

supported FTE hourly rate for work requiring domestic travel, \$354/hour, to calculate the portion of the user fee attributable to those activities: $\$354/\text{hour} \times 8 \text{ hours (i.e., one fully supported FTE} \times (1 \text{ day onsite} \times 8 \text{ hours})) = \$2,832$. Therefore, the total cost of conducting the domestic performance evaluation of a VQIP importer is determined to be $\$2,600 + \$2,832 = \$5,432$.

Coordination of the onsite performance evaluation of a foreign VQIP importer is estimated to take place at an FTE's worksite, so we use the fully supported FTE hourly rate excluding travel, \$325/hour, to calculate the portion of the user fee attributable to those activities: $\$325/\text{hour} \times (10 \text{ hours}) = \$3,250$. For the portion of the fee covering onsite evaluation of a foreign VQIP importer, we use the fully supported FTE hourly rate for work requiring foreign travel, \$414/hour, to calculate the portion of the user fee attributable to those activities: $\$414/\text{hour} \times 24 \text{ hours (i.e., one fully supported FTE} \times ((2 \text{ travel days} \times 8 \text{ hours}) + (1 \text{ day onsite} \times 8 \text{ hours}))) = \$9,936$. Therefore, the total cost of conducting the foreign performance evaluation of a VQIP importer is determined to be $\$3,250 + \$9,936 = \$13,186$.

Therefore, the estimated average cost of the work FDA performs in total for approving an application for a VQIP importer in FY 2027 based on these figures would be $(\$12,675 \times \frac{1}{4}) + (\$9,100 \times \frac{3}{4}) = \$9,994$.

IV. How must the fee be paid?

Section 743(a)(1)(C) of the FD&C Act requires FDA to assess and collect user fees from each importer participating in VQIP. An invoice will be sent to VQIP importers approved to participate in the program. Payment are to be made before October 1, 2026, to be eligible for VQIP participation for the benefit year beginning October 1, 2026. FDA will not refund the VQIP user fee for any reason.

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.

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 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 or U.S. credit cards.

For payments made by wire transfer, include the invoice number to ensure that the payment is applied to the correct fee(s). Without the invoice number, the payment may not be applied. 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.

V. What are the consequences of not paying this fee?

The consequences of not paying these fees are outlined in Section J of our Guidance for Industry, "FDA's Voluntary Qualified Importer Program" (November 2024) (available at <https://www.fda.gov/media/92196/download>). If the user fee is not paid before October 1, a VQIP importer will not be eligible to participate in VQIP. For the first year a VQIP application is approved, if the user fee is not paid before October 1, 2026, you are not eligible to participate in VQIP. If you subsequently pay the user fee, FDA will begin your benefits after we receive the full payment. The user fee may not be paid after December 31, 2026. For a subsequent year, if you do not pay the user fee before October 1, FDA will send a Notice of Intent to Revoke your participation in VQIP. If you do not pay the user fee within 30 days of the date of the Notice of Intent to Revoke, we will revoke your participation in VQIP.

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-2026-N-2526]

Butylated Hydroxytoluene (BHT); Request for Information; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the notice titled "Butylated Hydroxytoluene (BHT); Request for Information," which published in the **Federal Register** of May 13, 2026. We are taking this action in response to a request from stakeholders to extend the comment period to allow additional time for interested parties to develop and submit data, other information, and comments for this request for information.

DATES: FDA is reopening the comment period on the notice "Butylated Hydroxytoluene (BHT); Request for Information," which published in the **Federal Register** on May 13, 2026 (91 FR 27054). Submit either electronic or written comments by August 31, 2026.

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 31, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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-2026-N-2526 for “Butylated Hydroxytoluene (BHT); Request for Information.” 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.” We 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 “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For

more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: John Steele, Office of Food Chemical Safety, Dietary Supplements, and Innovation, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 301-796-1976; or Lauren Kleinman, Office of Policy and International Engagement, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2378.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 13, 2026 (91 FR 27054), FDA published a notice with a 60-day comment period to request information on the current uses and safety data for BHT in human food and as a food contact substance. We originally gave interested persons until July 13, 2026, to provide data and information.

Following publication of the notice, FDA received a request to allow interested parties additional time to comment. The request asserted that 60 days was insufficient to allow impacted stakeholders to develop a complete and scientifically robust submission, particularly due to supply chain communications. We have considered this request, and, because the request came too late for us to extend the comment period before it expired, we are reopening the comment period for 30 days. FDA believes that these additional 30 days will allow time for interested parties to submit data and other information to support our post-market assessment of the safety of BHT in food and as a food contact substance.

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-2026-N-7558]

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2027

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the fee rates and payment procedures for fiscal year (FY) 2027 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Drug User Fee Amendments of 2023 (ADUFA V), authorizes FDA to collect user fees for certain animal drug applications and supplemental animal drug applications, for certain animal drug products, for certain establishments where such products are made, and for certain sponsors of such animal drug applications and/or investigational animal drug submissions. This notice establishes the fee rates for FY 2027.

DATES: The application fee rates apply to applications submitted on or after October 1, 2026, and will remain in effect through September 30, 2027.

FOR FURTHER INFORMATION CONTACT: Visit FDA’s website at: <https://www.fda.gov/industry/fda-user-fee-programs/animal-drug-user-fee-act-adufa>. For general questions, you may also email FDA’s Center for Veterinary Medicine (CVM) at: cvmadufa@fda.hhs.gov. For questions relating to this notice: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 301-796-7900; or FDAUserFees@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Section 740(a) of the FD&C Act (21 U.S.C. 379j-12), as amended by ADUFA V, establishes four different types of user fees: (1) fees for certain animal drug applications and supplemental animal drug applications; (2) annual fees for certain animal drug products; (3) annual fees for certain establishments where such products are made; and (4) annual fees for certain sponsors of animal drug applications and/or investigational animal drug submissions. When certain conditions are met, FDA will waive or reduce fees per section 740(d) of the FD&C Act.

For FYs 2024 through 2028, section 740(b)(1) of the FD&C Act establishes