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

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 2026.

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

FDA estimates 100 percent of its costs for each activity to establish fee rates for FY 2026 (see section 743(b)(2)(A) of the FD&C Act).

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, nonpayroll, 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, IT, 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, nonpayroll, 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 reinspection and recall order fees for FY 2026 before including domestic or foreign 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 fiscal year 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 inspection 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, we estimate 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 that FDA has used consistently. 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** (89 FR 61474, July 31, 2024). Using the method set forth in section 736(c)(1) of the FD&C Act, FDA calculated an inflation rate of 4.1167 percent for FY 2025 and 5.0313 percent for FY 2026, and FDA intends to use these inflation rates to make inflation adjustments for FY 2026 for several of its user fee programs.

In FY 2024, FDA's Office of Regulatory Affairs (ORA) spent a total of $7,498,059 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 7,851 CFSAN and CVM domestic inspections, which averages a total of $955 per inspection. These inspections average 45.09 hours per inspection. Dividing $955 per inspection by 45.09 hours per inspection results in a total and an additional cost of $21 (rounded to the nearest dollar) per hour spent for domestic inspection travel costs in FY 2024. To adjust for the $21 per hour additional domestic cost inflation increases for FY 2025 and FY 2026, we multiply the FY 2025 PDUFA inflation rate adjustor (1.041167) times the FY 2026 PDUFA inflation rate adjustor (1.050313) times the $21 additional domestic cost, which results in an estimated cost of $23 (rounded to the nearest dollar) per paid hour in addition to $316 for a total of $339 per paid hour ($316 plus $23) for each direct hour of work requiring domestic inspection travel. FDA will use these rates in charging fees in FY 2026 when domestic travel is required.

In FY 2024, ORA spent a total of $3,209,026 on 487 foreign inspection trips related to FDA's CFSAN and CVM field activities programs, which averaged a total of $6,589 per foreign

inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing $6,589 per trip by 120 hours per trip results in a total and an additional cost of $55 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2024. To adjust $55 for inflationary increases in FY 2025, and FY 2026, FDA multiplies it by the same inflation factors mentioned previously in this document (1.041167 and 1.050313), which results in an estimated cost of $60 (rounded to the nearest dollar) per paid hour in addition to $316 for a total of $376 per paid hour ($316 plus $60) for each direct hour of work requiring foreign inspection travel. FDA will use these rates in charging fees in FY 2026 when foreign travel is required.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2026

Fee category	Fee rates for FY 2026
Hourly rate if domestic travel is required	$339
Hourly rate if foreign travel is required	376

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. Payment is to be made within 30 days of the invoice date in U.S. currency by electronic check, credit card, or wire transfer. 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 25, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–14414 Filed 7–29–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; The Stem Cell Therapeutic Outcomes Database

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than August 29, 2025.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The Stem Cell Therapeutic Outcomes Database OMB No. 0915–0310—Revision.

Abstract: The Stem Cell Therapeutic and Research Act of 2005 (Pub. L. 109–129, December 20, 2005) as amended and codified in Section 379A of the Public Health Service Act (42 U.S.C. 247l), provides for the collection and maintenance of human blood stem cells for the treatment of patients and research. The Public Health Service Act requires the Secretary of HHS to contract for the establishment and maintenance of information related to patients who have received stem cell therapeutic products and to do so using an electronic format. HRSA has established the Stem Cell Therapeutic Outcomes Database (SCTOD), a component of the C.W. Bill Young Cell Transplantation Program (Program), which necessitates certain electronic record-keeping and reporting requirements to perform functions related to hematopoietic stem cell transplantation (HCT) under contract to HHS. Data are collected from transplant centers by the Center for International Blood and Marrow Transplant Research. They are used for ongoing analysis of transplant outcomes to improve treatment and survival for patients who may benefit from cellular therapies.

The proposed revisions to this ICR reflect the most up-to-date medical evidence while also reducing the burden on hematopoietic stem cell transplantation facilities. Revisions fall into several categories: consolidating questions, implementing interactive requests (such as electronic check boxes, ''check all that apply,'' and pull-down menus) to reduce data entry time, adding necessary information fields, clarifying information requests, and removing items that are no longer clinically significant.

Over time, there is an expected increase in the information reported as the number of transplants performed annually increases and survivorship after transplantation improves. Similarly, because of the ongoing rapid evolution in transplant indications, methods to establish diagnoses, disease prognostic factors, treatments provided before HCT, methods to determine donor matching, and transplantation techniques, the Program anticipates incremental changes in the information collected by the SCTOD after OMB approval to reflect current clinical care, facilitate statistical modeling throughout the approval period to fulfill Program requirements, keep pace with changes in the field, and to enhance the ability to collect information in an automated fashion from respondent source systems, such as electronic health records. Interim updates to the information collected about disease indications, disease definitions, and disease prognostic factors will be triggered by the publication of peer-reviewed scientific articles or public reference materials of updated criteria by organizations such as the World Health Organization, national or international scientific consensus panels (*e.g.,* European LeukemiaNet, International Working Group for Prognosis in MDS), or similar. The updates mentioned above are anticipated to be reflected as changes in