Patients who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. These patients also must send to *PatientFocused@fda.hhs.gov* a brief summary of responses to the topic questions by March 20, 2017. Panelists will be notified of their selection approximately 7 days before the public meeting. We will try to accommodate all patients and patient stakeholders who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov*. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A link to the transcript will also be available on the Internet at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm527587.htm.*

Dated: December 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–29998 Filed 12–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2013–N–0375; FDA–2013–N–0370; FDA–2013–N–0134; FDA–2009–N–0511; FDA–1997–N–0020; FDA–2011–N–0902; FDA–2013–N–0662; FDA–2013–N–0450; FDA–2012–N–0477; FDA–2013–N–0519]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Agreement for Shipments of Devices for Sterilization	0910–0131	9/30/2019
Export of Medical Devices—Foreign Letters of Approval	0910–0264	9/30/2019
Mammography Facilities, Standards, and Lay Summaries for Patients	0910–0309	9/30/2019
Medicated Fee Mill License Application	0910–0337	9/30/2019
Substances Generally Recognized as Safe: Notification Procedure	0910–0342	9/30/2019
Prescription Drug Product Labeling; Medication Guide Requirements	0910–0393	9/30/2019
Applications for FDA Approval to Market a New Drug: Patent Submission and Listing Requirements and Application of 30-month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug is Invalid or Will Not be Infringed	0910–0513	9/30/2016
Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed	0910–0339	10/31/2019
Investigational Device Exemptions Reports and Records—21 CFR 812	0910–0078	11/30/2019
Guidance for Industry on How to Submit Information in Electronic Format to the Center for Veterinary Medicine Using the FDA Electronic Submission Gateway	0910–0454	11/30/2019

Dated: December 9, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–30035 Filed 12–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–4119]

Food Safety Modernization Act Third-Party Certification Program User Fee Rate for Fiscal Year 2017

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2017 fee rate for accreditation bodies applying to be recognized in the third-party certification program that is authorized by the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA).

FOR FURTHER INFORMATION CONTACT: Sylvia Kim, Office of Foods and Veterinary Medicine, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3212, Silver Spring, MD 20993, 301–796–7599.

DATES: This fee is effective January 13, 2017, and will remain in effect through September 30, 2017.

SUPPLEMENTARY INFORMATION:

I. Background

Section 307 of FSMA, Accreditation of Third-Party Auditors, amends the FD&C Act to create a new provision, section 808, under the same name. Section 808 of the FD&C Act (21 U.S.C. 384d) directs us to establish a new program for accreditation of third-party certification bodies [1] conducting food safety audits and issuing food and facility certifications to eligible foreign entities (including registered foreign

[1] For the reasons explained in the third-party certification final rule (80 FR74570 at 74578–74579, November 27, 2015), and for consistency with the implementing regulations for the third-party certification program in 21 CFR parts 1, 11, and 16, this notice uses the term ''third-party certification body'' rather than the term ''third-party auditor'' used in section 808(a)(3) of the FD&C Act.

food facilities) that meet our applicable requirements. Under this provision, we will recognize accreditation bodies to accredit certification bodies, except for limited circumstances in which we may directly accredit certification bodies to participate in the third-party certification program.

Section 808(c)(8) of the FD&C Act directs FDA to establish a reimbursement (user fee) program by which we assess fees and require reimbursement for the work FDA performs to establish and administer the third-party certification program under section 808 of the FD&C Act. The FSMA FY 2017 third-party certification program user fee rate announced in this notice is effective on January 13, 2017, and will remain in effect through September 30, 2017. We plan to publish the FSMA third-party certification program user fee rates for FY 2018 prior to the beginning of the next fiscal year.

Section 808(c)(8) of the FD&C Act requires FDA to establish the user fee program for the third-party certification program by regulation. Elsewhere in this issue of the **Federal Register** we are issuing a final rule entitled ''Amendments to Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and To Issue Certifications to Provide for the User Fee Program.''

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2017

In each year, the costs of salary (or personnel compensation) and benefits for FDA employees account for between 50 and 60 percent of the funds available to, and used by, FDA. Almost all of the remaining funds (operating funds) available to FDA are used to support FDA employees for paying rent, travel, utility, information technology, and other operating costs.

A. Estimating the Full Cost per Direct Work Hour in FY 2015

In general, the starting point for estimating the full cost per direct work hour is to estimate the cost of a full-time equivalent (FTE) or paid staff year for the relevant activity. This is done by dividing the total funds allocated to the elements of FDA primarily responsible for carrying out the activities for which fees are being collected by the total FTEs allocated to those activities. For the purposes of the third-party certification program user fees authorized by section 808(c)(8) of the FD&C Act (the fees that are the subject of this notice), primary responsibility for the activities for which fees will be collected rests with FDA's Office of Regulatory Affairs (ORA). ORA carries out field-based activities on behalf of FDA's product centers, including the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM). Thus, as the starting point for estimating the full cost per direct work hour, FDA will use the total funds allocated to ORA for CFSAN and CVM related field activities. The most recent fiscal year with available data was FY 2015. In that year, FDA obligated a total of $666,722,326 for ORA in carrying out the CFSAN and CVM related field activities work, excluding the cost of inspection travel. In that same year, the number of ORA staff primarily conducting the CFSAN and CVM related field activities was 3,022 FTEs or paid staff years. Dividing $666,722,326 by 3,022 FTEs results in an average cost of $220,623 per paid staff year, excluding travel costs.

Not all of the FTEs required to support the activities for which fees will be collected are conducting direct work such as conducting onsite assessments. Data collected over a number of years and used consistently in other FDA user fee programs (*e.g.,* under the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee and Modernization Act (MDUFA)) show that every seven FTEs who perform direct FDA work require three indirect and supporting FTEs. These indirect and supporting FTEs function in budget, facility, human resource, information technology, planning, security, administrative support, legislative liaison, legal counsel, program management, and other essential program areas. On average, two of these indirect and supporting FTEs are located in ORA or the FDA center where the direct work is being conducted, and one of them is located in the Office of the Commissioner. To get the fully supported cost of an FTE, FDA needs to multiply the average cost of an FTE by 1.43, to take into account the indirect and supporting functions. The 1.43 factor is derived by dividing the 10 fully supported FTEs by 7 direct FTEs. In FY 2015, the average cost of an FTE was $220,623. Multiplying this amount by 1.43 results in an average fully supported cost of $315,491 per FTE, excluding the cost of travel.

To calculate an hourly rate, FDA must divide the average fully supported cost of $315,491 per FTE by the average number of supported direct FDA work hours. See table 1.

TABLE 1—SUPPORTED DIRECT FDA WORK HOURS IN A PAID STAFF YEAR

Total number of hours in a paid staff year	2,080
Less:	
10 paid holidays	80
20 days of annual leave	160
10 days of sick leave	80
10 days of training	80
2 hours of meetings per week	80
Net Supported Direct FDA Work Hours Available for Assignments	1,600

Dividing the average fully supported cost of an FTE in FY 2015 ($315,491) by the total number of supported direct work hours available for assignment (1,600) results in an average fully supported cost of $197 (rounded to the nearest dollar), excluding travel costs, per supported direct work hour in FY 2015—the last fiscal year for which complete data are available.

B. Adjusting FY 2015 Costs for Inflation To Estimate FY 2017 Costs

To adjust the hourly rate for FY 2017, FDA must estimate the cost of inflation in each year for FY 2016 and FY 2017. FDA uses the method prescribed for estimating inflationary costs under the PDUFA provisions of the FD&C Act (section 736(c)(1) (21 U.S.C. 379h(c)(1)), the statutory method for inflation adjustment in the FD&C Act that FDA has used consistently. FDA previously determined the FY 2016 inflation rate to be 2.0266; this rate was published in the FY 2016 PDUFA user fee rates notice in the **Federal Register** of August 3, 2015 (80 FR 46028). Utilizing the method set forth in section 736(c)(1) of the FD&C Act, FDA has calculated an inflation rate of 1.5468 percent for FY 2017 and FDA intends to use this inflation rate to make inflation adjustments for FY 2017 for several of its user fee programs; the derivation of this rate is published in the **Federal Register** in the FY 2017 notice for the PDUFA user fee rates (81 FR 49674). The compounded inflation rate for FYs 2016 and 2017, therefore, is 3.6047 percent (1 plus 2.0266 percent times 1 plus 1.5468 percent).

Increasing the FY 2015 average fully supported cost per supported direct FDA work hour of $197 (excluding travel costs) by 3.6047 percent yields an inflationary adjusted estimated cost of $204 per a supported direct work hour in FY 2017, excluding travel costs. FDA will use this base unit fee in determining the hourly fee rate for third-party certification program fee for FY 2017 prior to including travel costs as applicable for the activity. For the purpose of estimating the fee, we are

using the travel cost rate for foreign travel, because we anticipate that the vast majority of onsite assessments made by FDA under this program will require foreign travel. In FY 2015, ORA spent a total of $2,521,216 on 269 foreign inspection trips related to FDA's CFSAN and CVM field activities programs, which averaged a total of $9,373 per foreign inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing $9,373 per trip by 120 hours per trip results in a total and an additional cost of $78 per paid hour spent for foreign inspection travel costs in FY 2015. To adjust $78 for inflationary increases in FY 2016 and FY 2017, FDA must multiply it by the same inflation factor mentioned previously in this document (1.036047), which results in an estimated cost of $81 dollars per paid hour in addition to $204 for a total of $285 per paid hour ($204 plus $81) for each direct hour of work requiring foreign inspection travel. FDA will use these rates in charging fees in FY 2017 when travel is required for the third-party certification program.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2017

Fee category	Fee rates for FY 2017
Hourly rate without travel	$204
Hourly rate if travel is required	285

III. Application Fee for Accreditation Bodies Applying for Recognition in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

In FY 2017 (the first fiscal year in which the program will operate), the only fee that will be collected by FDA under section 808(c)(8) of the FD&C Act is the initial application fee for accreditation bodies seeking recognition. Section 1.705(a)(1) establishes an application fee for accreditation bodies applying for initial recognition that represents the estimated average cost of the work FDA performs in reviewing and evaluating initial applications for recognition of accreditation bodies.

The fee is based on the fully supported FTE hourly rates and estimates of the number of hours it would take FDA to perform relevant activities. These estimates represent FDA's current thinking, and as the program evolves, FDA will reconsider the estimated hours. We estimate that it would take, on average, 60 person-hours to review an accreditation body's submitted application, 48 person-hours for an onsite performance evaluation of the applicant (including travel and other steps necessary for a fully supported FTE to complete an onsite assessment), and 45 person-hours to prepare a written report documenting the onsite assessment.

FDA employees are likely to review applications and prepare reports from their worksites, so we use the fully supported FTE hourly rate excluding travel, $204/hour, to calculate the portion of the user fee attributable to those activities: $204/hour × (60 hours + 45 hours) = $21,420. FDA employees will likely travel to foreign countries for the onsite performance evaluations because most accreditation bodies are located in foreign countries. For this portion of the fee we use the fully supported FTE hourly rate for work requiring travel, $285/hour, to calculate the portion of the user fee attributable to those activities: $285 × 48 hours (*i.e.,* 2 fully supported FTEs × (2 travel days + 1 day onsite)) = $13,680. The estimated average cost of the work FDA performs in total for reviewing an initial application for recognition for an accreditation body based on these figures would be $21,420 + $13,680 = $35,100. Therefore the application fee for accreditation bodies applying for recognition in FY 2017 will be $35,100.

IV. Estimated Fees for Accreditation Bodies and Certification Bodies in Fee Categories Not Applicable in FY 2017

The third-party certification program will also assess other application fees and annual fees in future years of this program. Section 1.705(a) also establishes application fees for recognized accreditation bodies submitting renewal applications, certification bodies applying for direct accreditation, and certification bodies applying for renewal of direct accreditation. Section 1.705(b) establishes annual fees for recognized accreditation bodies, certification bodies directly accredited by FDA, and certification bodies accredited by recognized accreditation bodies.

Although we will not be collecting these other fees in FY 2017, for transparency and planning purposes, we have provided an estimate of what these fees could have been for FY 2017 based on the fully supported FTE hourly rates for FY 2017 and estimates of the number of hours it would take FDA to perform relevant activities as outlined in the Final Regulatory Impact Analysis for the Third-Party Certification Regulation. Table 3 provides an overview of the estimated fees for other fee categories.

Fee category	Estimated fee rates for FY 2017
Renewal application fee for recognized accreditation body	$18,855
Initial application fee for certification body seeking direct-accreditation from FDA	35,100
Renewal application fee for directly-accredited certification body	26,460
Annual fee for recognized accreditation body	1,579
Annual fee for certification body directly-accredited by FDA	20,208
Annual fee for accredited certification body	1,974

V. How Must the Fee Be Paid?

Accreditation bodies seeking initial recognition must submit the application fee with the application.

VI. What Are the Consequences of Not Paying This Fee?

The consequence of not paying this fee is outlined in § 1.725. If FDA does not receive an application fee with an application for recognition, the application will be considered incomplete and FDA would not review the application.

Dated: *December 9, 2016.*

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–30034 Filed 12–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–4803]

Public Notification of Emerging Postmarket Medical Device Signals (''Emerging Signals''); Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled ''Public Notification of Emerging Postmarket Medical Device Signals ('Emerging Signals').'' FDA is issuing this guidance to describe the Center for Devices and Radiological Health's (CDRH) policy for notifying the public about medical device ''emerging signals.'' This guidance describes the