2. Establishment Fee for Non-Small Businesses

Under section 744K(c) of the FD&C Act, the amount of the establishment fee for a non-small business is equal to $15,000 multiplied by the inflation adjustment factor for that fiscal year, plus the small business adjustment factor for that fiscal year, and plus or minus an adjustment factor to account for over or under collections due to the small business adjustment factor in the prior year. The inflation adjustment factor for FY 2026 is 1.365750. The small business adjustment amount for FY 2026 is $240. See section II.A.2 of this document for the methodology used to calculate the small business adjustment factor for FY 2026. Therefore, the establishment fee for a non-small business for FY 2026 is $15,000 multiplied by 1.365750 plus $240, which equals $20,726 (rounded to the nearest dollar).

3. Reinspection Fee

Section 744K(c)(1)(B) of the FD&C Act provides that the amount of the FY 2026 reinspection fee is equal to $15,000, multiplied by the inflation adjustment factor for that fiscal year. The inflation adjustment factor for FY 2026 is 1.365750. Therefore, the reinspection fee for FY 2026 is $15,000 multiplied by 1.365750, which equals $20,486 (rounded to the nearest dollar). There is no reduction in this fee for small businesses.

C. Summary of FY 2026 Fee Rates

TABLE 4—OUTSOURCING FACILITY FEES

Fee category	Fee rates for FY 2026
Qualified Small Business Establishment Fee	$6,829
Non-Small Business Establishment Fee	20,726
Reinspection Fee	20,486

III. Fee Payment Options and Procedures

A. Establishment Fee

Once an entity submits registration information and FDA has determined that the information is complete, the entity will incur the annual establishment fee. FDA will send an invoice to the entity, via email to the email address indicated in the registration file. The invoice will contain information regarding the obligation incurred, the amount owed, and payment procedures. A facility will not be registered as an outsourcing facility until it has paid the annual establishment fee under section 744K of the FD&C Act. Accordingly, it is important that facilities seeking to operate as outsourcing facilities pay all fees immediately upon receiving an invoice. If an entity does not pay the full invoiced amount within 15 calendar days after FDA issues the invoice, FDA will consider the submission of registration information to have been withdrawn and adjust the invoice to reflect that no fee is due.

Outsourcing facilities that registered in FY 2025 and wish to maintain their status as an outsourcing facility in FY 2026 must register during the annual registration period that lasts from October 1, 2025, to December 31, 2025. Failure to register and complete payment by December 31, 2025, will result in a loss of status as an outsourcing facility on January 1, 2026. Entities should submit their registration information no later than December 10, 2025, to allow enough time for review of the registration information, invoicing, and payment of fees before the end of the registration period.

B. Reinspection Fee

FDA will issue invoices for each reinspection after the conclusion of the reinspection, via email to the email address indicated in the registration file. Payments must be made within 30 days of the invoice date.

C. Fee Payment Procedures

1. The preferred payment method is online using 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.* (*Note:* only full payments are accepted. No partial payments can be made online.) Once you search for your invoice, click ''Pay Now'' 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 as well as U.S. credit cards.

2. For payments made by wire transfer, the invoice number must be included. Without the invoice number, the payment may not be applied. Regarding reinspection fees, if the payment amount is not applied, the invoice amount will be referred to collections. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required that the outsourcing facility add that amount to the payment to ensure that the invoice is paid in full. Use the following account information when sending a wire transfer: U.S. Dept of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53–0196965.

Dated: July 25, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–14410 Filed 7–29–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–2337]

Food Safety Modernization Act Third-Party Certification Program User Fee Rate for Fiscal Year 2026

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the fiscal year (FY) 2026 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, 2025, through September 30, 2026.

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, 10903 New Hampshire Ave, Silver Spring, MD 20993, 240–402–4989; or the User Fees Support Staff at *UFSS@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 2026 third-party certification program user fee rates announced in this notice is effective from October 1, 2025, through September 30, 2026.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2026

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 2026

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 2026 cost. The FY 2026 FDA-wide average cost for payroll (salaries and benefits) is $225,917; non-payroll (including equipment, supplies, information technology, general and administrative overhead) is $116,581; and rent (including cost allocation analysis and adjustments for other rent and rent-related costs) is $24,627 per paid staff year, excluding travel costs.

Summing the average cost of an FTE for payroll, non-payroll, and rent brings the FY 2026 average fully supported cost to $367,125 (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 2026 before including travel costs as applicable for the activity.

To calculate an hourly rate, we divide the FY 2026 average fully supported cost of $367,125 per FTE by the average number of supported direct FDA work hours in FY 2024 (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 2024

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 2026 ($367,125) by the total number of supported direct work hours available for assignment in FY 2024 (1,160) results in an average fully supported cost of $316 (rounded to the nearest dollar), excluding travel costs, per supported direct work hour in FY 2026.

B. Adjusting FY 2024 Travel Costs for Inflation To Estimate FY 2026 Travel Costs

To adjust the hourly rate for FY 2026, FDA estimates the cost of inflation in each year for FY 2025 and FY 2026. 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 2025 inflation rate to be 4.1167 percent; this rate was published in the FY 2025 PDUFA user fee rates notice in the **Federal Register** (July 31, 2024, 89 FR 61474). Using the method set forth in section 736(c)(1) of the FD&C Act, FDA has calculated an inflation rate of 4.1167 percent for FY 2025 and 5.0313 percent for FY 2026, and FDA intends to use this inflation rate to make inflation adjustments for FY 2026.

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 2024, the Office of Regulatory Affairs spent a total of $3,209,026 on 487 foreign inspection trips (averaging $6,589 per foreign inspection trip) related to FDA's Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine field activities programs. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing $6,589 per trip by 120 hours per trip equals $55 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2024. To adjust $55 for inflation in FY 2025 and FY 2026, FDA multiplies it by the inflation factor (1.09355 or 9.355 percent), which results in an estimated cost of $60 per paid hour. That plus $316 in other costs per average supported direct work hour equals $376 per paid hour for each direct hour of work requiring foreign inspection travel. FDA will use this rate in charging fees in FY 2026 when travel is required for the third-party certification program.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2026

Fee category	Fee rates for FY 2026
Hourly rate without travel	$316
Hourly rate if travel is required	376

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. 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 2026.

TABLE 3—FSMA THIRD-PARTY CERTIFICATION PROGRAM USER FEE SCHEDULE FOR FY 2026

Fee category	Fee rates for FY 2026
Initial Application Fee for Accreditation Body Seeking Recognition	$53,440
Annual Fee for Recognized Accreditation Body	2,498
Annual Fee for Accredited Certification Body	3,122
Initial Application Fee for a Certification Body Seeking Direct Accreditation from FDA	53,440
Renewal Application Fee for Recognized Accreditation Body	32,724

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 ($316 per hour) to calculate the user fee attributable to those activities: $316/hour × (80 hours (application review) + 32 hours (written report)) = $35,392. We use the fully supported FTE hourly rate for work requiring travel ($376 per hour) to calculate the user fee for onsite performance evaluations, since historically most accreditation bodies are in foreign countries: $376/hour × 48 hours (*i.e.,* two fully supported FTEs × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) = $18,048. The estimated average cost of our total work for reviewing an application for recognition for an accreditation body based on these figures would be $35,392 + $18,048 = $53,440. Therefore, the application fee for accreditation bodies applying for recognition in FY 2026 will be $53,440.

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 $9,480 ($316/hour × (22 hours (records review) + 8 hours (written report))) plus $3,008 ($376/hour × 8 hours (onsite evaluation)), which is $12,488. Annualizing this amount over 5 years leads to an annual fee for recognized accreditation bodies of $2,498 for FY 2026.

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 $9,480 ($316/hour × (22 hours (records review) + 8 hours (written report))) plus $3,008 ($376/hour × 8 hours (onsite evaluation)), which is $12,488. Annualizing this amount over 4 years leads to an annual fee for accredited certification bodies of $3,122 for FY 2026.

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, $316 per hour, to calculate the portion of the user fee attributable to those activities: $316/hour × (80 hours (application review) + 32 hours (written report)) = $35,392. For the portion of the fee attributable to onsite performance evaluations, we use the fully supported FTE hourly rate for work requiring travel ($376 per hour) since historically most certification bodies are in foreign countries: $376/hour × 48 hours (*i.e.,* two fully supported FTEs × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) = $18,048. The estimated average cost of our work to review an application for direct accreditation of a certification body is $35,392 + $18,048 = $53,440. Therefore, the application fee for certification bodies applying for direct accreditation from FDA in FY 2026 will be $53,440.

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 ($316 per hour) to calculate the portion of the user fee attributable to those activities: $316/hour × (43 hours (application review) + 32 hours (written report)) = $23,700. For the portion of the fee attributable to onsite performance evaluations, we use the fully supported FTE hourly rate for work requiring travel ($376 per hour) since historically most accreditation bodies are in foreign countries: $3763/hour × 24 hours (*i.e.,* fully supported FTE × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) = $9,024. The estimated average cost of our work for reviewing a renewal application for recognition of an accreditation body is $23,700 + $9,024 = $32,724. Therefore, the renewal application fee for recognized accreditation bodies in FY 2026 will be $32,724.

IV. Estimated Fees for Accreditation Bodies and Certification Bodies in Other Fee Categories for FY 2026

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 2026
Renewal application fee for directly accredited certification body	$32,724
Annual fee for certification body directly accredited by FDA	25,152

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. Payment must be made within 30 days of receipt of billing for the fee (§ 1.715(b)). The payment is to be in U.S. currency drawn on a U.S. bank by electronic check, credit card, or wire transfer. 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*. (Note: The system only accepts full payments.) Alternatively, electronic invoices will have a ''Pay Now'' option that redirects 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 should be made using U.S. bank accounts or credit cards.

When paying by wire transfer, the invoice number should be 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, that amount should be added to the payment to ensure that the invoice is paid in full. For international wire transfers, please inquire with the financial institutions before 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.

The tax identification number of FDA 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.

Dated: July 25, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–14415 Filed 7–29–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–1731]

General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee; Amendment of Notice—Establishment of Public Docket; Request for Comments—Dermal Fillers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee (the Committee). This meeting was announced in the **Federal Register** of July 3, 2025. The amendment is being made to reflect a change in the **ADDRESSES** and **SUPPLEMENTARY INFORMATION** portions of the document. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Evella Washington, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2404, Silver Spring, MD 20993–0002, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 3, 2025 (90 FR 29570), FDA announced that a meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee would be held on August 13, 2025. On page 29570, in the first column, ''The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 13, 2025,'' the date portion of the document is changed to read as follows:

The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 13, 2025.

On page 29571, in the first column, ''Background material and the link to the online teleconference and/or video conferencing meeting will be available at the location of the advisory committee meeting and at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.html.* Scroll down to the appropriate advisory committee meeting link,'' the link to the website portion of the document is changed to read as follows:

Background material and the link to the online teleconference and/or video conferencing meeting will be available at the location of the advisory committee meeting and at *https://www.fda.gov/advisory-committees/advisory-committee-calendar.* Scroll down to the appropriate advisory committee meeting link.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*) and 21 CFR part 14, relating to the advisory committees.

Dated: July 25, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–14346 Filed 7–29–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–2362]

Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2026

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the fiscal year (FY) 2026 fee rates for certain domestic and foreign facility reinspections, failures to comply with a recall order, and importer reinspections that are authorized by the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA).

DATES: These fees apply to the period from October 1, 2025, and will remain in effect through September 30, 2026.

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, 10903 New Hampshire Ave, Silver Spring, MD 20993, 240–402–4989; or the User Fees Support Staff at *UFSS@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 743 of the FD&C Act (21 U.S.C. 379j-31) authorizes FDA to assess and collect fees from, in part: (1) the responsible party for each domestic facility and the U.S. agent for each foreign facility subject to a reinspection to cover reinspection-related costs; (2) the responsible party for a domestic facility and an importer who does not comply with a recall order to cover food recall activities associated with such order; and (3) each importer subject to a reinspection to cover reinspection-related costs (sections 743(a)(1)(A), (B), and (D) of the FD&C Act). Section 743 of the FD&C Act directs FDA to establish fees for each of these activities based on an estimate of 100 percent of the costs of each activity for each year (sections 743(b)(2)(A)(i), (ii), and (iv) of the FD&C Act), and these fees must be made available solely to pay for the costs of each activity for which the fee was incurred (section 743(b)(3) of the FD&C Act). These fees are effective on October 1, 2025, and will remain in effect through September 30, 2026.

In section 743(b)(2)(B)(iii) of the FD&C Act, Congress directed FDA to develop a proposed set of guidelines in consideration of the burden of fee amounts on small businesses. FDA issued guidance on this subject in October 2011 (2011 Fee Provision Guidance) (FDA Guidance for Industry, ''Implementation of the Fee Provisions of Section 107 of the FDA Food Safety Modernization Act'' (October 2011)). As stated in our 2011 Fee Provision Guidance, FDA recognizes that the full