Statutory Authority: The Consolidated Appropriations Act, 2023 (H.R. 2617).

Elizabeth Leo,

Grants Policy Branch Chief, Office of Grants Policy, Office of Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–7896]

Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates 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 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, 2026, and will remain in effect 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 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, 2026, and will remain in effect through September 30, 2027.

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 cost recovery of FDA reinspection or recall oversight could impose severe economic hardship for small businesses (id.). Therefore, as the 2011 Fee Provision Guidance explains, FDA intends to consider reducing certain fees for those firms (id.). Consistent with the 2011 Fee Provision Guidance, FDA does not intend to issue invoices for reinspection or recall order fees until FDA publishes a separate guidance document outlining the process through which firms may request a reduction in fees.

In addition, as stated in the 2011 Fee Provision Guidance, FDA is considering various issues associated with the assessment and collection of importer reinspection fees. The fee rates set forth in this notice will be used to determine any importer reinspection fees assessed in FY 2027.

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

FDA estimates 100 percent of its costs for each activity to establish fee rates for FY 2027 (see section 743(b)(2)(A) of the FD&C Act).

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, nonpayroll, 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, IT, 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, nonpayroll, 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 reinspection and recall order fees for FY 2027 before including domestic or foreign 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 fiscal year 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

TABLE 1—SUPPORTED DIRECT FDA WORK HOURS IN A PAID STAFF YEAR IN FY 2025—Continued

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 inspection 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, we estimate 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 that FDA has used consistently. 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** (90 FR 35866, July 30, 2025). Using the method set forth in section 736(c)(1) of the FD&C Act, FDA calculated an inflation rate of 5.0313 percent for FY 2026 and 4.7210 percent for FY 2027, and FDA intends to use these inflation rates to make inflation adjustments for FY 2028 for several of its user fee programs.

In FY 2025, FDA's Office of Inspections and Investigation (OII) spent a total of $10,002,278 for domestic regulatory inspection travel costs and General Services Administration Vehicle costs related to FDA's Human Foods Program (HFP) and Center for Veterinary Medicine (CVM) field activities programs.[1] The total OII domestic travel costs spent is then divided by the 9,485 HFP and CVM domestic inspections, which averages a total of $1,055 (rounded) per inspection. These inspections average 40.76 hours per inspection. Dividing $1,055 per inspection by 40.76 hours per inspection results in a total and an additional cost of $26 (rounded to the nearest dollar) per hour spent for domestic inspection travel costs in FY 2025. To adjust for the $26 per hour additional domestic cost inflation increases for FY 2026 and FY 2027, we multiply the FY 2026 PDUFA inflation rate adjustor (1.050313) times the FY 2027 PDUFA inflation rate adjustor (1.047210) times the $26 additional domestic cost, which results in an estimated cost of $29 (rounded to the nearest dollar) per paid hour in addition to $325 for a total of $354 per paid hour ($325 plus $29) for each direct hour of work requiring domestic inspection travel. FDA will use these rates in charging fees in FY 2027 when domestic travel is required.

In FY 2025, OII spent a total of $2,689,902 on 277 foreign inspection trips related to FDA's HFP and CVM field activities programs, which averaged a total of $9,711 per foreign inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing $9,711 per trip by 120 hours per trip results in a total and an additional cost of $81 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2025. To adjust $81 for inflationary increases in FY 2026, and FY 2027, FDA multiplies it by the same inflation factors mentioned previously in this document (1.050313 and 1.042710), which results in an estimated cost of $89 (rounded to the nearest dollar) per paid hour in addition to $325 for a total of $414 per paid hour ($325 plus $89) for each direct hour of work requiring foreign inspection travel. FDA will use these rates in charging fees in FY 2027 when foreign travel is required.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2027

Fee category	Fee rates for FY 2027
Hourly rate if domestic travel is required	$354
Hourly rate if foreign travel is required	414

[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.*

III. Fees for Reinspections of Domestic or Foreign Facilities Under Section 743(a)(1)(A) of the FD&C Act

A. What will cause this fee to be assessed?

The fee will be assessed for a reinspection conducted under section 704 of the FD&C Act (21 U.S.C. 374) to determine whether corrective actions have been implemented and are effective and compliance has been achieved to the Secretary of Health and Human Services' (the Secretary) (and, by delegation, FDA's) satisfaction at a facility that manufactures, processes, packs, or holds food for consumption necessitated as a result of a previous inspection (also conducted under section 704 of the FD&C Act) of this facility, which had a final classification of Official Action Indicated (OAI) conducted by or on behalf of FDA, when FDA determined the noncompliance was materially related to food safety requirements of the FD&C Act. FDA considers such noncompliance to include noncompliance with a statutory or regulatory requirement under section 402 of the FD&C Act (21 U.S.C. 342) and section 403(w) of the FD&C Act (21 U.S.C. 343(w)). However, FDA does not consider noncompliance that is materially related to a food safety requirement to include circumstances where the noncompliance is of a technical nature and not food safety related (*e.g.,* failure to comply with a food standard or incorrect font size on a food label). Determining when noncompliance, other than under sections 402 and 403(w) of the FD&C Act, is materially related to a food safety requirement of the FD&C Act may depend on the facts of a particular situation. FDA intends to issue guidance to provide additional information about the circumstances under which FDA would consider noncompliance to be materially related to a food safety requirement of the FD&C Act.

Under section 743(a)(1)(A) of the FD&C Act, FDA is directed to assess and collect fees from the responsible party for each domestic facility (as defined in section 415(b) of the FD&C Act (21 U.S.C. 350d(b))) and the U.S. agent for each foreign facility subject to a reinspection to cover reinspection-related costs.

Section 743(a)(2)(A)(i) of the FD&C Act defines the term ''reinspection'' with respect to domestic facilities as 1 or more inspections conducted under

section 704 of the FD&C Act subsequent to an inspection conducted under such provision which identified noncompliance materially related to a food safety requirement of this Act, specifically to determine whether compliance has been achieved to the Secretary's satisfaction.

The FD&C Act does not contain a definition of ''reinspection'' specific to foreign facilities. In order to give meaning to the language in section 743(a)(1)(A) of the FD&C Act to collect fees from the U.S. agent of a foreign facility subject to a reinspection, we are using the following definition of ''reinspection'' for purposes of assessing and collecting fees under section 743(a)(1)(A) of the FD&C Act, with respect to a foreign facility: ''1 or more inspections conducted by officers or employees duly designated by the Secretary subsequent to such an inspection which identified noncompliance materially related to a food safety requirement of the FD&C Act, specifically to determine whether compliance has been achieved to the Secretary's (and, by delegation, FDA's) satisfaction.''

This definition allows FDA to fulfill the mandate to assess and collect fees from the U.S. agent of a foreign facility in the event that an inspection reveals noncompliance materially related to a food safety requirement of the FD&C Act, causing one or more subsequent inspections to determine whether compliance has been achieved to the Secretary's (and, by delegation, FDA's) satisfaction. By requiring the initial inspection to be conducted by officers or employees duly designated by the Secretary, the definition ensures that a foreign facility would be subject to fees only in the event that FDA, or an entity designated to act on its behalf, has made the requisite identification at an initial inspection of noncompliance materially related to a food safety requirement of the FD&C Act. The definition of ''reinspection-related costs'' in section 743(a)(2)(B) of the FD&C Act relates to both a domestic facility reinspection and a foreign facility reinspection, as described in section 743(a)(1)(A) of the FD&C Act.

B. Who will be responsible for paying this fee?

The FD&C Act states that this fee is to be paid by the responsible party for each domestic facility (as defined in section 415(b) of the FD&C Act) and by the U.S. agent for each foreign facility (section 743(a)(1)(A) of the FD&C Act). This is the party to whom FDA will send the invoice for any fees that are assessed under this section.

C. How much will this fee be?

The fee is based on the number of direct hours spent on such reinspections, including time spent conducting the physical surveillance and/or compliance reinspection at the facility, or whatever components of such an inspection are deemed necessary, making preparations and arrangements for the reinspection, traveling to and from the facility, preparing any reports, analyzing any samples or examining any labels if required, and performing other activities as part of the OAI reinspection until the facility is again determined to be in compliance. The direct hours spent on each such reinspection will be billed at the appropriate hourly rate shown in table 2 of this document.

IV. Fees for Noncompliance With a Recall Order Under Section 743(a)(1)(B) of the FD&C Act

A. What will cause this fee to be assessed?

The fee will be assessed for not complying with a recall order under section 423(d) (21 U.S.C. 350l(d)) or section 412(f) of the FD&C Act (21 U.S.C. 350a(f)) to cover food recall activities associated with such order performed by the Secretary (and by delegation, FDA) (section 743(a)(1)(B) of the FD&C Act). Noncompliance may include the following: (1) not initiating a recall as ordered by FDA; (2) not conducting the recall in the manner specified by FDA in the recall order; or (3) not providing FDA with requested information regarding the recall, as ordered by FDA.

B. Who will be responsible for paying this fee?

Section 743(a)(1)(B) of the FD&C Act states that the fee is to be paid by the responsible party for a domestic facility (as defined in section 415(b) of the FD&C Act) and an importer who does not comply with a recall order under section 423 or under section 412(f) of the FD&C Act. In other words, the party paying the fee would be the party that received the recall order.

C. How much will this fee be?

The fee is based on the number of direct hours spent taking action in response to the firm's failure to comply with a recall order. Types of activities could include conducting recall audit checks, reviewing periodic status reports, analyzing the status reports and the results of the audit checks, conducting inspections, traveling to and from locations, and monitoring product disposition. The direct hours spent on each such recall will be billed at the appropriate hourly rate shown in table 2 of this document.

D. How must the fees be paid?

Section 743(a)(1)(A) and (B) of the FD&C Act require FDA to assess and collect reinspection and recall fees, as appropriate, from responsible parties for domestic and foreign food facilities. Further, section 743(a)(1)(D) requires FDA to assess and collect reinspection fees from importers. An invoice will be sent to the responsible party for paying the fee after FDA completes the work on which the invoice is based. 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. If a fee is not paid in full, the fee will be treated as a claim of the U.S. Government (see section 743(e)(2)

of the FD&C Act and 45 CFR part 30), meaning the invoice balance due amount is referred to collections.

V. What are the consequences of not paying these fees?

Under section 743(e)(2) of the FD&C Act and 45 CFR part 30, any fee that is not paid within 30 days after it is due shall be treated as a claim of the U.S. Government subject to provisions of subchapter II of chapter 37 of title 31, United States Code.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–7559]

Over-the-Counter Monograph Drug User Fee Rates for Fiscal Year 2027

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Over-the-Counter Monograph Drug User Fee Amendments (herein referred to as ''OMUFA II''), authorizes the Food and Drug Administration (FDA, the Agency, or we) to assess and collect user fees from qualifying manufacturers of over-the-counter (OTC) monograph drugs and submitters of OTC monograph order requests (OMORs) for fiscal years 2026 through 2030. This notice publishes the OMUFA fee rates for fiscal year (FY) 2027.

DATES: These fees are effective on October 1, 2026, and will remain in effect through September 30, 2027.

FOR FURTHER INFORMATION CONTACT: For more information on OTC monograph drug fees, visit FDA's website at: *https://www.fda.gov/industry/fda-user-fee-programs/over-counter-monograph-drug-user-fee-program-omufa. For questions relating 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 744M of the FD&C Act (21 U.S.C. 379j–72), as amended by OMUFA II,[1] authorizes FDA to assess and collect, for each of fiscal years 2026 through 2030: (1) facility fees from qualifying owners of OTC monograph drug facilities and (2) fees from submitters of qualifying OMORs. These fees are to support FDA's OTC monograph drug activities, which are detailed in section 744L(6) of the FD&C Act (21 U.S.C. 379j–71(6)) and include specified FDA activities associated with OTC monograph drugs. For OMUFA purposes:

- An OTC monograph drug is a nonprescription drug without an approved new drug application that is governed by the provisions of section 505G of the FD&C Act (21 U.S.C. 355h) (see section 744L(5) of the FD&C Act);
- An OTC monograph drug facility (MDF) is a foreign or domestic business or other entity that, in addition to meeting other criteria, is engaged in manufacturing or processing the finished dosage form of an OTC monograph drug (see section 744L(10) of the FD&C Act); and
- A contract manufacturing organization (CMO) facility is an OTC monograph drug facility where neither the owner nor any affiliate of the owner or facility sells the OTC monograph drug produced at such facility directly to wholesalers, retailers, or consumers in the United States (see section 744L(2) of the FD&C Act).
- An OMOR is a request for an administrative order, with respect to an OTC monograph drug, which is submitted under section 505G(b)(5) of the FD&C Act (see section 744L(7) of the FD&C Act).

Under section 744M(a)(1)(A) of the FD&C Act, a facility fee for FY 2027 shall be assessed with respect to each facility that is identified as an OTC monograph drug facility during the fee-liable period from January 1, 2026, through September 30, 2026.[2] Consistent with the statute, FDA will assess and collect facility fees with respect to the two types of OTC monograph drug facilities—MDF and CMO facilities. A full facility fee will be assessed to each qualifying person that owns a facility identified as an MDF (see section 744M(a)(1)(A) of the FD&C Act), and a reduced facility fee of two-thirds will be assessed to each qualifying person that owns a facility identified as a CMO facility (see section 744M(a)(1)(B)(ii) of the FD&C Act). The facility fees for FY 2027 are due in two equal installments, in a first installment representing 50 percent of such fee due on October 1, 2026, and in a second installment representing the remaining 50 percent of such fee due on February 1, 2027 (see section 744M(a)(1)(D)(ii) of the FD&C Act).[3]

As discussed in greater detail below, OTC monograph drug facilities are exempt from FY 2027 facility fees if they had ceased OTC monograph drug activities, and updated their registration with FDA to that effect, prior to January 1, 2026 (see section 744M(a)(1)(B)(i)(I)(bb) of the FD&C Act).

In addition to facility fees, the Agency is authorized to assess and collect fees from submitters of OMORs, except for OMORs that request certain safety-related changes (as discussed below). There are two levels of OMOR fees, based on whether the OMOR at issue is a Tier 1 or Tier 2 OMOR.[4]

For FY 2027, the OMUFA fee rates are: MDF facility fees ($47,891), CMO facility fees ($31,927), Tier 1 OMOR fees ($614,608), and Tier 2 OMOR fees ($122,921). These fees are effective for the period from October 1, 2026, through September 30, 2027.[5] This document is issued pursuant to section 744M(a)(4) and 744M(c)(5) of the FD&C Act and describes the calculations used to set the OMUFA facility fees and OMOR fees for FY 2027 in accordance with the directives in the statute.

II. Facility Fee Revenue Amount for FY 2027

Under OMUFA, FDA sets annual facility fees to generate the total facility fee revenues for each fiscal year established by section 744M(b) of the FD&C Act. The yearly base revenue amount is the starting point for setting annual facility fee rates. The base revenue for FY 2027 is the dollar amount of the total revenue amount for the previous fiscal year, without certain adjustments made for that previous

[1] Over-the-Counter Monograph Drug User Fee Amendments, title V of Division F of the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 (Pub. L. 119–37).

[2] Under section 744M(a)(1)(A)(i) of the FD&C Act, ''Each person that owns a facility identified as an OTC monograph drug facility at any time during the applicable period . . . for a fiscal year shall be assessed an annual fee for each such facility''. The applicable period for FY 2027 is the 9-month period ending September 30, 2026, per section 744M(a)(1)(A)(ii)(II) of the FD&C Act.

[3] Assuming that, as we anticipate, the FY 2027 fee appropriation will occur prior to October 1, 2026 for the first installment and prior to February 1, 2027, for the second installment of such fee. See section 744M(a)(1)(D)(ii) of the FD&C Act with respect to the due date for the two payment installments in relation to the timing of an OMUFA fee appropriation for fiscal year 2027.

[4] Under OMUFA, a Tier 1 OMOR is defined as any OMOR that is not a Tier 2 OMOR (see section 744L(8) of the FD&C Act). Tier 2 OMORs are detailed in section 744L(9) of the FD&C Act.

[5] These OMUFA facility fees are for FY 2027, per section 744M(a) of the FD&C Act.