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 (EO) 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Federal Digital Services*, which directs agencies to improve public-facing digital services and reduce reliance on outdated, manual, or paper-based processes, and EO 14249, *Modernizing Financial Transactions*, requiring modernization of federal financial transactions by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.

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