TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity; 21 CFR section	FDA form No.[2]	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Biennial renewals; 1.235	3537	97,883	1	97,883	0.38 (23 minutes)	37,196
3rd party registration verification.	3537	41,256	1	41,256	0.25 (15 minutes)	10,314
U.S. Agent verification	3537	57,070	1	57,070	0.25 (15 minutes)	14,268
Total						278,382

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Forms FDA 3537 and FDA 3537a refer to both the paper version of the form and the electronic system known as the Food Facility Registration Module, which is available at *https://www.access.fda.gov.*

These burden figures are based on currently available data and reflect an overall decrease to the information collection by 174,395 and 31,370 hours. The decrease results from the realization of burden associated with implementing measures on newly established electronic registration requirements.

Dated: July 17, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15636 Filed 7–22–19; 8:45 am]

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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 2020

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2020 annual fee rate for recognized accreditation bodies and accredited certification bodies, and the 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 (FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA). We are also announcing the fee rate for certification bodies that are applying to be directly accredited by FDA.

DATES: This fee is effective October 1, 2019.

FOR FURTHER INFORMATION CONTACT: Donald Prater, Office of Food Policy and Response, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3202, Silver Spring, MD 20993, 301–348–3007.

SUPPLEMENTARY INFORMATION:

I. Background

Section 307 of FSMA (Pub. L. 111–153), Accreditation of Third-Party Auditors, amended 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 FDA to establish a 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 food facilities) that meet our applicable requirements. Under this provision, we established a system for FDA to 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 user fee program for the third-party certification program was established by 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'' (81 FR 90186, December 14, 2016).

The FSMA FY 2020 third-party certification program user fee rate announced in this notice is effective on October 1, 2019, and will remain in effect through September 30, 2020.

[1] For the reasons explained in the third-party certification final rule (80 FR 74570 at 74578 to 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.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2020

FDA must estimate its costs for each activity in order to establish fee rates for FY 2020. 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 2020

Full-time Equivalent (FTE) reflects the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees, divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off, and other approved leave categories are considered ''hours worked'' for purposes of defining FTE employment.

In general, the starting point for estimating the full cost per direct work hour is to estimate the cost of an FTE or paid staff year. Calculating an Agency-wide total cost per FTE requires three primary cost elements: Payroll, non-payroll, and rent.

We have used an average of past year cost elements to predict the FY 2020 cost. The FY 2020 FDA-wide average cost for payroll (salaries and benefits) is $160,885; non-payroll—including equipment, supplies, information technology, general and administrative overhead—is $92,828; and rent, including cost allocation analysis and adjustments for other rent and rent-related costs, is $24,888 per paid staff year, excluding travel costs.

Summing the average cost of an FTE for payroll, non-payroll, and rent, brings the FY 2020 average fully supported cost to $278,602 per FTE, excluding travel costs. FDA will use this base unit

fee in determining the hourly fee rate for third-party certification user fees for FY 2020 prior to including travel costs as applicable for the activity.

To calculate an hourly rate, FDA must divide the FY 2020 average fully supported cost of $278,602 per FTE by the average number of supported direct FDA work hours in FY 2018—the last FY for which data are available. See table 1.

TABLE 1—SUPPORTED DIRECT FDA WORK HOURS IN A PAID STAFF YEAR IN FY 2018

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
12.5 days of training	−100
26.5 days of general administration	−184
26.5 days of travel	−212
2 hours of meetings per week	−104
Net Supported Direct FDA Work Hours Available for Assignments	1,160

Dividing the average fully supported FTE cost in FY 2020 ($278,602) by the total number of supported direct work hours available for assignment in FY 2018 (1,160) results in an average fully supported cost of $240 (rounded to the nearest dollar), excluding travel costs, per supported direct work hour in FY 2020.

B. Adjusting FY 2018 Travel Costs for Inflation To Estimate FY 2020 Travel Costs

To adjust the hourly rate for FY 2020, FDA must estimate the cost of inflation in each year for FY 2019 and FY 2020. FDA uses the method prescribed for estimating inflationary costs under the Prescription Drug User Fee Act (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 2019 inflation rate to be 1.7708 percent; this rate was published in the FY 2019 PDUFA user fee rates notice in the **Federal Register** 83 FR 37504, August 1, 2018). Utilizing the method set forth in section 736(c)(1) of the FD&C Act, FDA has calculated an inflation rate of 1.7708 percent for FY 2019 and 2.3964 percent for FY 2020, and FDA intends to use this inflation rate to make inflation adjustments for FY 2020 for several of its user fee programs; the derivation of this rate will be published in the **Federal Register** in the FY 2020 notice for the PDUFA user fee rates. The compounded inflation rate for FYs 2019 and 2020, therefore, is 1.042096 (or 4.2096 percent) (1 plus 1.7708 percent times 1 plus 2.3964 percent).

The average fully supported cost per supported direct FDA work hour, excluding travel costs, of $240 already takes into account inflation as the calculation above is based on FY 2020 predicted costs. FDA will use this base unit fee in determining the hourly fee rate for third-party certification program fees for FY 2020 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 2018, the Office of Regulatory Affairs spent a total of $3,229,335 on 455 foreign inspection trips related to FDA's Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine field activities programs, which averaged a total of $7,097 per foreign inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing $7,097 per trip by 120 hours per trip results in a total and an additional cost of $59 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2017. To adjust $59 for inflationary increases in FY 2019 and FY 2020, FDA must multiply it by the same inflation factor mentioned previously in this document (1.042096 or 4.2096 percent), which results in an estimated cost of $61 (rounded to the nearest dollar) per paid hour in addition to $240 for a total of $301 per paid hour ($240 plus $61) for each direct hour of work requiring foreign inspection travel. FDA will use these rates in charging fees in FY 2020 when travel is required for the third-party certification program.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2020

Fee category	Fee rates for FY 2020
Hourly rate without travel	$240
Hourly rate if travel is required	301

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

The third-party certification program assesses application fees and annual fees. In FY 2020, the only fees that could be collected by FDA under section 808(c)(8) of the FD&C Act are the initial application fee for accreditation bodies seeking recognition, the annual fee for recognized accreditation bodies, the annual fee for certification bodies accredited by a recognized accreditation body, and the initial application fee for a certification body seeking direct accreditation from FDA. Table 3 provides an overview of the fees for FY 2020.

TABLE 3—FSMA THIRD-PARTY CERTIFICATION PROGRAM USER FEE SCHEDULE FOR FY 2020

Fee category	Fee rates for FY 2020
Initial Application Fee for Accreditation Body Seeking Recognition	$41,328
Annual Fee for Recognized Accreditation Body	1,945
Annual Fee for Accredited Certification Body	2,432
Initial Application Fee for a Certification Body Seeking Direct Accreditation from FDA	41,328

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

Section 1.705(a)(1) (21 CFR 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 continue to reconsider the estimated hours. Based on data we have acquired since starting the program, we estimate that it would take, on average, 70 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 42 person-hours to prepare a written report documenting the onsite assessment.

FDA employees review applications and prepare reports from their worksites, so we use the fully supported FTE hourly rate excluding travel, $240/hour, to calculate the portion of the user

fee attributable to those activities: $240/hour × (70 hours + 42 hours) = $26,880. FDA employees will likely travel to foreign countries for the onsite performance evaluations because most accreditation bodies are anticipated to be located in foreign countries. For this portion of the fee we use the fully supported FTE hourly rate for work requiring travel, $301/hour, to calculate the portion of the user fee attributable to those activities: $301/hour × 48 hours (*i.e.,* two fully supported FTEs × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) = $14,448. 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 $26,880 + $14,448 = $41,328. Therefore, the application fee for accreditation bodies applying for recognition in FY 2020 will be $41,328.

B. Annual Fee for Accreditation Bodies Participating in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

To calculate the annual fee for each recognized accreditation body, FDA takes the estimated average cost of work FDA performs to monitor performance of a single recognized accreditation body and annualizes that over the average term of recognition. At this time we assume an average term of recognition of 5 years. We also assume that FDA will monitor 10 percent of recognized accreditation bodies onsite. As the program proceeds, we will adjust the term of recognition as appropriate. We estimate that for one performance evaluation of a recognized accreditation body, it would take, on average (taking into account that not all recognized accreditation bodies would be monitored onsite), 33 hours for FDA to conduct records review, 8 hours to prepare a report detailing the records review and onsite performance evaluation, and 6 hours of onsite performance evaluation (*i.e.,* 10 percent × 60 hours). Using the fully supported FTE hourly rates in table 2, the estimated average cost of the work FDA performs to monitor performance of a single recognized accreditation body would be $7,920 ($240/hour × (25 hours + 8 hours)) plus $1,806 ($301/hour × 6 hours), which is $9,726. Annualizing this amount over 5 years would lead to an annual fee for recognized accreditation bodies of $1,945 for FY 2020.

C. Annual Fee for Certification Bodies Accredited by a Recognized Accreditation Body in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

To calculate the annual fee for a certification body accredited by a recognized accreditation body, FDA takes the estimated average cost of work FDA performs to monitor performance of a single certification body accredited by a recognized accreditation body and annualizes that over the average term of accreditation. At this time we assume an average term of accreditation of 4 years. This 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. We estimate that FDA would conduct, on average, the same activities, for the same amount of time to monitor certification bodies accredited by a recognized accreditation body as we would to monitor an accreditation body recognized by FDA. Using the fully supported FTE hourly rates in table 2, the estimated average cost of the work FDA performs to monitor performance of a single accredited certification body would be $7,920 ($240/hour × (25 hours + 8 hours)) plus $1,806 ($301/hour × 6 hours), which is $9,726. Annualizing this amount over 4 years would lead to an annual fee for accredited certification bodies of $2,432 for FY 2020.

D. Initial Application Fee for Certification Bodies Seeking Direct Accreditation From FDA in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

Section 1.705(a)(3) establishes an application fee for certification bodies applying for direct accreditation from FDA that represents the estimated average cost of the work FDA performs in reviewing and evaluating initial applications for direct accreditation of certification 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, 70 person-hours to review a certification 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 42 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, $240/hour, to calculate the portion of the user fee attributable to those activities: $240/hour × (70 hours + 42 hours) = $26,880. FDA employees will likely travel to foreign countries for the onsite performance evaluations because most certification bodies are anticipated to be located in foreign countries. For this portion of the fee we use the fully supported FTE hourly rate for work requiring travel, $301/hour, to calculate the portion of the user fee attributable to those activities: $301/hour × 48 hours (*i.e.,* two fully supported FTEs × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) = $14,448. The estimated average cost of the work FDA performs in total for reviewing an initial application for direct accreditation of a certification body based on these figures would be $26,880 + $14,448 = $41,328. Therefore, the application fee for certification bodies applying for direct accreditation from FDA in FY 2020 will be $41,328.

IV. Estimated Fees for Accreditation Bodies and Certification Bodies in Other Fee Categories for FY 2020

Section 1.705(a) also establishes application fees for recognized accreditation bodies submitting renewal applications and certification bodies applying for renewal of direct accreditation. Section 1.705(b) also establishes annual fees for certification bodies directly accredited by FDA.

Although we will not be collecting these other fees in FY 2020, for transparency and planning purposes, we have provided an estimate of what these fees would be for FY 2020 based on the fully supported FTE hourly rates for FY 2020 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 4 provides an overview of the estimated fees for other fee categories.

TABLE 4—ESTIMATED FEE RATES FOR OTHER FEE CATEGORIES UNDER THE FSMA THIRD-PARTY CERTIFICATION PROGRAM

Fee category	Estimated fee rates for FY 2020
Renewal application fee for recognized accreditation body	$24,622
Renewal application fee for directly accredited certification body	24,622

TABLE 4—ESTIMATED FEE RATES FOR OTHER FEE CATEGORIES UNDER THE FSMA THIRD-PARTY CERTIFICATION PROGRAM—Continued

Fee category	Estimated fee rates for FY 2020
Annual fee for certification body directly accredited by FDA	19,720

V. How must the fee be paid?

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

For recognized accreditation bodies and accredited certification bodies, an invoice will be sent annually. Payment must be made within 30 days of the receipt date. The payment must be made in U.S. currency from a U.S. bank by one of the following methods: Wire transfer, electronically, check, bank draft, or U.S. postal money order made payable to the Food and Drug Administration. The preferred payment method is online using an electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay* or the *Pay.gov* payment option is available to you after you submit a cover sheet. (*Note:* Only full payments are accepted. No partial payments can be made online.) Once you have found your invoice, select ''Pay Now'' to be redirected to *Pay.gov.* Electronic payment options are based on the balance due. Payment by credit card is available only for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

When paying by check, bank draft, or U.S. postal money order, please include the invoice number. Also write the FDA post office box number (P.O. Box 979108) on the enclosed check, bank draft, or money order. Mail the payment and a copy of the invoice to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000.

When paying by wire transfer, it is required that the invoice number is included; without the invoice number the payment may not be applied. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required to add that amount to the payment to ensure that the invoice is paid in full. For international wire transfers, please inquire with the financial institutions prior to submitting the payment. Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account No.: 75060099, Routing No.: 021030004, Swift No.: FRNYUS33.

To send a check by a courier such as Federal Express, the courier must deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (*Note:* This address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314–418–4013. This phone number is only for questions about courier delivery.)

The tax identification number of FDA is 53–0196965. (*Note:* In no case should the payment for the fee be submitted to FDA with the invoice.)

VI. What are the consequences of not paying this fee?

The consequences of not paying these fees are outlined in 21 CFR 1.725. If FDA does not receive an application fee with an application for recognition, the application will be considered incomplete and FDA will not review the application. If a recognized accreditation body fails to submit its annual user fee within 30 days of the due date, we will suspend its recognition. If the recognized accreditation body fails to submit its annual user fee within 90 days of the due date, we will revoke its recognition. If an accredited certification body fails to pay its annual fee within 30 days of the due date, we will suspend its accreditation. If the accredited certification body fails to pay its annual fee within 90 days of the due date, we will withdraw its accreditation.

Dated: July 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–15622 Filed 7–22–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2018–N–3138; FDA–2009–N–0232; FDA–2018–N–4465; FDA–2018–N–4206; FDA–2018–N–3758; FDA–2015–D–1163; FDA–2012–N–0559; FDA–2015–N–3815; FDA–2018–N–3353; and FDA–2018–N–2973]

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: 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: 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
Experimental Study of an Accelerated Approval Disclosure	0910–0872	6/30/2020
Interstate Shellfish Dealer's Certificate	0910–0021	5/31/2022
Administrative Detention and Banned Medical Devices	0910–0114	5/31/2022
Medical Device User Fee Small Business Qualifications and Certifications	0910–0508	5/31/2022