Revised 5/8/13; add'l revisions 7/17/13

Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types (2013-2022)

0910-NEW

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The statutory basis for the U.S. Food and Drug Administration's (FDA) conducting this survey is the Public Health Service Act (the PHS Act) (42 U.S,C 243, Section 311(a)) (Also 21 CFR 5.10(a)(2) and (4) which requires that the FDA provide assistance to state and local governments relative to the prevention and suppression of communicable diseases. In addition, the PHS Act requires that FDA cooperate with and aid state and local authorities in the enforcement of their health regulations and provide advice on matters relating to the preservation and improvement of public health. Additionally, the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301) and Economy Act (31 U.S.C. 1535) require that FDA provide assistance to other Federal, state, and local governmental bodies.

In this advisory capacity, the FDA National Retail Food Team conducted a ten-year voluntary survey from 1998-2008 to generate the first ever nationally representative estimates of the occurrence of foodborne illness risk factors, or those 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. Foodborne illness risk factors include:

- Food from Unsafe Sources
- Poor Personal Hygiene
- Inadequate Cooking
- Improper Holding/Time and Temperature
- Contaminated Equipment/Protection from Contamination

The survey included data collection inspections of various facility types of retail and foodservice establishments at five-year intervals (1998, 2003, and 2008). The initial data collection in 1998 provided the baseline measurement from which trends of improvement and regression were analyzed using data collected in 2003 and 2008. FDA summarizes the results of each of data collections in separate reports[1][2][3]. The trend analysis report

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[1] Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors (2000). Found at: *http://www.fda.gov/downloads/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/ucm123546.pdf*

[2] *Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2004).* Found at: *http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/ucm089696.htm*

[3] *Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2009).* Found at: *http://www.fda.gov/downloads/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/UCM224682.pdf*

summarizes any improvement or regression made over time and whether progress had been made toward the goal of reducing the occurrence of foodborne illness risk factors in the select retail and foodservice facility types[4].

This research 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.

Using the 1998-2008 survey as a foundation, this new survey will collect information from full service and fast food restaurants.

For the purposes of this information collection, a full service restaurant is defined as: "Establishments where customers place their order at their table, are served their meal at the table, receive the service of the wait staff, and pay at the end of the meal." A fast food establishment is defined as: "any restaurant that is not a full service restaurant. Customers generally order and pay for their meals at a counter. Also referred to as quick service restaurants."

The following will be determined for each restaurant facility type:

- The foodborne illness risk factors that are in most need of priority attention during each data collection period.
- Changes in the occurrence of foodborne illness risk factors over time.
- Potential correlations between operational aspects of the industry, such as average number of meals per day, number of employees, complexity of food preparation, and the control of foodborne illness risk factors.
- Potential correlations between elements within regulatory retail food protection programs, such as enrollment in the *FDA Voluntary National Retail Food Regulatory Program Standards*, timing of regulatory inspections, grading systems, posting of inspections results, manager certification requirements and required food handler training, and the control of foodborne illness risk factors.
- Potential correlations between the implementation of industry food safety management systems and the control of foodborne illness risk factors**.**

2. Purpose and Use of the Information Collection

The information gathered from this survey will be used to:

[4] Trend Analysis Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (1998 – 2008). Found at: *http://www.fda.gov/downloads/Food/FoodSafety/RetailFoodProtection/FoodborneIllnessandRiskFactorReduction/RetailFoodRiskFactorStudies/UCM224152.pdf*

- Formulate Agency retail food safety policies and initiatives.
- Identify retail food 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.
- Recommend best practices and targeted intervention strategies to assist the retail and foodservice industry and state, local, and tribal regulators with reducing foodborne illness risk factors.

This survey will involve State and local health departments, State agriculture departments, and private sector businesses.

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 selected retail and foodservice establishments during hours of operation. In addition, information collected during interviews with the retail and foodservice industry and regulatory professionals is often in response to direct observations made by the data collectors. 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.

Though the initial data collection for the restaurant industry will be collected using a paper document that will be manually coded into an ACCESS database, FDA intends to move to electronic data collection that can be transmitted to a web-based database. To that end, FDA's Office of Regulatory Affairs (ORA) has entered into a cooperative agreement with the National Center for Food Protection and Defense (NCFPD) to develop a web-based (i.e. FoodSHIELD) platform to collect, store, and analyze data for the Retail Risk Factor Study.

The attached "Risk Factor Study Online Portal" project summary outlines the proposed tasks and deliverables for this initiative. One of the deliverables includes: *Create a user interface and backend database to record and store the Risk Factor Study. The interface should allow the manual entering of data as well as the ability to upload a fillable pdf.*

FDA and NCFPD IT Specialists recommend the development and completion of the central database before decisions are made regarding the purchase of hand held equipment. Upon completion of the web-based platform for the Risk Factor Study, FDA intends to conduct an assessment of hand-held electronic equipment and software that are compatible with the database and will facilitate the efficient entry of information by Specialists while they are conducting the data collection. Based on available funding, FDA intends to begin the integration of hand-held equipment for the FY15 institution foodservice data collection.

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 national representative sample. Thus, no comparable data have been collected by other Federal, State, or local regulatory agencies or industry. FDA has reached out to CDC to identify potential areas of overlap with our study and their respective studies. A determination was made that our studies capture different information, but are nevertheless complimentary in nature. FDA will continue dialogue with CDC to ensure there is no overlap between our respective data collection projects.

5. Impact on Small Businesses or Other Small Entities

There will be 176 respondents surveyed for the pilot collections and an additional 1,600 surveyed for the 2013 baseline data collection in the two restaurant facility types. 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

The pilot data collection in each of the two facility types (full service and fast food) is needed to establish a baseline measurement. There will be two subsequent data collections to establish the minimum three data points needed to determine statistically significant trends in improvement or regression over time. If the collection is not conducted or is conducted less frequently, 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 and 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.

Postings in the Federal Register for the additional data points will occur in the future. We anticipate these data collections to occur in FY17 and FY20.

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 of June 19, 2012 (FDA-2012-N-0547). FDA received five comments. The comments, and the Agency's response, are discussed on pages 5-8 of this supporting statement. Please note that FDA originally published 60 and 30 day Federal Register notices for the entire 10-year study which included estimated burden for restaurant, institutional foodservice, and retail food store facility types. Subsequent to publishing the 30 day Federal Register notice, OMB directed FDA to only include the restaurant industry segment in this application; hence, the comments we provided in the 30 day notice may not be applicable to the current application. FDA plans to publish separate Federal Register notices for a data collection effort in institutional foodservice facility types in 2014 and retail food store facility types in 2015. If a comment received during the 60 day Federal Register notice no longer applies based on these circumstances, we have made note of it following the text of the original response we provided:
(Comment 1) Jane Public commented that she does not see the usefulness of the Study. She also commented that most foodborne illness resulting from food from unsafe sources caused by agribusiness. She commented that having a website on which the public or doctors treating the sick and deceased can post information about foodborne illness would be more effective and targeted than the data collection being proposed by FDA.

(Response 1) FDA believes that many of the comments made by this submitter are unrelated to the proposed data collection. Relative to the suggestion to have a website on which the public or doctors treating the sick or deceased can post information about foodborne illness, surveillance systems like this are already used in the United States to provide information about the occurrence of foodborne disease including, but not limited to, the following: Foodborne Disease Active Surveillance Network (FoodNet); National Antimicrobial Resistance Monitoring System—enteric bacteria (NARMS); National Electronic Norovirus Outbreak Network (CaliciNet); National Molecular Subtyping Network for Foodborne Disease Surveillance (PulseNet); National Notifiable Diseases Surveillance System (NNDSS); National Outbreak Reporting System (NORS); Environmental Health Specialists Network (EHS-Net); and the Public Health Laboratory Information System (PHLIS). While each surveillance system plays an important role in detecting and preventing foodborne disease and outbreaks, surveillance statistics reflect only a fraction of the cases that occur in the community. This is because foodborne illnesses are largely under-diagnosed and underreported. In addition, surveillance statistics are, by nature, reactive, meaning information is obtained on foodborne illness that has already occurred. In contrast, the data collection proposed by FDA is proactive, in nature, because it seeks to collect data on the behaviors and practices that could lead to foodborne illness or deaths if not controlled. Using this data, FDA will formulate and implement intervention strategies to proactively reduce foodborne illness risk factors that lead to illness or death if not controlled. For these reasons, FDA does not agree with the submitter that another surveillance-type reporting system would be more effective or targeted than the data collection being proposed by FDA.

(Comment 2) The Food Marketing Institute (FMI) commented that FDA appears to have underestimated the amount of time needed at 15 minutes per event. The commenter states

that based on the retail industry's experience during the last survey (2008), the time spent collecting and monitoring data points took up 120 minutes per event per retail grocer and this caused an undue interruption to business operations and passed on unnecessary costs to those surveyed.

(Response 2). OMB's regulations at 5 CFR 1320.3(h) define the term "information." Numbered paragraphs under (h) list categories of data that are not "information," and thus do not require OMB approval under the Paperwork Reduction Act (PRA). Under paragraph (h)(3), "[f]acts or opinions obtained through direct observation by an employee or agent of the sponsoring agency or through non-standardized oral communication in connection with such direct observations," is not "information collection" subject to OMB approval under the PRA. Thus, the estimate of burden is not required to account for the duration of the entire inspection since the data collector's questions will largely be non-standardized, oral communication in connection with his or her direct observations.

In contrast, information collected in Sections 1 and 2 and Section 3, part B of the data collection form is not available to the data collectors by direct observation together with non-standardized, oral communication and can only be obtained by asking the establishment's representatives to respond to a set of standardized questions. Thus, the burden is accurately calculated based solely on the time it will take for the data collectors to interview the respondents to complete these specific sections of the form. However, in consideration of FMI's comment and recent data collection training that was conducted with FDA's National Retail Food Team in September 2012, FDA believes that the original burden for the respondents that was published in Table 1 of the 60-day notice may have been underestimated. For this reason, FDA is increasing the burden estimate for each respondent to 30 minutes per response.

In addition, to ease confusion, upon arrival to the establishment, the Specialists will explain to the owner or person-in-charge the purpose of the visit and present an introductory letter (see Attachment 4 to the Supporting Statement) that explains the following:

- Purpose of the visit – 1st and 4th Paragraphs
- Voluntary Nature of the Visit – 2nd Paragraph
- Length of the Visit – 2nd Paragraph
- Confidentially information (to the extent possible under the law)
- Burden for the information collection associated with the visit – 2nd Paragraph

If entry into the selected establishment is denied by the owner, the Specialist will not conduct the data collection. The Specialist will contact the FDA CFSAN Biostatistics Branch and request a substitute restaurant establishment as a replacement.

Note: Comment 2 challenges the estimated burden for grocery stores in the burden table included in the 60 day NOA. As indicated on page 5 of this supporting statement, per OMB's instructions, the current application is for the restaurant facility type data collection only. The estimated burden for the retail food store facility type data collection

will be provided in a separate Federal Register notice in 2015. Hence, this comment and our original response are no longer applicable to the current. However, related to comment 2, FDA acknowledges that based on guidance provided by OMB on 7/15/13, the time it will take for the data collector to perform the entire data collection inspection should be calculated in the burden. Therefore, we have made the necessary changes to the burden table for the restaurant facility type data collection and the associated explanation that precedes it.

(Comment 3) FMI commented that the FDA is not aligned with the CDC in the development of the study. According to CDC data, most foodborne illness outbreaks occur in restaurants (39% compared to <1% foodborne illness events occurring in grocery stores as well as 21% compared to <1% actual foodborne illnesses occurring in grocery stores). Based on the data, FMI believes the study seems to put an unnecessary burden on retail grocery stores as retail grocery stores will be surveyed at a 4:1 ratio. The study should be more balanced between the restaurants and grocers.
(Response 3) 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.

The proposed sample size for each facility type is not intended to mirror the respective burden of foodborne illness caused by each type, but rather represents the minimum number of inspections needed to obtain the number of observations needed to draw statistically significant conclusions. If FDA reduced the number of establishments inspected for the retail food store facility types, it is likely FDA would not obtain the number of observations needed to draw statistically valid conclusions or have the desired confidence level in the data that is obtained.

The restaurant industry segment includes two facility types, institutional foodservice includes three facility types, and the retail food store industry segment includes four facility types. While the total number of data collection inspections in retail food store segment will be higher than that for the restaurant segment, the number of data collection inspections for each facility type will be the same.

Note: Comment 3 challenges the estimated burden for grocery stores in the burden table included in the 60 day NOA. As indicated on page 5 of this supporting statement, per OMB's instructions, the current application is for the restaurant facility type data collection only. The estimated burden for the retail food store facility type data collection will be provided in a separate Federal Register notice in 2015. Hence, certain aspects of this comment and our original response are no longer applicable to the current.

(Comment 4) FMI believes the proposed study fails to meet FDA's Information Quality Guidelines and the requirements of the Data Quality Act because its structure will not provide information of utility to the public or the Agency as it is disproportionately focused on retail food stores when statistics indicate that far more foodborne illness events occur in restaurants.

(Response 4) Information dissemination is an important part of FDA's mission to promote and protect the public health. FDA recognizes that public access to high quality information is critical to achieving this mission and public input, in turn, improves the quality of the information we disseminate. Because of the nature of this information, our goal has been and remains to ensure that all the information we disseminate meets the high standards of quality (including objectivity, utility, and integrity) described in the OMB and HHS Guidelines and the Data Quality Act (DQA).

To that end, FDA does not agree with FMI's comment that the proposed information collection fails to meet FDA's Information Quality Guidelines and the requirements of the DQA. The sample size in the proposed information collection is not intended to mirror the respective burden of foodborne illness caused by each facility type. Rather, it represents the minimum number of inspections needed for each facility type in order to obtain a sufficient number of observations to draw statistically significant conclusions. If FDA were to reduce the sample size of the retail food store facility types to be more reflective of the burden of foodborne illness caused by these entities, the quality of the data would be compromised and its utility would be severely limited. This is because it would be unlikely that FDA could obtain the number of observations needed to draw statistically valid conclusions or have the desired confidence level in the conclusions we are able to make.

(Comment 5) The American Meat Institute Foundation (AMIF) commented that they support FDA's proposed survey of selected retail and foodservice facility types. According to AMIF, the survey findings will have practical utility by enhancing the knowledge of foodborne illness risk factors in these types of facilities; informing decisions for developing and implementing risk mitigation strategies; and guiding food safety resource allocation. The follow-up data collection periods will be useful tools to track trends and benchmark improvements in reducing risk factors.

(Response 5) FDA thanks the AMIF for their comments and appreciates their support in this undertaking.

Efforts to Consult with Industry on the Proposed Information Collection

The proposed study builds on the design of the previous 10-year risk factor study that included three separate data collection efforts. 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 has helped to inform the process of designing the proposed data collection.

With the enactment of the Food Safety Modernization Act (FSMA), FDA developed a Retail Food Safety Initiative to address some specific agency mandates included in the legislation. One of the objectives within the Retail Food Safety Initiative requires FDA to seek input from industry stakeholder groups, among others, for enhancing the effectiveness of the nation's food safety system. FDA's National Retail Food Team has established a structure for quarterly meeting with the trade associations representing the restaurant and retail food industry, including the National Restaurant Association, the National Council of Chain Restaurants, and the Food Marketing Institute. The design and methodology of the FDA's Risk Factor Study has been an agenda item for several of these meetings. Industry has provided recommendations for improving the introductory letter describing the purpose and burden of the study. In addition, industry 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.

In addition, key industry committees have been made aware of FDA's plan to update the study design and proceed with a new data collection starting in 2013. 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-FSIS, USDA-FNS, and the CDC. Specifically:

- The results of the study can assist FSIS in their efforts to assure the safety of meat and poultry, as the study will reflect on practices at retail that can directly impact the survival and proliferation of pathogens in these products. The results may assist FSIS target resources to the retail sector where training and/or enforcement action on meat and poultry handling practices are most needed;
- 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

FDA will collect the following information associated with the establishment's identity: establishment name, street address, city, state, zip code, county, industry segment, and facility type. Other information collected is directly related to the survey and has no identifying factors such as seating capacity and number of employees per shift.

The establishment identifying information is collected to ensure the survey is not duplicative. When an inspector is assigned a specific firm, the inspector will conduct the survey and log the information into a tracking system from a secure FDA computer. This tracking system, explained in A.3, will remove the completed establishment from the list of possible establishments so that the random generator will not include the establishment when finding the next assignment. The establishment identifying information will be kept electronically as well as in hard copy form at the FDA district offices associated with the inspections and will not be published.

FDA will seek assistance from its privacy officers to develop an appropriate system of records notice and privacy impact assessment, as appropriate.

The privacy of the establishment and the individual responding on behalf of the establishment will be provided to the extent permitted by law.

11. Justification for Sensitive Questions

There are no sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

For each data collection, the respondents will include: 1) the person in charge of the selected restaurant facility (whether it be a fast food or full service restaurant); and 2) the program director (or designated individual) of the respective regulatory authority.

For the FY13 pilot, 22 Specialists will conduct 4 data collection inspections (2 fast food restaurants and 2 full service restaurants); thus, FDA estimates the number of respondents to be 176 (22 Specialists x 4 data collection inspections x 2 respondents per data collection). For the FY14 data collection in restaurants, FDA has determined that 400 inspections will be required of each of the two restaurant facility type to provide the

sufficient number of observations needed to conduct a statistically significant analysis of the data. Therefore, the total number of responses for restaurants will be 1,600 (800 inspections x 2 respondents per data collection).

The data collection form is divided into three sections: Section 1 - Establishment Information; Section 2 - Jurisdiction with Regulatory Authority Information; and Section 3 for tabulating the Specialists' observations of (a) the food employees' behaviors and practices related to personal hygiene and food storage, preparation, and service, (b) the industry food safety management being employed, and (c) the frequency of food employee hand washing.

The burden associated with the completion of Sections 1 and 3 of the form is specific to the persons in charge of the selected facilities. This burden includes the time necessary for the person in charge to answer standardized questions asked by the data collector to complete Section 1 and 2 and Section 3, part B, of the form. The burden also includes the time it will take the person in charge to accompany the data collector as he or she completes Section 3, parts A and C. In the completion of the latter, the data collector may ask infrequent, non-standardized questions of the person in charge to seek clarification on what he or she is observing. The burden related to the completion of Section 2 of the form is specific to the program directors (or designated individuals) of the respective regulatory authorities.

The estimate of the hours per response is based on its previous experience with collecting similar information in previous data collection efforts.[5] We estimate that it will take the persons in charge of full service restaurants and fast food restaurants 106 minutes (1.76 hours) and 73 minutes (1.21 hours), respectfully, to complete Sections 1 and 3 of the form. We estimate 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. Hence, the total burden estimate for a data collection in a full service restaurant, including the both the program director's and the person in charge's responses, is 136 minutes (106 + 30)(2.26 hours). The total burden estimate for a data collection in a fast food restaurant, including the both the program director's and the person in charge's responses, is 103 minutes (73 + 30)(1.71 hours).
We estimate a 98% response rate. We base this estimate on the number of entry refusals and closures we had during the previous 10-year study. The burden for the 2% nonresponse is calculated in the revised burden table below. The estimate of the hours per non-respondent is five 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 3: ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of	No. of	Total	No. of Non-	No. of	Total	Average	Total

[5] Table 6 "Average Inspection Time per Establishment for each of the 9 Facility Types" in *FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2009)*: Found at: http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/ FoodborneIllnessRiskFactorReduction/ UCM224682.pdf.

	Respondents	Responses per Respondent	Annual Responses	Respondents	Responses per Non-Respondent	Annual Non-Responses	Burden per Response	Hours
FY13 Pilot-Completion of Sections 1 and 3 – Fast Food Facility Type	44	1	44	-	-	-	1.21 (73 minutes)	53.24
FY13 Pilot-Completion of Sections 1 and 3 – Full Service Facility Type	44	1	44	-	-	-	1.76 (106 minutes)	77.44
FY13 pilot-Completion of Section 2 – All Facility Types	88	1	88	-	-	-	0.5 (30 minutes)	44
FY13 Pilot-Entry Refusals – All Facility Types	-	-	-	2	1	2	0.08 (5 minutes)	0.16
FY14 Baseline Data Collection (Fast Food Restaurants) - Completion of Sections 1 and 3	400	1	400	-	-	-	1.21 (73 minutes)	484
FY14 Baseline Data Collection (Full Service Restaurants) - Completion of Sections 1 and 3	400	1	400	-	-	-	1.76 (106 minutes)	704
FY14 Baseline Data Collection-Completion of Section 2 – All Facility Types	800	1	800	-	-	-	0.5 (30 minutes)	400
FY14 Baseline Data Collection-Entry Refusals – All Facility	-	-	-	32	1	32	0.08 (5 minutes)	2.56

Types								
Total Hours	-	-	-	-	-	-	-	1765.40

[1]There are no capital costs or 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 complete the survey. A study by the U.S. Bureau of Labor Statistics in 2011 found that state/local government employees earn an average of $40.76 per hour and private industry employees earn an average of $28.57 per hour.[6] This includes the total wages and other compensation as well as benefits like health insurance and retirement contributions.

TABLE 2. Estimates of annualized cost burden

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Person in charge of the selected facility – fast food and full service restaurants	1321.40	$28.57	$37,752.39
Program director of the respective regulatory authority	444	$40.76	$18,097.44
Total			$55,849.83

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 FY13 pilot and FY14 restaurant baseline data collections is $270,508. 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	3,600 work plan hours x $37.78 (hourly rate of pay for GS-13, Step 4)	$136,008

[6]United States Bureau of Labor Statistics. (2011). Employer Costs for Employee Compensation. Retrieved from http://www.bls.gov/news.release/pdf/ecec.pdf.

writing		
Travel expenses of FDA staff (to perform data collection inspections)	$37.50 per inspection x 888 inspections	$33,300
Travel expenses of FDA staff (specific to training for data collectors)	$57,000 per training event x 1 event	$57,000
Travel expenses of FDA staff (specific to study design, data analysis, and report writing)	$8,000 per year x 1 year	$8,000
Miscellaneous (equipment, printing, etc.)	$1,000 per year x 2 years	$2,000
Total Cost		$236,308

15. Explanation for Program Changes or Adjustments

This is a new information 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 Table 3.

TABLE 3. Project Schedule

Date	**Activity**	**Audience**
Within 3 days after receipt of OMB approval of collection of information	Notification to the data collectors to initiate the pilot data collection	Not applicable
By September 30, 2013	Pilot data collection completed	Not applicable
By October 31, 2013	Baseline data collection for the restaurant facility types initiated	Not applicable
By September 30, 2014	Baseline data collection for the restaurant facility types completed	Not applicable
By December 1, 2015	Data analysis completed for the baseline data collection for the restaurant facility types	FDA
By March 1, 2014	Final report summarizing the results	Public

	of the baseline data collection for the restaurant facility types issued	

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.