

applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to <https://www.regulations.gov> at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: January 31, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0547]

Agency Information Collection Activities; Proposed Collection; Comment Request; Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on “Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types.”

DATES: Submit either electronic or written comments on the collection of information by April 9, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before April 9, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of April 9, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be

considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2012–N–0547 for “Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types.” Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential

information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each

proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques,

when appropriate, and other forms of information technology.

Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Retail and Foodservice Facility Types

OMB Control Number 0910-0744—Extension

I. Background

From 1998 to 2008, FDA’s National Retail Food Team conducted a study to measure trends in the occurrence of foodborne illness risk factors, preparation practices, and employee behaviors most commonly reported to the Centers for Disease Control and Prevention as contributing factors to foodborne illness outbreaks at the retail level. Specifically, data was collected by FDA Specialists in retail and foodservice establishments at 5-year intervals (1998, 2003, and 2008) to observe and document trends in the occurrence of the following foodborne illness risk factors:

- Food from Unsafe Sources,
- Poor Personal Hygiene,

- Inadequate Cooking,
- Improper Holding/Time and Temperature, and
- Contaminated Equipment/Cross-Contamination.

FDA developed reports summarizing the findings for each of the three data collection periods (1998, 2003, and 2008) (Refs. 1 to 3). Data from all three data collection periods were analyzed to detect trends in improvement or regression over time and to determine whether progress had been made toward the goal of reducing the occurrence of foodborne illness risk factors in selected retail and foodservice facility types (Ref. 4).

Using this 10-year survey as a foundation, in 2013–2014, FDA initiated a new study in full service and fast food restaurants. This study will span 10 years with a data collection currently being conducted in 2017–2018 and another data collection planned for 2021–2022 (the subject of this information collection request extension).

TABLE 1—DESCRIPTION OF THE FACILITY TYPES INCLUDED IN THE SURVEY

Facility type	Description
Full Service Restaurants	A restaurant 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.
Fast Food Restaurants	A restaurant that is not a full service restaurant. This includes restaurants commonly referred to as quick service restaurants and fast casual restaurants.

The purpose of the study is to:

- Assist FDA with developing retail food safety initiatives and policies focused on the control of foodborne illness risk factors;
- 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; and
- 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.

The statutory basis for FDA conducting this study is derived from the Public Health Service Act (PHS Act) (42 U.S.C. 243, section 311(a)). Responsibility for carrying out the provisions of the PHS Act relative to food protection was transferred to the Commissioner of Food and Drugs in 1968 (21 CFR 5.10(a)(2) and (4)). Additionally, the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) and the Economy Act (31 U.S.C. 1535)

require FDA to provide assistance to other Federal, State, and local government bodies.

The objectives of the study are to:

- Identify the least and most often occurring foodborne illness risk factors and food safety behaviors/practices in retail and foodservice facility types during each data collection period;
- Track improvement and/or regression trends in the occurrence of foodborne illness risk factors during the 10-year study period;
- Examine potential correlations between operational characteristics of food establishments and the control of foodborne illness risk factors;
- Examine potential correlations between elements within regulatory retail food protection programs and the control of foodborne illness risk factors; and
- Determine the extent to which food safety management systems and the presence of a certified food protection manager impact the occurrence of foodborne illness risk factors.

The methodology to be used for this information collection is described as follows. To obtain a sufficient number of observations to conduct statistically

significant analysis, FDA will conduct approximately 400 data collections in each facility type. This sample size has been calculated to provide for sufficient observations to be 95 percent confident that the compliance percentage is within 5 percent of the true compliance percentage.

A geographical information system database containing a listing of businesses throughout the United States provides the establishment inventory for the data collections. FDA samples establishments from the inventory based on the descriptions in table 1. FDA does not intend to sample operations that handle only prepackaged food items or conduct low-risk food preparation activities. The “FDA Food Code” contains a grouping of establishments by risk, based on the type of food preparation that is normally conducted within the operation (Ref. 5). The intent is to sample establishments that fall under risk categories 2 through 4.

FDA has approximately 25 Retail Food Specialists (Specialists) who serve as the data collectors for the 10-year study. The Specialists are geographically dispersed throughout the

United States and possess technical expertise in retail food safety and a solid understanding of the operations within each of the facility types to be surveyed. The Specialists are also standardized by FDA's Center for Food Safety and Applied Nutrition personnel in the application and interpretation of the FDA Food Code (Ref. 5).

Sampling zones have been established that are equal to the 150-mile radius around a Specialist's home location. The sample is selected randomly from among all eligible establishments located within these sampling zones. The Specialists are generally located in major metropolitan areas (*i.e.*, population centers) across the contiguous United States. Population centers usually contain a large concentration of the establishments FDA intends to sample. Sampling from the 150-mile radius sampling zones around the Specialists' home locations provides three advantages to the study:

1. It provides a cross section of urban and rural areas from which to sample the eligible establishments.
2. It represents a mix of small, medium, and large regulatory entities having jurisdiction over the eligible establishments.
3. It reduces overnight travel and therefore reduces travel costs incurred by the Agency to collect data.

The sample for each data collection period is evenly distributed among Specialists. Given that participation in the study by industry is voluntary and the status of any given randomly selected establishment is subject to change, substitute establishments have been selected for each Specialist for cases where the restaurant facility is misclassified, closed, or otherwise unavailable, unable, or unwilling to participate.

Prior to conducting the data collection, Specialists contact the State or local jurisdiction that has regulatory responsibility for conducting retail food inspections for the selected establishment. The Specialist verifies with the jurisdiction that the facility has been properly classified for the purposes of the study and is still in operation. The Specialist ascertains whether the selected facility is under legal notice from the State or local regulatory authority. If the selected facility is under legal notice, the Specialist will not conduct a data collection, and a substitute establishment will be used. An invitation is extended to the State or local regulatory authority to accompany the Specialist on the data collection visit.

A standard form is used by the Specialists during each data collection. The form is divided into three sections: Section 1—"Establishment Information"; Section 2—"Regulatory Authority Information"; and Section 3—"Foodborne Illness Risk Factor and Food Safety Management System Assessment." The information in Section 1—"Establishment Information" of the form is obtained during an interview with the establishment owner or person in charge by the Specialist and includes a standard set of questions.

The information in Section 2—"Regulatory Authority Information" is obtained during an interview with the program director of the State or local jurisdiction that has regulatory responsibility for conducting inspections for the selected establishment. Section 3 includes three parts: Part A for tabulating the Specialists' observations of the food employees' behaviors and practices in limiting contamination, proliferation, and survival of food safety hazards; Part B for assessing the food safety management system being implemented by the facility; and Part C for assessing the frequency and extent of food employee hand washing. The information in Part A is collected from the Specialists' direct observations of food employee behaviors and practices. Infrequent, nonstandard questions may be asked by the Specialists if clarification is needed on the food safety procedure or practice being observed. The information in Part B is collected by making direct observations and asking follow up questions of facility management to obtain information on the extent to which the food establishment has developed and implemented food safety management systems. The information in Part C is collected by making direct observations of food employee hand washing. No questions are asked in the completion of Section 3, Part C of the form.

FDA collects the following information associated with the establishment's identity: Establishment name, street address, city, state, zip code, county, industry segment, and facility type. The establishment identifying information is collected to ensure the data collections are not duplicative. Other information related to the nature of the operation, such as seating capacity and number of employees per shift, is also collected. Data will be consolidated and reported in a manner that does not reveal the identity of any establishment included in the study.

FDA has collaborated with the Food Protection and Defense Institute to

develop a web-based platform in FoodSHIELD to collect, store, and analyze data for the Retail Risk Factor Study. This platform is accessible to State, local, territorial, and tribal regulatory jurisdictions to collect data relevant to their own risk factor studies. For the 2015–2016 data collection, FDA piloted the use of hand-held technology for capturing the data onsite during the data collection visits. The tablets that were made available for the data collections were part of a broader Agency initiative focused on internal uses of hand-held technology. The tablets provided for the data collection presented several technical and logistical challenges and increased the time burden associated with the data collection as compared to the manual entry of data collections. FDA continues to assess the feasibility for fully incorporating use of hand-held technology in subsequent data collections during the 10-year study period.

When a data collector is assigned a specific establishment, he or she conducts the data collection and enters the information into the web-based data platform. The interface will support the manual entering of data, as well as the ability to directly enter information into the database via a web browser.

The burden for the 2021–2022 data collection is as follows. For each data collection, the respondents will include: (1) The person in charge of the selected facility (whether it be a fast food or full service restaurant) and (2) the program director (or designated individual) of the respective regulatory authority. 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 in each of the two restaurant facility types. Therefore, the total number of responses will be 1,600 (400 data collections × 2 facility types × 2 respondents per data collection).

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. It includes the time it will take the person in charge to accompany the data collector during the site visit and answer the data collector's questions. 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. 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 will use the average

data collection duration for the same facility types during the 2013–2014 data collection. FDA estimates that it will take the persons in charge of full service restaurants and fast food restaurants 104 minutes (1.73 hours) and 82 minutes (1.36 hours), respectively, to accompany the data collectors while they complete Sections 1 and 3 of the form. In comparison, for the 2013–2014 data collection, the burden estimate was 106 minutes (1.76 hours) in full service restaurants and 73 minutes (1.21 hours) in fast food restaurants. 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. This burden estimate is unchanged from the last data collection. Hence, the total burden estimate for a data collection in a full service restaurant, including the responses of both the program director and the person in charge, is 134 minutes (104 + 30) (2.23 hours). The total burden estimate for a data collection in a fast food restaurant, including the responses of both the program director and the

person in charge, is 112 minutes (82 + 30) (1.86 hours).

Based on the number of entry refusals from the 2013–2014 baseline data collection, we estimate a refusal rate of 2 percent for the data collections within restaurant facility types. 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.

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

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Number of non-respondents	Number of responses per non-respondent	Total annual non-responses	Average burden per response	Total hours
2021–2022 Data Collection (Fast Food Restaurants)—Completion of Sections 1 and 3.	400	1	400	1.36	544
2021–2022 Data Collection (Full Service Restaurants)—Completion of Sections 1 and 3.	400	1	400	1.73	692
2021–2022 Data Collection—Completion of Section 2—All Facility Types.	800	1	800	0.5 (30 minutes)	400
2021–2022 Data Collection—Entry Refusals—All Facility Types.	—	—	—	16	1	16	0.08 (5 minutes)	1.28
Total Hours	1,637.28

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

The burden for this information collection has not changed since the last OMB approval.

II. References

The following references are on display in the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday, they are also available electronically at <https://www.regulations.gov>. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. “Report of the FDA Retail Food Program Database of Foodborne Illness Risk Factors” (2000). Available at: <https://wayback.archive-it.org/7993/20170406023019/https://www.fda.gov/downloads/Food/GuidanceRegulation/UCM123546.pdf>.

2. “FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and

Retail Food Store Facility Types (2004).” Available at: <https://wayback.archive-it.org/7993/20170406023011/https://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/UCM423850.pdf>.

3. “FDA Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (2009).” Available at: <https://wayback.archive-it.org/7993/20170406023004/https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm224321.htm>.

4. FDA National Retail Food Team. “FDA Trend Analysis Report on the Occurrence of Foodborne Illness Risk Factors in Selected Institutional Foodservice, Restaurant, and Retail Food Store Facility Types (1998–2008).” Available at: <https://wayback.archive-it.org/7993/20170406022950/https://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodborneIllnessRiskFactorReduction/ucm223293.htm>.

5. “FDA Food Code.” Available at: <https://www.fda.gov/FoodCode>.

Dated: January 31, 2018.

Leslie Kux,
Associate Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2015–E–0857 and FDA–2015–E–0858]

Determination of Regulatory Review Period for Purposes of Patent Extension; FARXIGA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for FARXIGA and is publishing this