

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]

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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.

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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