4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-7712]

Food Safety Modernization Act Third-Party Certification Program User Fee Rate for Fiscal Year 2027

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the fiscal year (FY) 2027 annual fee rate for recognized accreditation bodies and accredited certification bodies, and the initial and renewal fee rate for accreditation bodies applying to be recognized in the third-party certification program 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 applying for direct FDA accreditation.

DATES: The fees apply from October 1, 2026, through September 30, 2027.

FOR FURTHER INFORMATION CONTACT: *For Questions Related to FSMA Program Fees*: FSMAFeeStaff@fda.hhs.gov. *For Questions Related to This Notice*: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 301-796-7900; or FDAUserFees@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 808(b)(1)(A) of the FD&C Act (21 U.S.C. 384d(b)(1)(A)) directed FDA to establish a recognition system for entities that accredit third-party certification bodies to conduct food safety audits and issue food and facility certifications to eligible foreign entities. (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 our 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 of the FD&C Act.) Section 808(b)(1)(A)(ii) of the FD&C Act also allowed us to directly accredit certain third-party certification bodies.

Section 808(c)(8) of the FD&C Act directed FDA to establish a reimbursement (user fee) program by which we assess fees and require reimbursement for our work to administer the third-party certification program. Our regulations pertaining to the user fee program for the third-party certification program can be found at 21 CFR §§ 1.700 through 1.725.

The FY 2027 third-party certification program user fee rates announced in this notice is effective from October 1, 2026, through September 30, 2027.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2027

FDA estimates its costs for each activity to establish fee rates (see 21 CFR § 1.705(b)).

A. Estimating the Full Cost per Direct Work Hour in FY 2027

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 FDA-wide total cost per FTE requires three primary cost elements: payroll, non-payroll, and rent.

We used an average of past year cost elements to predict the FY 2027 cost. The FY 2027 FDA-wide average cost for payroll (salaries and benefits) is $244,029; non-payroll (including equipment, supplies, information technology, general and administrative overhead) is $108,488; and rent (including cost allocation analysis and adjustments for other rent and rent-related costs) is $24,118 per paid staff year, excluding travel costs.

Summing the average cost of an FTE for payroll, non-payroll, and rent brings the FY 2027 average fully supported cost to $376,635 (total includes rounding) 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 2027 before including travel costs as applicable for the activity.

To calculate an hourly rate, we divide the FY 2027 average fully supported cost of $376,635 per FTE by the average number of supported direct FDA work hours in FY 2025 (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 2025

Total number of hours in a paid staff year	2,080
Less:	
11 paid holidays	-88
20 days of annual leave	-160
10 days of sick leave	-80
12.5 days of training	-100
22 days of general administration	-176
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 2027 ($376,635) by the total number of supported direct work hours available for assignment in FY 2025 (1,160) results in an average fully supported cost of $325 (rounded to the nearest dollar), excluding travel costs, per supported direct work hour in FY 2027.

B. Adjusting FY 2025 Travel Costs for Inflation to Estimate FY 2027 Travel Costs

To adjust the hourly rate for FY 2027, FDA estimates the cost of inflation in each year for FY 2026 and FY 2027. 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) of the FD&C Act (21 U.S.C. 379h(c)(1))), the statutory method for inflation adjustment in the FD&C Act. FDA previously determined the FY 2026 inflation rate to be 5.0313 percent; this rate was published in the FY 2026 PDUFA user fee rates notice in the *Federal Register* (July 30, 2025, 90 FR 35866). Using the method set forth in section 736(c)(1)

of the FD&C Act, FDA has calculated an inflation rate of 5.0313 percent for FY 2026 and 4.7210 percent for FY 2027, and FDA intends to use this inflation rate to make inflation adjustments for FY 2027.

For the purpose of estimating the fee, we are using the travel cost rate for foreign travel because the majority of onsite assessments made by FDA under this program will require foreign travel. In FY 2025, the Office of Inspections and Investigation (OII) spent a total of $2,689,902 on 277 foreign inspection trips (averaging $9,711 per foreign inspection trip) related to FDA's Human Foods Program and Center for Veterinary Medicine field activities programs.[1] These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing $9,711 per trip by 120 hours per trip equals $81 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2025. To adjust $81 for inflation in FY 2026 and FY 2027, FDA multiplies it by the same inflation factors mentioned previously in this document (1.050313 and 1.047210), which results in an estimated cost of $89 per paid hour. That plus $325 in other costs per average supported direct work hour equals $414 per paid hour for each direct hour of work requiring foreign inspection travel. FDA will use this rate in charging fees in FY 2027 when travel is required for the third-party certification program.

Table 2.--FSMA Fee Schedule for FY 2027

Fee Category	Fee Rates for FY 2027
Hourly rate without travel	$325
Hourly rate if travel is required	$414

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

[1] Effective October 1st, 2024, FDA implemented a reorganization to establish a unified Humans Foods Program and restructured its field operations, formerly the Office of Regulatory Affairs and now the Office of Inspections and Investigations (OII). The establishment of the Human Foods Program allows us to most effectively deliver on our mission to protect and promote public health through science-based approaches to prevent foodborne illness, reduce diet-related chronic disease, and ensure the safety of chemicals in our food. For more information, see https://www.fda.gov/news-events/press-announcements/fdas-unified-human-foods-program-new-model-field-operations-and-other-modernization-efforts-go.

The third-party certification program assesses application fees and annual fees. Specifically, FDA can collect an initial application fee for accreditation bodies seeking recognition, an annual fee for recognized accreditation bodies, an annual fee for certification bodies accredited by a recognized accreditation body, an initial application fee for a certification body seeking direct accreditation from FDA, and a renewal application fee for recognized accreditation bodies. Table 3 provides an overview of the fees for FY 2027.

Table 3.--FSMA Third-Party Certification Program User Fee Schedule for FY 2027

Fee Category	Fee Rates for FY 2027
Initial Application Fee for Accreditation Body Seeking Recognition	$56,272
Annual Fee for Recognized Accreditation Body	$2,612
Annual Fee for Accredited Certification Body	$3,266
Initial Application Fee for a Certification Body Seeking Direct Accreditation from FDA	$56,272
Renewal Application Fee for Recognized Accreditation Body	$34,311

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

Our regulations, at § 1.705(a)(1), require an application fee for accreditation bodies applying for recognition; that fee covers the estimated average cost of the work FDA performs in reviewing and evaluating 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. Based on our data since starting the program, we estimate that it would take, on average, 80 person-hours to review an accreditation body's 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 32 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 ($325 per hour) to calculate the user fee attributable to those activities: $325/hour × (80 hours (application review) + 32 hours (written report)) = $36,400. We use the fully supported FTE hourly rate for work requiring travel ($414

per hour) to calculate the user fee for onsite performance evaluations, since historically most accreditation bodies are in foreign countries: $414/hour × 48 hours (i.e., two fully supported FTEs × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) =$19,872. The estimated average cost of our total work for reviewing an application for recognition for an accreditation body based on these figures would be $36,400 + $19,872 = $56,272. Therefore, the application fee for accreditation bodies applying for recognition in FY 2027 will be $56,272.

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 our work to monitor performance of a single recognized accreditation body and annualizes that over the average term of recognition. We assume an average term of recognition of 5 years. We also assume that FDA will monitor 10 percent of recognized accreditation bodies onsite. We estimate that one performance evaluation of a recognized accreditation body would take, on average, 22 hours to conduct records review, 8 hours to prepare a report detailing the records review and onsite performance evaluation, and 8 hours of onsite performance evaluation. Using the fully supported FTE hourly rates in table 2, the estimated average cost of our work to monitor performance of a single recognized accreditation body would be $9,750 ($325/hour × (22 hours (records review) + 8 hours (written report))) plus $3,312 ($414/hour × 8 hours (onsite evaluation)), which is $13,062. Annualizing this amount over 5 years leads to an annual fee for recognized accreditation bodies of $2,612 for FY 2027.

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 our work to monitor performance of a single certification body accredited by a recognized accreditation body and annualizes that over the average term of accreditation. We assume an average term of accreditation of 4 years. 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 our work to monitor performance of a single accredited certification body would be $9,750 ($325/hour × (22 hours (records review) + 8 hours (written report))) plus $3,312 ($414/hour × 8 hours (onsite evaluation)), which is $13,062. Annualizing this amount over 4 years leads to an annual fee for accredited certification bodies of $3,266 for FY 2027.

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

Our regulations, at § 1.705(a)(3), require an application fee for certification bodies applying for direct accreditation from FDA to cover the estimated average cost of our work to review 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. We estimate that it would take, on average, 80 person-hours to review a certification body's application, 48 person-hours for an onsite performance evaluation of the applicant, and 32 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, $325 per hour, to calculate the portion of the user fee attributable to those activities: $325/hour × (80 hours (application review) + 32 hours (written report)) = $36,400. For the portion of the fee attributable to onsite performance evaluations, we use the fully supported FTE hourly rate for work requiring travel ($414 per hour) since historically most certification bodies are in foreign countries: $414/hour × 48 hours (i.e., two fully supported FTEs × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) = $19,872. The estimated average cost of our work to review an

application for direct accreditation of a certification body is $36,400 + $19,872 = $56,272. Therefore, the application fee for certification bodies applying for direct accreditation from FDA in FY 2027 will be $56,272

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

Our regulations, at § 1.705(a)(2), require a renewal application fee for recognized accreditation bodies to cover the estimated average cost of our work to review and evaluate renewal 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. We estimate that it would take, on average, 43 person-hours to review an accreditation body's submitted renewal application, 24 person-hours for an onsite performance evaluation of the applicant, and 32 person-hours to prepare a written report documenting the onsite assessment.

FDA employees are likely to review renewal applications and prepare reports from their worksites, so we use the fully supported FTE hourly rate excluding travel ($325 per hour) to calculate the portion of the user fee attributable to those activities: $325/hour × (43 hours (application review) + 32 hours (written report)) = $24,375. For the portion of the fee attributable to onsite performance evaluations, we use the fully supported FTE hourly rate for work requiring travel ($414 per hour) since historically most accreditation bodies are in foreign countries: $414/hour × 24 hours (i.e., fully supported FTE × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) = $9,936. The estimated average cost of our work for reviewing a renewal application for recognition of an accreditation body is $24,375 + $9,936 = $34,311. Therefore, the renewal application fee for recognized accreditation bodies in FY 2027 will be $34,311.

IV. Estimated Fees for Accreditation Bodies and Certification Bodies in Other Fee Categories for FY 2027

Our regulations, at § 1.705(a)(4), require application fees for certification bodies applying for renewal of direct accreditation, while § 1.705(b)(2) requires annual fees for certification bodies directly accredited by FDA.

Although to date we have not directly accredited any certification bodies under the Third-Party Certification Program, FDA notifies the public of the program fee schedule annually (21 CFR § 1.710). Therefore, we are providing estimates of annual fees and renewal applications for directly accredited certification bodies, based on the fully supported FTE hourly rates for FY 2026 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 these other categories.

Table 4.--Estimated Fee Rates for Other Fee Categories Under the FSMA Third-Party Certification Program

Fee Category	Estimated Fee Rates for FY 2027
Renewal application fee for directly accredited certification body	$34,311
Annual fee for certification body directly accredited by FDA	$26,960

V. How Must the Fees Be Paid?

Accreditation bodies seeking recognition must submit the application fee with the application (21 CFR § 1.715(a)). For recognized accreditation bodies and accredited certification bodies, an invoice will be sent annually. Payments made to FDA must be made, within 30 days of the invoice date, in U.S. currency drawn on a U.S. bank by electronic check, credit card, or wire transfer. The preferred method for payments to FDA is online using electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). FDA has partnered with the U.S. Department of the Treasury to utilize Pay.gov, a web-based payment application, for online electronic payment. The Pay.gov feature is available on the FDA website upon receipt of an invoice.

Secure electronic payments to FDA can be submitted using the User Fees Payment Portal at https://userfees.fda.gov/pay. (Note: Only full payments are accepted; no partial payments can

be made online.) Once an invoice is located, "Pay Now" should be selected to be redirected to Pay.gov. Electronic payment options are based on the balance due. Payment by credit card is available 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 or U.S. credit cards.

For payments made by wire transfer, include the invoice number to ensure that the payment is applied to the correct fee(s). Without the invoice number, the payment may not be applied. The originating financial institution may charge a wire transfer fee. Include applicable wire transfer fees with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The following account information should be used to send payments by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account No: 75060099, Routing No: 021030004, SWIFT: FRNYUS33.

FDA's tax identification number is 53-0196965.

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.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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