safety issue otherwise unreported under the MDR regulation. The report should also include any subsequent change to the preamendments class III device requiring a 30-day notice in accordance with 21 CFR 814.39(f).

Blood collection establishments and transfusion services, the intended users of the device, and the device manufacturers have certain responsibilities under the Federal regulations. For example, collection establishments and or transfusion services are required to maintain records of any reports of complaints of adverse reactions (21 CFR 606.170), while the device manufacturer is responsible for conducting an investigation of each event that is reasonably known to the manufacturer and evaluating the cause of the event (§ 803.50(b) (21 CFR 803.50(b))). In addition, manufacturers of medical devices are required to submit to FDA individual adverse event reports of death, serious injury, and malfunctions (§ 803.50).

Other burden hours required for § 864.9245 are reported and approved under OMB control number 0910–0120 (premarket notification submission 510(k), 21 CFR part 807, subpart E), and OMB control number 0910–0437 (MDR, part 803).

Based on a review of the information collection from our last request for OMB approval, we estimate that the number of manufacturers of automated blood cell separator devices remains unchanged. As a result, we have made no adjustments to our burden estimates.

Dated: July 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16831 Filed 7–30–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3382]

Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the fiscal year (FY) 2025 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, 2024, and will remain in effect through September 30, 2025.

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 20903, 240–402–4989; or the User Fees Support Staff at *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 107 of the FSMA (Pub. L. 111–353) added section 743 to the FD&C Act (21 U.S.C. 379j–31) to provide FDA with the authority 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 [1] 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)), 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)). These fees are effective on October 1, 2024, and will remain in effect through September 30, 2025. Section 743(b)(2)(B)(iii) of the FD&C Act directs FDA to develop a proposed set of guidelines in consideration of the burden of fee amounts on small businesses. As a first step in developing these guidelines, FDA invited public comment on the potential impact of the fees authorized by section 743 of the FD&C Act on small businesses (76 FR 45818, August 1, 2011). The comment period for this request ended November 30, 2011. As stated in FDA's October 2011 ''Guidance for Industry: Implementation of the Fee Provisions of Section 107 of the FDA Food Safety Modernization Act'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-implementation-fee-provisions-section-107-fda-food-safety-modernization-act*), because FDA recognizes that for small businesses the full cost recovery of FDA reinspection or recall oversight could impose severe economic hardship, FDA intends to consider reducing certain fees for those firms. FDA does not intend to issue invoices for reinspection or recall order fees until FDA publishes a guidance document outlining the process through which firms may request a reduction in fees.

In addition, as stated in the October 2011 Guidance, FDA is in the process of 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 2025.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2025

FDA is required to estimate 100 percent of its costs for each activity in order to establish fee rates for FY 2025. 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 the remaining funds (operating funds) available to FDA are used to support FDA employees by paying for rent, travel, utility, information technology (IT), and other operating costs.

A. Estimating the Full Cost per Direct Work Hour in FY 2025

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, nonpayroll, and rent.

We have used an average of past year cost elements to predict the FY 2025 cost. The FY 2025 FDA-wide average cost for payroll (salaries and benefits) is

[1] The term ''food'' for purposes of this document has the same meaning as such term in section 201(f) of the FD&C Act (21 U.S.C. 321(f)).

$213,556; non-payroll (including equipment, supplies, IT, general and administrative overhead) is $131,739; and rent (including cost allocation analysis and adjustments for other rent and rent-related costs) is $23,750 per paid staff year, excluding travel costs.

Summing the average cost of an FTE for payroll, nonpayroll, and rent, brings the FY 2025 average fully supported cost to $369,046 [2] 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 2025 prior to including domestic or foreign travel costs as applicable for the activity.

To calculate an hourly rate, FDA must divide the FY 2025 average fully supported cost of $369,046 per FTE by the average number of supported direct FDA work hours in FY 2023 (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 2023

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 2025 ($369,046) by the total number of supported direct work hours available for assignment in FY 2023 (1,160) results in an average fully supported cost of $318 (rounded to the nearest dollar), excluding inspection travel costs, per supported direct work hour in FY 2025.

B. Adjusting FY 2023 Travel Costs for Inflation To Estimate FY 2025 Travel Costs

To adjust the hourly rate for FY 2025, FDA must estimate the cost of inflation in each year for FY 2024 and FY 2025. 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 2024 inflation rate to be 3.8896 percent; this rate was published in the FY 2024 PDUFA user fee rates notice in the **Federal Register** (88 FR 48881, July 28, 2023). Utilizing the method set forth in section 736(c)(1) of the FD&C Act, FDA has calculated an inflation rate of 3.8896 percent for FY 2024 and 4.1167 percent for FY 2025, and FDA intends to use these inflation rates to make inflation adjustments for FY 2025 for several of its user fee programs; the derivation of this rate will be published in the **Federal Register** in the FY 2025 notice for the PDUFA user fee rates.

The average fully supported cost per supported direct FDA work hour, excluding travel costs, of $318 already takes into account inflation as the calculation above is based on FY 2025 predicted costs. FDA will use this base unit fee in determining the hourly fee rate for reinspection and recall order fees for FY 2025 prior to including domestic or foreign travel costs as applicable for the activity. In FY 2023, FDA's Office of Regulatory Affairs (ORA) spent a total of $7,463,679 for domestic regulatory inspection travel costs and General Services Administration Vehicle costs related to FDA's Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM) field activities programs. The total ORA domestic travel costs spent is then divided by the 8,811 CFSAN and CVM domestic inspections, which averages a total of $847 per inspection. These inspections average 41.35 hours per inspection. Dividing $847 per inspection by 41.35 hours per inspection results in a total and an additional cost of $20 (rounded to the nearest dollar) per hour spent for domestic inspection travel costs in FY 2023. To adjust for the $20 per hour additional domestic cost inflation increases for FY 2024 and FY 2025, FDA must multiply the FY 2024 PDUFA inflation rate adjustor (1.038896) times the FY 2025 PDUFA inflation rate adjustor (1.041167) times the $20 additional domestic cost, which results in an estimated cost of $22 (rounded to the nearest dollar) per paid hour in addition to $318 for a total of $340 per paid hour ($318 plus $22) for each direct hour of work requiring domestic inspection travel. FDA will use these rates in charging fees in FY 2025 when domestic travel is required.

In FY 2023, ORA spent a total of $2,629,906 on 431 foreign inspection trips related to FDA's CFSAN and CVM field activities programs, which averaged a total of $6,102 per foreign inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing $6,102 per trip by 120 hours per trip results in a total and an additional cost of $51 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2023. To adjust $51 for inflationary increases in FY 2024, and FY 2025, FDA must multiply it by the same inflation factors mentioned previously in this document (1.038896 and 1.041167), which results in an estimated cost of $55 (rounded to the nearest dollar) per paid hour in addition to $318 for a total of $373 per paid hour ($318 plus $55) for each direct hour of work requiring foreign inspection travel. FDA will use these rates in charging fees in FY 2025 when foreign travel is required.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2025

Fee category	Fee rates for FY 2025
Hourly rate if domestic travel is required	$340
Hourly rate if foreign travel is required	373

III. Fees for Reinspections of Domestic or Foreign Facilities Under Section 743(a)(1)(A)

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 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

[2] Total includes rounding.

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) (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 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, the Agency is using the following definition of ''reinspection'' for purposes of assessing and collecting fees under section 743(a)(1)(A), 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).

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)

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?

An invoice will be sent to the responsible party for paying the fee after FDA completes the work on which the invoice is based. Payment must be made within 30 days of the invoice date in U.S. currency by electronic check, credit card, check, bank draft, U.S. postal money order, or wire transfer payable to the order of the Food and Drug Administration. Detailed payment information will be included with the invoice when it is issued.

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

Under section 743(e)(2) of the FD&C Act, 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.

Dated: July 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16877 Filed 7–30–24; 8:45 am]

BILLING CODE 4164–01–P