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

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR–6 Performance Report	59	2	15	1,770

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. 2018–15987 Filed 7–27–18; 8:45 am]

BILLING CODE 4184–45–P

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).

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 (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.

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 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 5433), 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 relative to 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.

(Response 2) FDA thanks the submitter for their comments and appreciates their support. Regarding general areas of the study, FDA provides the following responses:

a. The current 10-year study estimates 90 minutes as the average time needed to adequately collect necessary information, taking into account both small and large facilities. This average time is consistent with the amount of time burden estimated for the previous data collection periods and provides a sufficient timeframe to observe food safety practices and procedures that are the focus of the study.

b. Based on the methodology of the study, the information collection is performed during hours of operation of the randomly selected facility. Data collections are scheduled at times that provide the best opportunity to observe food preparation activities.

c. Information collection related to handwashing and no bare hand contact with ready to eat foods, which may include use of gloves, is based on assessment of observations against the most current addition of the FDA Model Food Code. Provisions of the FDA Food Code identify when handwashing and no bare hand contact with ready to eat food are required during food preparation and service. The current FDA Food Code does not recognize the use of hand antiseptics in lieu of handwashing during food preparation and service.

d. The study is collecting information regarding the knowledge of the person in charge related to food allergens and training of food service employees on allergy awareness as it relates to their assigned duties in their facility.

e. The scope of this data collection focuses on foodborne illness risk factors and does not include assessment of expiration dates of manufactured foods as part of this research assessment.

Related to foodservice operations at the retail level, FDA provides the following responses:

a. This type of research requires a standardized design and methodology to ensure that the occurrences of the foodborne illness risk factors are uniformly assessed. Retail Food Specialists are standardized by Center for Food Safety and Applied Nutrition and have a strong working knowledge of retail food industry. State and local regulators are encouraged to accompany the data collectors during the data collection.

b. The research from this study facilitates the development of culturally guided, multi-language education outreach materials that can be shared with regulatory and industry partners.

c. The study design accounts for a variety of food conveyances in the retail food setting. The study includes four major segments of the retail and foodservice industries that account for over a million varied and diverse types of operations in the United States:

- Restaurants
- Healthcare Facilities
- Schools (K–12)
- Retail Food Stores

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 to 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 to 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 to 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 (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.

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: July 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–16189 Filed 7–27–18; 8:45 am]

BILLING CODE 4164–01–P

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.

FOR 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 the MDUFA Small Business Program, please visit CDRH's website: https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/ucm577696.htm.

For questions relating to this notice: David Haas, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd. (COLE–14202I), 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. 379j(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 application (a premarket application is a 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 application 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. From this starting point, this document establishes FY 2019 fee rates for certain types of submissions, and for periodic reporting, by applying criteria specified in the FD&C Act.

The FD&C Act specifies the base fee for establishment registration for each year from FY 2018 through FY 2022; the base fee for an establishment registration in FY 2019 is $4,548. There is no reduction in the registration fee for small businesses. Each establishment that is registered (or is required to register) with the Secretary of Health and Human Services under section 510 of the FD&C Act (21 U.S.C. 360) because such establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of a device is required to pay the annual fee for establishment registration.

II. Revenue Amount for FY 2019

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. 379j(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. 379j(c)(2)(C) and 379j(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. 379j(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 1—FDA PC&BS EACH YEAR AND PERCENT CHANGE

Fiscal year	2015	2016	2017	3-Year average
Total PC&B	$2,232,304,000	$2,414,728,159	$2,581,551,000	