section E that currently asks ''May we give your name and contact information to the company that makes the product (manufacturer) to help them evaluate the product?'' to ''If you do NOT want your identity disclosed to the manufacturer, place an 'X' in this box.''

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

FDA Center/21 CFR section/FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total
Center for Biologics Evaluation and Research/ Center for Drug Evaluationand Research:.					
Form 3500	14,727	1	14,727	0.66 (40 minutes)	9,720
Form 3500A (§§ 310.305, 314.80, 314.98, 600.80, 1271.350).	599	98	58,702	1.21	71,029
Center for Devices and Radiological Health:.					
Form 3500	5,233	1	5,233	0.66 (40 minutes)	3,454
Form 3500A (§ 803)	2,277	296	673,992	1.21	815,530
Center for Food Safety and Applied Nutrition:.					
Form 3500	1,793	1	1,793	0.66 (40 minutes)	1,183
Form 3500A	1,659	1	1,659	1.21	2,007
Center for Tobacco Products.					
Form 3500	39	1	39	0.66 (40 minutes)	26
All Centers.					
Form 3500B	13,750	1	13,750	0.46 (30 minutes)	6,325
Total					909,274

VI. References

1. Kessler, D. A, ''Introducing MEDWatch: A New Approach to Reporting Medication and Device Adverse Effects and Product Problems,'' *Journal of the American Medical Association,* 269(21), June 2, 1993, pp. 2765–2768.

Dated: December 5, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–29064 Filed 12–10–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2076]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 a survey entitled, ''Occurrence of Foodborne Illness Risk Factors in Selected Restaurant Facility Types (2013–2022).''

DATES: Submit either electronic or written comments on the collection of information by February 9, 2015.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@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 Restaurant Facility Types (2013–2022) (OMB Control Number 0910–0744)

I. Background

In 2013–2014, the U.S. Food and Drug Administration (FDA) initiated a study in two foodservice facility types: Full service and fast food restaurants. The study will span 10 years in its entirety and aims to:

- Assist 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 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/cross-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; 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.

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 statutory basis for FDA conducting this study is derived from the Public Health Service Act (42 U.S.C. 243, section 311(a)). Responsibility for carrying out the provisions of the 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 foodborne illness risk factors that are in most need of priority attention during each data collection period;
- Track trends in the occurrence of foodborne illness risk factors over time;
- 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
- Evaluate the impact of industry food safety management systems in controlling the occurrence of foodborne illness risk factors.

The data from the 2013–2014 information collection in restaurants is currently being analyzed by FDA. A report summarizing the findings is expected to be released in 2015. In order to analyze trends, FDA is proposing to conduct two additional data collections in 2017–2018 and 2021–2022 using the same methodology employed in the 2013–2014 data collection. This methodology is described as follows.

In order to obtain a sufficient number of observations to conduct statistically significant analysis, FDA will conduct approximately 400 data collections in each restaurant facility type during each data collection period. 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 will be used as the establishment inventory for the data collections. FDA will sample 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. 1). The intent is to sample establishments that fall under risk categories 2 through 4.

FDA has approximately 25 Regional Retail Food Specialists (Specialists) who will 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. 1).

Sampling zones will be established which are equal to the 150 mile radius around a Specialist's home location. The sample will be 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 will be 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 will be 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 will contact the state or local jurisdiction that has regulatory responsibility for conducting retail food inspections for the selected establishment. The Specialist will verify

with the jurisdiction that the facility has been properly classified for the purposes of the study and is still in operation. The Specialist will also ascertain 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 will be extended to the state or local regulatory authority to accompany the Specialist on the data collection visit.

A standard form will be 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 will be obtained during an interview with the establishment owner or person in charge by the Specialist and will include a standard set of questions.

The information in Section 2—''Regulatory Authority Information'' will be 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 being implemented by the facility; and Part C for assessing the frequency and extent of food employee hand washing. The information in Part A will be 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 will be 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 will be collected by making direct observations of food employee hand washing. No questions will be asked in the completion of Section 3, Part C of the form.

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. The establishment identifying information is collected to ensure the survey is not duplicative. 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, will also be collected. Data will be consolidated and reported in a manner that does not reveal the identity of any establishment included in the study.

FDA is working with the National Center for Food Protection and Defense to develop a Web-based platform in FoodSHIELD to collect, store, and analyze data for the Retail Risk Factor Study. Once developed, this platform will be accessible to state, local, territorial, and tribal regulatory jurisdictions to collect data relevant to their own risk factor studies. FDA is currently transitioning from the manual entry of data to the use of hand-held technology. FDA will be pilot testing the use of hand-held technology during its 2015–2016 risk factor study data collection in institutional foodservice and retail food stores, with the goal to have it fully implemented for the 2017–2018 data collection in restaurants. When a data collector is assigned a specific establishment, he or she will conduct the data collection and enter the information into the Web-based data platform. The interface will support the manual entering of data, as well as the ability to upload a fillable PDF.

The burden for the 2017–2018 data collection is as follows. 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. In order to provide the sufficient number of observations needed to conduct a statistically significant analysis of the data, FDA has determined that the same number of data collections will be required in each of the two restaurant facility types as was required in the 2013–2014 data collection (*i.e.* 400). Therefore, the total number of responses for restaurants 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 as he or she completes Sections 1 and 3 of the form. 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), respectfully, 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 both the program director's and the person in charge's responses, is 134 minutes (104 + 30)(2.23 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 112 minutes 82 + 30) (1.86 hours).

Based on the number of entry refusals from the 2013–2014 data collection, we estimate a refusal rate of 2 percent. The estimate of the time 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 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
2017–2018 Data Collection (Fast Food Restaurants)—Completion of Sections 1 and 3.	400	1	400				1.36	544
2017–2018 Data Collection (Full Service Restaurants)—Completion of Sections 1 and 3.	400	1	400				1.73	692
2017–2018 Data Collection-Completion of Section 2—All Facility Types.	800	1	800				0.5 (30 minutes).	400
2017–2018 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.

II. Reference

The following reference has been placed on display in the Division of Dockets Management (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.*

1. *FDA Food Code.* Available at: *http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/default.htm.*

Dated: December 5, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–29065 Filed 12–10–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–P–0320]

Determination That PFIZERPEN (Penicillin G Potassium) Injection, 1 Million Units/Vial, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that PFIZERPEN (penicillin G potassium) Injection, 1 million units/vial, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for penicillin G potassium injection, 1 million units/vial, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Nikki Mueller, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products with Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (21 CFR 314.161). FDA may not approve an ANDA that does not refer to a listed drug.

PFIZERPEN (penicillin G potassium) Injection, 1 million units/vial, is the subject of ANDA 60–657, held by Pfizer, Inc., and initially approved on August 30, 1968. ANDA 60–657 is considered the designated reference standard. PFIZERPEN is indicated in the treatment of serious infections caused by susceptible strains of the designated microorganisms in certain conditions such as septicemia, pneumonia, meningitis, anthrax, and listeria.

PFIZERPEN (penicillin G potassium) Injection, 1 million units/vial, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. Lachman Consultant Services, Inc., submitted a citizen petition dated May 27, 2008 (Docket No. FDA–2008–P–0320), under 21 CFR 10.30,