TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; guidance section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Meeting Requests					
Combining and sending meeting request letters for manufacturers, importers, and researchers; Guidance section III.E	60	1	60	12	720
Meeting Information Packages					
Combining and submitting meeting information packages for manufacturers, importers, and researchers; Guidance section III.K	60	1	60	18	1,080
Total					1,800

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA's estimate of the number of respondents for meeting requests in table 1 is based on the number of meeting requests received and projected over the next 3 years. FDA estimates that 60 meetings will be requested over the next 3 years. We have revised this estimate from 65 respondents to 60 respondents.

The hours per response for combining and sending meeting request letters are estimated at 12 hours each, and the total burden hours for meeting requests are expected to be 720 hours. We have revised the average burden per response from 10 hours to 12 hours. Based on FDA's experience, the Agency expects it will take respondents 720 hours to prepare, gather, copy, and submit brief statements about the product and a description of the purpose and details of the meeting, including identifying prior FDA employment for any individual who will attend the meeting on behalf of the tobacco product manufacturer, importer, researcher, or investigator.

FDA estimates that 60 respondents will compile and submit meeting information packages at 18 hours per response, and the total burden hours for submitting meeting information packages are expected to be 1,080 hours. We have revised this estimate from 65 respondents to 60 respondents. Based on FDA's experience, the Agency expects that it will take respondents, collectively, 1,080 hours to gather, copy, and submit brief statements about the product, a description of the details of the anticipated meeting, and data and information, that generally would already have been generated for the planned research and/or product development.

The total number of burden hours for this collection of information is estimated to be 1,800 hours (720 hours to prepare and submit meeting requests and 1,080 hours to prepare and submit information packages).

Our estimated burden for the information collection reflects an overall decrease of 20 hours. We attribute this adjustment to a decrease in the number of submissions we received over the last few years and our projections for the next 3 years.

Dated: June 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11948 Filed 6–26–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–2253]

Medical Device User Fee Amendments; Stakeholder Meetings on the Medical Device User Fee Amendments of Fiscal Years 2028 to 2032 Reauthorization; Request for Notification of Stakeholder Intention To Participate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing this notice to request that public stakeholders—including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts—notify FDA of their intent to participate in periodic consultation meetings on the reauthorization of the Medical Device User Fee Amendments (MDUFA). The statutory authority for MDUFA expires September 30, 2027. At that time, new legislation will be required for FDA to continue collecting user fees for the medical device program. The Federal Food, Drug, and Cosmetic Act (FD&C Act) requires that FDA consult with a range of stakeholders in developing recommendations for the next MDUFA program. The FD&C Act also requires that FDA hold discussions (at least every month) with patient and consumer advocacy groups during FDA's negotiations with the regulated industry. The purpose of this request for notification is to ensure continuity and progress in these monthly discussions by establishing consistent stakeholder representation.

DATES: Submit notification of intention to participate in these series of meetings on or before July 28, 2025. Stakeholder meetings will be held monthly. It is anticipated that they will commence by October 2025. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: Submit notification of intention to participate in monthly stakeholder meetings by email to *MDUFAVIReauthorization@fda.hhs.gov.* The meetings will be held in person at the FDA White Oak campus, 10903 New Hampshire Ave., Silver Spring, MD 20993 and virtually using the Microsoft Teams platform. Participants must be REAL ID compliant to access federal facilities. For additional information regarding REAL ID, refer to *https://www.dhs.gov/real-id/real-id-faqs.*

FOR FURTHER INFORMATION CONTACT: Nia Benjamin, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993–0002, 301–796–5424, *MDUFAVIReauthorization@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is requesting that public stakeholders—including patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts—notify the Agency of

their intent to participate in periodic stakeholder consultation meetings on the reauthorization of MDUFA. MDUFA authorizes FDA to collect user fees from the regulated industry for the process for the review of medical devices. The authorization for the current program (MDUFA V) expires September 30, 2027.

Section 738A(b)(1) of the FD&C Act (21 U.S.C. 379j–1(b)(1)) requires that FDA consult with a range of stakeholders, including representatives from patient and consumer advocacy groups, healthcare professionals, and scientific and academic experts, in developing recommendations for the next MDUFA program. FDA will initiate the reauthorization process by holding a public meeting on August 4, 2025, where stakeholders and other members of the public will be given an opportunity to present their views on the reauthorization. The FD&C Act further requires that FDA continue meeting with the representatives of patient and consumer advocacy groups at least once every month during negotiations with the regulated industry to continue discussions of stakeholder views on the reauthorization. It is anticipated that these monthly stakeholder consultation meetings will commence by October 2025.

FDA is issuing this **Federal Register** notice to request that stakeholder representatives from patient and consumer advocacy groups, healthcare professional associations, as well as scientific and academic experts, notify FDA of their intent to participate in the periodic stakeholder consultation meetings on MDUFA reauthorization. FDA believes that consistent stakeholder representation at these meetings will be important to ensure progress in these discussions. If you wish to participate in the stakeholder consultation meetings, please designate one or more representatives from your organization who will commit to attending these meetings and preparing for the discussions. Stakeholders who identify themselves through this notice, and are otherwise eligible to attend, may participate in all stakeholder consultation discussions while FDA negotiates with the regulated industry. These stakeholder discussions will satisfy the consultation requirement in section 738A(b)(3) of the FD&C Act (21 U.S.C. 379j–1(b)(3)).

II. Notification of Intent To Participate in Periodic Stakeholder Consultation Meetings

If you intend to participate in continued periodic stakeholder consultation meetings regarding MDUFA reauthorization, please provide notification by email to *MDUFAVIReauthorization@fda.hhs.gov* on or before July 28, 2025. Your email should contain complete contact information, including name, title, affiliation, address, email address, phone number, and notice of any special accommodations required because of disability. Stakeholders will receive confirmation and additional information about the first meeting after FDA receives this notification.

Dated: June 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11911 Filed 6–26–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–1687]

Change in Federal Payment and Collection Options

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is providing notice that, effective October 1, 2025, it will no longer use paper-based (checks, bank drafts, money orders, etc.) methods for federal payments (any payment made by an agency) or collections (the transfer of monies from a source outside the Federal Government to an agency or to a financial institution acting as an agent of the Government) except in limited circumstances where an exemption or waiver exists.

FOR FURTHER INFORMATION CONTACT: 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 *OO-OFBA-OFM-UFSS-Government@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Federal payments will be made electronically unless the recipient qualifies for a waiver under 31 CFR part 208. All collections will be processed electronically unless the individuals or entities do not have access to banking services or electronic payment systems; or they qualify for an exception under applicable law. These changes do not apply to national security- or law enforcement-related activities where non-electronic fund transfer transactions are necessary or desirable.

This policy aligns with Executive Order (E.O.) 14247, *Advancing Federal Digital Services,* which directs agencies to improve public-facing digital services and reduce reliance on outdated, manual, or paper-based processes, and E.O. 14249, *Modernizing Financial Transactions,* requiring modernization of federal financial transactions by accelerating the shift toward secure electronic payments and collections, phasing out inefficient legacy methods.

This change has a direct impact on the fiscal year 2026 collections for the following FDA User Fee programs:

- Animal Drug User Fee Act (ADUFA)
- Animal Generic Drug User Fee Act (AGDUFA)
- Prescription Drug User Fee Amendments (PDUFA)
- Medical Device User Fee Amendments (MDUFA)
- Generic Drug User Fee Amendments (GDUFA)
- Biosimilar User Fee Amendments (BsUFA)
- Over-the-Counter Monograph Drug User Fee Program (OMUFA)
- Food Safety Modernization Act (FSMA)
- Compounding Quality Act (CQA)
- Priority Review Vouchers (PRV)
- Mammography Quality Standards Act (MQSA)
- Tobacco User Fees under Section 919 of the Federal Food, Drug, and Cosmetic Act (FD&C Act)
- Export Certificates under Section 801(e)(4)(B) of the FD&C Act
- Color Additive Certification under section 721 of the FD&C Act
- Fees collected under the Freedom of Information Act.

Individuals, corporations, or other public or private entities that qualify for an exemption from the use of electronic funds transfers should reach out to the User Fees Support Staff at *OO-OFBA-OFM-UFSS-Government@fda.hhs.gov* for assistance.

II. Electronic Collection Methods

Beginning on October 1, 2025, payments made to FDA must be made 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