrence of Foodborne Illness Risks Factors in Selected Institutional Foodservice and Retail Food Stores Facility Types

OMB Control No. 0910-0799

SUPPORTING STATEMENT **Part A: Justification**

Terms of Clearance: None.

1. Circumstances Making the Collection of Information Necessary

   This information collection supports Food and Drug Administration (FDA, us or we) food safety programs. The statutory basis for FDA conducting this survey comes from section 311 of the Public Health Service (PHS) Act [42 USC 243], which authorizes FDA to cooperate with state and local governments in the prevention and suppression of communicable diseases. Actions for food protection under provisions of the Act is delegated to the Commissioner of Food and Drugs (21 CFR 5.10(a)(2) and (4)). Additionally, the Federal Food, Drug, and Cosmetic Act [21 USC 301 et seq] and the Economy Act [31 USC 1535] authorizes FDA to provide assistance to other federal, state, and local government bodies in these efforts.
   This study provides FDA with a solid foundation for developing and maintaining a national retail food program model that can be used by federal, state, local, and tribal agencies to:

   - Identify essential food safety program performance measurements.
   - Assess strengths and gaps in the design, structure, and delivery of program services.
   - Establish program priorities and intervention strategies focused on reducing the occurrence of foodborne illness risk factors.
   - Create a mechanism that justifies program resources and allocates them to program areas that will provide the most significant public health benefits.

   We therefore request extension of OMB approval for the Occurrence of Foodborne Illness Risks Factors in Selected Institutional Foodservice and Retail Food Stores Facility Types Survey, form FDA 3967 and the associated forms as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

   Information will be gathered from state/local governments and businesses in the private sector to:

   - Assist the FDA with developing retail food safety initiatives and policies focused on the control of foodborne illness risk factors – preparation practices and employee behaviors most commonly reported to the Centers for Disease Control

and Prevention (CDC) as contributing factors to foodborne illness outbreaks at the retail level. (i.e. Food from Unsafe Sources, Poor Personal Hygiene, Inadequate Cooking, Improper Holding/Time and Temperature, and Contaminated Equipment/Protection from Contamination).

- Identify retail food safety work plan priorities and allocate resources to enhance retail food safety nationwide.
- Track changes in the occurrence of foodborne illness risk factors in retail and foodservice establishments over time.
- Inform recommendations to the retail and foodservice industry and state, local, tribal, and territorial regulatory professionals on reducing the occurrence of foodborne illness risk factors.

3. Use of Improved Information Technology and Burden Reduction

This survey involves collection of information related to the behaviors and practices of food employees. In order to accurately document food employee behavior, the FDA data collectors must be physically located in the establishments during hours of operation. Data is gathered through interviewing, actual observations, and record reviews. Data will be entered into a web-based data platform from secured computers. The interface will support the manual entering of data, as well as the ability to upload a fillable and fileable PDF, should the need arise. The PDF is not signable by the data collector.

FDA will minimize burden by conducting the data collection during normal hours of operation and in a manner that is customary with routine inspections performed by the establishments' normal regulatory authorities.

4. Efforts to Identify Duplication and Use of Similar Information

There are no other nationally representative estimates of the occurrence of foodborne illness risk factors in retail and foodservice establishments. Some State and local regulatory authorities have conducted risk factor surveys within their jurisdictions; however, these studies do not provide a nationally representative sample. Thus, no comparable data have been collected by other Federal, State, or local regulatory agencies or industry.

FDA partners with the CDC to compare various retail food studies and surveillance systems. CDC and FDA will conduct joint annual reviews of the data collected through our various data collections systems. These reviews will be used to determine if changes are needed to future information collections to ensure the data collected are optimal to meet our collective needs and missions to reduce foodborne illness.

5. Impact on Small Businesses or Other Small Entities

Of the 400 respondents in this survey, 200 will be from small businesses. FDA will minimize burden by conducting the data collections during normal hours of operation and in a manner that is customary with routine inspections performed by the industry

operator's respective regulatory authority. The information being requested has been held to the absolute minimum required for the intended use of the data.

6. Consequences of Collecting the Information Less Frequently

A data collection was performed in 2015-2016 to establish a baseline measurement. A minimum of three data points are needed to determine statistically significant trends in improvement or regression over time; thus, FDA began follow-up data collections from October 1, 2019 through March, 2020 which was halted due to COVID-19. We intend to complete the second data collection when it is safe to do so and will continue on to a third data collection in 2023-2024 (the subject of this ICR extension). If the data collections are conducted less frequently or not at all, the data will have less statistical power and the Agency will be unable to measure trends of improvement or regression in foodborne illness risk factor occurrence over time. This lack of information will impede FDA's ability to formulate Agency retail food safety policies, initiatives, and work plan priorities based on sound science. In addition, the lack of information will hamper FDA's ability to allocate resources in a strategic and efficient manner based on the specific needs of our stakeholders. Lastly, without this information, FDA will be unable to recommend targeted intervention strategies to assist the retail food and institutional foodservice industry and state, local, and tribal regulators with reducing foodborne illness risk factors. The study is part of the Agency's mission critical work to reduce foodborne illnesses. There are no legal obstacles to reduce the burden. Respondents will only respond once during each data collection period.

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), FDA published a 60 day notice for public comment in the FEDERAL REGISTER February 18, 2021 (86 FR 10087). FDA received one comment.

(Comment 1) An interested citizen submitted the following comments:

a. The previous 10 year study conducted by FDA did not mention negative trends in the 'other' category which included information about contamination risk factors as they relate to food or color additives, poisonous or toxic materials, or storage of poisonous or toxic materials for retail sale. This negative trend should be reported.
b. The 2013-2014 report on restaurants the 'other' contamination risk factor did not appear in the report. This should remain the same as the previous 10-year study for comparison purposes.
c. The FDA should keep chemicals as a risk factor for future research on the occurrence of foodborne illness risk factors

(Response 1) The FDA acknowledges the submission of the question from a concerned citizen and provides the following response:

a. FDA acknowledges the commenter's concern on a perceived lack of reporting on trends within the previous 10-year study.

b. The FDA report on the results of the 2013-2014 data collection was the first report with the new study design of the 10-year study. One of the significant design changes from the 1998-2008 Study is the reduction of the number of data items from 42 to 10. The focus on the 10 primary data items provides the opportunity to obtain enough observations of food safety practices and procedures to report statistically significant study conclusions and correlations.
In an effort to focus messaging on the most prevalent food safety practices and behaviors found out of compliance, in secondary data items (items 11-19) were not reported at that time. FDA focused the report on the primary 10 data items which directly correspond with the foodborne illness risk factors included in the study. The new study design includes "Other Areas of Interest" that support the primary data items or track an area that is not likely to have a sufficient enough number of observations for statistical purposes but is an important food safety practice within the retail segment of the industry – such as Item 18, which addresses the concern of the commenter. Item 18 Toxic materials are identified, used, and stored properly as outlined in the marking instructions (Attachment B). The current data collection continues to collect information on the provisions within the food code that address the safe storage, handling, and use of toxic and poisonous substances. If significant findings occur FDA is committed to reporting those findings. From the 2015 data collection forward the FDA will be publishing a topline summary report to include information on data items 11-18. These reports can be accessed at www.fda.gov/retailfoodriskfactorstudy.

c. While not listed as one of the five main foodborne illness risk factors in the current study design, FDA recognizes the importance of controlling chemicals and toxic substances in food service facilities to prevent injury and illness. The information gathered in Data Item 18 as described above helps FDA keep a pulse on risky behaviors surrounding toxic or poisonous materials in retail facilities. The purpose of this 10-year study is primarily to collect information on the five foodborne illness risk factors and study to elucidate relationships between the foodborne illness risk factors and food safety management systems, and certified food protection managers.

Efforts to Consult with Representatives from Industry on the Proposed Information Collection

The current 10-year study builds on the design of a previous 10-year risk factor study that included three separate data collections. At the completion of each of the three previous data collections in 1998, 2003, and 2008, results were shared via presentations to small groups and established committees made up of retail food and restaurant industry leaders. Feedback was obtained on the study design and the reporting of the results. This feedback helped to inform the process of designing the current 10-year study.

FDA seeks input from industry stakeholder groups, among others, for enhancing the effectiveness of the nation's food safety system. FDA has established a partnership with food safety leaders from the foodservice industry and separate partnership with leaders from the retail food store industry. These partnerships provide an opportunity for FDA personnel to meet with industry leaders three times a year to discuss ways to best achieve our food safety objectives. During these meetings, FDA provides the partnership members with regular updates on the Risk Factor Study and seeks suggestions for improving the study design and for optimizing access to the food establishments. For example, the industry partnership groups provided recommendations for improving the introductory letter describing the purpose and burden of the study. In addition, industry partnership groups provided recommendations for phrasing some of the interview questions so they are asked in a manner that will be clear to the person in charge. They also suggested that the wording of the data items be phrased as positive statements (i.e. the desired behavior) versus negative statements (i.e. undesired behavior or violations).

In addition, key industry committees are continually informed on the progress of the study and key results from each of the data collection periods. These groups include the National Restaurant Association's Quality Assurance Executive Study Group, the National Council of Chain Restaurants' Food Safety Task Force, and the FMI Food Protection Committee.

Efforts to Consult with Representatives of Other Federal Programs on the Proposed Information Collection

The results of the FDA Retail Risk Factor Study have impact on the following Federal agencies: USDA-FNS and the CDC. Specifically:

- The USDA Food and Nutrition Service has used the results of the previous studies to call attention to key food safety practices in school cafeterias and direct research funds to institutions that can provide operators with appropriate educational materials.
- CDC conducts and funds research that seeks a better understanding of the prevalence and prevention of the transmission of disease via food, including several studies as part of its EHS-Net program that targets foodservice operations. FDA has kept and will continue to keep key CDC staff informed of the plans for and results of the Risk Factor Study so that areas in which our concurrent studies reinforce or run counter to one another can be analyzed and appropriate prevention-based messages developed.

While FDA's data collections are not targeting establishments operating on Federal installations, any Federal agency that has responsibility for the oversight of foodservice or retail food store operations could derive benefit from the results of this Retail Risk Factor Study. Organizations such as the Indian Health Service, the National Park Service, the Bureau of Prisons, and the branches of the Department of Defense can gain insight into which foodborne illness risk factors present the greatest challenge for control and the potential value of certain intervention strategies.

9. Explanation of Any Payment or Gift to Respondents

There will be no payments to the respondents.

10. Assurance of Confidentiality Provided to Respondents

We have consulted with the FDA Privacy Office and confirmed this ICR does not collect personally identifiable information (PII) or information of a personal nature. This information collection supports "Survey on the Occurrence of Foodborne Illness Risks in Selected Institutional Foodservice and Retail Stores Facility Types" and does not require the collection of PII.

FDA further determined that this collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA (including vendors or service providers acting on behalf of FDA) does not use name or any other personal identifier to retrieve records from the information collected.

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

There are no sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

The burden for the 2023-2024 collection is as follows. For each data collection, the respondents include: (1) The person in charge of the selected facility; and (2) the program director (or designated individual) of the respective regulatory authority. In order to provide the sufficient number of observations needed to conduct a statistically significant analysis of the data, FDA has determined that 400 data collections will be required retail food store facility type. Therefore, the total number of responses will be 400.

The burden associated with the completion of Sections 1 and 3 of Form FDA 3967 is specific to the persons in charge of the selected facilities. It includes the time it will take the persons in charge to accompany the data collectors during the site visit and answer the data collectors' questions. The burden related to the completion of Section 2 of Form FDA 3967 is specific to the program directors (or designated individuals) of the respective regulatory authorities. It includes the time it will take to answer the data collectors' questions and is the same regardless of the facility type.

To calculate the estimate of the hours per response, FDA uses the average data collection duration for similar facility types during FDA's 2015-2016 Risk Factor Study (Ref. 3) plus an extra 30 minutes (0.5 hours) for the information collection related to Section 3, Part B of the form. FDA estimates that it will take the persons in charge of retail food stores 180 minutes (3 hours) to accompany the data collectors while they complete Sections 1 and 3 of the form. FDA estimates that it will take the program director (or designated individual) of the respective regulatory authority 30 minutes (0.5 hours) to answer the questions related to Section 2 of the form.

Based on the number of entry refusals from the 2015–2016 Risk Factor Study data collections in the restaurant facility types, we estimate a refusal rate of 2 percent in the retail food store facility type. The estimate of the time per non-respondent is 5 minutes (0.08 hours) for the person in charge to listen to the purpose of the visit and provide a verbal refusal of entry.

Table 1: Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (hours)	Total Hours
Data Collection (Retail Food Stores) - Completion of Form FDA 3967, Sections 1 and 3	400	1	400	3	1,200
Data Collection (Retail Food Stores) - Completion of Form FDA 3967, Section 2	400	1	400	0.5 (30 minutes)	200
Data Collection-Entry Refusals	8	1	8	0.08 (5 minutes)	.64
Total Hours	-	-	-	-	1,400.64

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

12b. Annualized Cost Burden Estimate

The cost associated with this collection is directly related to the speed at which a respondent can respond to the survey. A study by the U.S. Bureau of Labor Statistics in December 2020 found that managers in state/local government employees earn an average of $64.02 per hour and private industry employees earn an average of $36.23 per

hour.[1] This includes the total wages and other compensation, as well as benefits like health insurance and retirement contributions. Estimates of annualized cost burden are tabulated below:

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Person in charge of the selected facility –retail food store facility types	1,200.64	$36.23	$43,499.19
Program director of the respective regulatory authority	200	$64.02	$12,804.00
Total			$56,303.19

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 information collection.

14. Annualized Cost to the Federal Government

The estimated total cost to the Federal Government for completing the 2023-2024 data collection is $111,024.00. This value is derived as follows:

Description of Cost	Factor Used	Total Cost
Cost of FDA staff involved in study design, data collection and analysis, database maintenance, and report writing	1,600 work plan hours x $41.89 (2021 hourly rate of pay for GS-13, Step 4)	$67,024.00
Travel expenses of FDA staff (to perform data collection inspections)	$37.50 (average) per inspection x 400 inspections	$15,000.00
Travel expenses of FDA staff (two face-to-face meetings to analyze the data and write the reports)	$24,000 per year x 1 year	$24,000.00
Miscellaneous (equipment, printing, etc.)	$2,500 per year x 2 years	$5,000.00
Total Cost		$111,024.00

15. Explanation for Program Changes or Adjustments

[1]United States Bureau of Labor Statistics. (December 2020). Employer Costs for Employee Compensation. Retrieved from http://www.bls.gov/news.release/ecec.toc.htm.

Since the last renewal, we submitted a change request to OMB, which was approved September 13, 2019. This change request adjusted the information collection to reflect a decrease of 1,616 responses and 2,201 hours annually. Upon our submission, however, we note we inadvertently published the previous figures in the 60-day and 30-day notice. There are no adjustments or changes made to the collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The Agency anticipates disseminating the results of the data collection after the data is collected, analyzed, tabulated in written reports, and cleared. Activities associated with the outcomes of this research will primarily consist of written and oral presentations as well as a written final report. 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. This dialogue will help improve the effectiveness of the agency's regulatory and education initiatives in promoting and protecting the public health. The planned schedule for project activities is shown in the table below:

Project Schedule

Date	**Activity**	**Audience**
October 1, 2023	Data collection initiated	Not applicable
By December 31, 2024	Data collection completed	Not applicable
By October 1, 2025	Data analysis completed	FDA
By July 1, 2026	Final report summarizing the results issued	Public

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

We are not seeking approval to exempt display of the OMB approval date on any documents that are associated with this information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.