priorities, standards, budget requests, and assistance policies. ORR regulations require that State Refugee Resettlement and Wilson-Fish agencies, and local and Tribal governments complete Form ORR–6 in order to participate in the above-mentioned programs.

Respondents: State governments, Replacement Designees, and Wilson/Fish Alternative Projects.

### ANNUAL BURDEN ESTIMATES

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>ORR–6 Performance Report</td>
<td>59</td>
<td>2</td>
<td>15</td>
<td>1,770</td>
</tr>
</tbody>
</table>

**Estimated Total Annual Burden Hours**: 1,770.

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

**OMB Comment**: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the Federal Register. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,
Reports Clearance Officer.

[FR Doc. 2016–15987 Filed 7–27–18; 8:45 am]

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Food and Drug Administration

[Docket No. FDA–2012–N–0547]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES**: Fax written comments on the collection of information by August 29, 2018.

**ADDRESSES**: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910–0744. Also include the FDA docket number found in brackets in the heading of this document.

**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, PRAStaff@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION**: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**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 to 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 to 2018 and another data collection planned for 2021 to 2022 (the subject of this information collection request extension).
The purpose of the study is to:

- Assist FDA with developing retail food safety behaviors/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 (FD&C 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.

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.

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

<table>
<thead>
<tr>
<th>Facility type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Service Restaurants ..........</td>
<td>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.</td>
</tr>
<tr>
<td>Fast Food Restaurants ............</td>
<td>A restaurant that is not a full service restaurant. This includes restaurants commonly referred to as quick service restaurants and fast casual restaurants.</td>
</tr>
</tbody>
</table>
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 followup 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 to 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 in the database via a web browser.

The burden for the 2021 to 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.

In the Federal Register of February 7, 2018 (83 FR 54331), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received two comments.

(Comment 1) We received comments related to FDA’s authority for collaboration with State and local governments regarding food safety at the retail level.

(Response 1) The statutory basis for FDA conducting this survey is the PHS Act, which requires that FDA provide assistance to State and local governments in the prevention and suppression of communicable diseases. 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 FD&C 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.

(Comment 2) The Academy of Nutrition and Dietetics (the Academy) commented that they support the proposed information collection for the survey on the occurrence of foodborne illness risk factors in various settings. The Academy provided comments pertaining to the following general areas of the study:

a. Question as to whether 90 minutes is adequate for surveying larger facilities.

b. Request FDA evaluate the impact of conducting surveys during non-peak hours of operation.

c. Suggest that the use of gloves is not adequately addressed in the survey.

d. Recommend adding a food allergy component.

e. Encourage continued efforts to simplify and standardize expiration dates.

Related to foodservice operations at the retail level, the Academy provided the following comments:

a. Suggest that FDA consider conducting the survey by using local inspectors who already inspect facilities for other purposes.

b. Suggest that educational efforts should be culturally guided, provided in multiple languages, and include photos or illustrations to facilitate remediation.

c. FDA consider modifying the survey to account for new foods and new means of conveying food.

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b. Suggest that educational efforts should be culturally guided, provided in multiple languages, and include photos or illustrations to facilitate remediation.

c. FDA consider modifying the survey to account for new foods and new means of conveying food.
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 (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 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.


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0007]

Medical Device User Fee Rates for Fiscal Year 2019

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fee rates and payment procedures for medical device user fees for fiscal year (FY) 2019. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Medical Device User Fee Amendments of 2017 (MDUFA IV), authorizes FDA to collect user fees for certain medical device submissions and annual fees both for certain periodic reports and for establishments subject to registration. This notice establishes the fee rates for FY 2019, which apply from October 1, 2018, through September 30, 2019. To avoid delay in the review of your application, you should pay the application fee before or at the time you submit your application to FDA. The fee you must pay is the fee that is in effect on the later of the date that your application is received by FDA or the date your fee payment is recognized by the U.S. Treasury. If you want to pay a reduced small business fee, you must qualify as a small business before making your submission to FDA; if you do not qualify as a small business before making your submission to FDA, you will have to pay the higher standard fee. Please note that the establishment registration fee is not eligible for a reduced small business fee. As a result, if the establishment registration fee is the only medical device user fee that you will pay in FY 2019, you should not submit a Small Business Certification Request. This document provides information on how the fees for FY 2019 were determined, the payment procedures you should follow, and how you may qualify for reduced small business fees.

FURTHER INFORMATION CONTACT:

For information on Medical Device User Fees: Visit FDA’s website at: https://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm20081521.htm.


For questions relating to this notice: David Haas, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd. (COLE–14202l), Silver Spring, MD 20993–0002, 240–402–9845.

SUPPLEMENTARY INFORMATION:

I. Background

Section 738 of the FD&C Act (21 U.S.C. 379j) establishes fees for certain medical device applications, submissions, supplements, notices, and requests (for simplicity, this document refers to these collectively as “submissions” or “applications”); for periodic reporting on class III devices; and for the registration of certain establishments. Under statutorily defined conditions, a qualified applicant may receive a fee waiver or may pay a lower small business fee (see 21 U.S.C. 379(j)(d) and (e)).

Under the FD&C Act, the fee rate for each type of submission is set at a specified percentage of the standard fee for a premarket approval (premarket approval application (PMA), a product development protocol (PDP), or a biologics license application (BLA)). The FD&C Act specifies the base fee for a premarket approval for each year from FY 2018 through FY 2022; the base fee for a premarket application received by FDA during FY 2019 is $300,000.

The total revenue amount for FY 2019 is $190,654,875, as set forth in the statute prior to the inflation adjustment (see 21 U.S.C. 379(j)(b)(3)). MDUFA directs FDA to use the yearly total revenue amount as a starting point to set the standard fee rates for each fee type. The fee calculations for FY 2019 are described in this document.

Inflation Adjustment

MDUFA specifies that the $190,654,875 is to be adjusted for inflation increases for FY 2019 using two separate adjustments—one for payroll costs and one for non-payroll costs (see 21 U.S.C. 379j(c)(2)). The base inflation adjustment for FY 2019 is the sum of one plus these two separate adjustments, and is compounded as specified in the statute (see 21 U.S.C. 379(j)(c)(2)(C) and 379(j)(c)(2)(B)).

The component of the inflation adjustment for payroll costs is the average annual percent change in the cost of all personnel compensation and benefits (PC&B) paid per full-time equivalent position (FTE) at FDA for the first 3 of the 4 preceding FYs, multiplied by 0.60, or 60 percent (see 21 U.S.C. 379(j)(c)(2)(C)).

Table 1 summarizes the actual cost and FTE data for the specified FYs, and provides the percent change from the previous FY and the average percent change over the first 3 of the 4 FYs preceding FY 2019. The 3-year average is 2.4152 percent (rounded).

<table>
<thead>
<tr>
<th>Fiscal year</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>3-Year average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total PC&amp;B</td>
<td>$2,232,304,000</td>
<td>$2,414,728,159</td>
<td>$2,581,551,000</td>
<td></td>
</tr>
</tbody>
</table>