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

payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website upon receipt of an invoice or after completing the User Fee Cover Sheet and generating the user fee ID number.

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 or cover sheet 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 as well as U.S. credit cards.

For payments made by wire transfer, include the unique user fee ID or invoice number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID or invoice number, the payment may not be applied. If the payment amount is not applied, the invoice balance due amount will be referred to collections. 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.

III. Electronic Federal Payment Methods

All entities receiving funds from FDA, including but not limited to vendors or other entities receiving reimbursements or refunds, must have a valid and active electronic payment method on file with the Agency, such as ACH Direct Deposit or other Treasury-authorized payment methods (FedWire or International ACH). Failure to provide this information may result in delays in payment or inability to receive funds.

Dated: June 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11920 Filed 6–26–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0351]

Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Health Document Submission

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection associated with tobacco health document submissions.

DATES: Either electronic or written comments on the collection of information must be submitted by August 26, 2025.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 26, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2025–N–0351 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Health Document Submission.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as