4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2025-N-2359]

Food Safety Modernization Act Voluntary Qualified Importer Program User Fee Rate 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 annual fee rate for importers approved to participate in the Voluntary Qualified Importer Program (VQIP) that is authorized by the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA). This fee is effective on August 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 806 of the FD&C Act (21 U.S.C. 384b) directs FDA to establish a program to provide for the expedited review and importation of food offered for importation by importers who have voluntarily agreed to participate in such program, and a process, consistent with section 808 of the FD&C Act (21 U.S.C. 384d), for the issuance of a facility certification to accompany a food offered for importation by importers participating in VQIP.

Section 743 of the FD&C Act (21 U.S.C. 379j-31) authorizes FDA to assess and collect fees from each importer participating in VQIP to cover FDA's costs of administering the

program. Each fiscal year, fees are to be established based on an estimate of 100 percent of the costs for the year (section 743(b)(2)(A)(iii) of the FD&C Act). The fee rates must be published in a *Federal Register* notice not later than 60 days before the start of each fiscal year (section 743(b)(1) of the FD&C Act). After FDA approves a VQIP application, the user fee is to be paid before October 1, the start of the VQIP fiscal year, to begin receiving benefits for that VQIP fiscal year.

The FY 2026 VQIP user fee will support benefits from October 1, 2025, through September 30, 2026.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2026

FDA estimates 100 percent of its costs for each activity to establish fee rates for FY 2026 (see section 743(b)(2)(A) of the FD&C Act).

A. Estimating the Full Cost per Direct Work Hour in FY 2026

Full-time Equivalent (FTE) reflects the total number of regular straight-time hours--not including overtime or holiday hours--worked by employees, divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off, and other approved leave categories are considered "hours worked" for purposes of defining FTE employment.

In general, the starting point for estimating the full cost per direct work hour is to estimate the cost of an FTE or paid staff year. Calculating an FDA-wide total cost per FTE requires three primary cost elements: payroll, non-payroll, and rent.

We used an average of past year cost elements to predict the FY 2026 cost. The FY 2026 FDA-wide average cost for payroll (salaries and benefits) is $225,917; non-payroll -- including equipment, supplies, IT, general and administrative overhead -- is $116,581; and rent, including cost allocation analysis and adjustments for other rent and rent-related costs, is $24,627 per paid staff year, excluding travel costs.

Summing the average cost of an FTE for payroll, non-payroll, and rent, brings the FY 2026 average fully supported cost to $367,125 (total includes rounding) per FTE, excluding travel costs. FDA will use this base unit fee in determining the hourly fee rate for VQIP fees for FY 2026 before including domestic or foreign travel costs as applicable for the activity.

To calculate an hourly rate, we divide the FY 2026 average fully supported cost of $367,125 per FTE by the average number of supported direct FDA work hours in FY 2024 -- the last FY for which data are available. See table 1.

Table 1.--Supported Direct FDA Work Hours in a Paid Staff Year in FY 2024

Total number of hours in a paid staff year	2,080
Less:	
11 paid holidays	-88
20 days of annual leave	-160
10 days of sick leave	-80
12.5 days of training	-100
22 days of general administration	-176
26.5 days of travel	-212
2 hours of meetings per week	-104
Net Supported Direct FDA Work Hours Available for Assignments	1,160

Dividing the average fully supported FTE cost in FY 2026 ($367,125) by the total number of supported direct work hours available for assignment in FY 2024 (1,160) results in an average fully supported cost of $316 (rounded to the nearest dollar), excluding inspection travel costs, per supported direct work hour in FY 2026.

B. Adjusting FY 2024 Travel Costs for Inflation to Estimate FY 2025 Travel Costs

To adjust the hourly rate for FY 2026, FDA estimates the cost of inflation in each year for FYs 2025 and 2026. FDA uses the method prescribed for estimating inflationary costs under the Prescription Drug User Fee Act (PDUFA) provisions of the FD&C Act (section 736(c)(1) of the FD&C Act (21 U.S.C. 379h(c)(1))), the statutory method for inflation adjustment in the FD&C Act that FDA has used consistently. FDA previously determined the FY 2025 inflation rate to be 4.1167 percent; this rate was published in the FY 2025 PDUFA user fee rates notice in the *Federal Register* (July 31, 2024, 89 FR 61474). Using the method set forth in section

736(c)(1) of the FD&C Act, FDA calculated an inflation rate of 4.1167 percent for FY 2025 and 5.0313 percent for FY 2026, and FDA intends to use these inflation rates to make inflation adjustments for FY 2026.

In FY 2024, FDA's Office of Regulatory Affairs (ORA) spent a total of $7,498,059 for domestic regulatory inspection travel costs and General Services Administration Vehicle costs related to FDA's Center for Food Safety and Applied Nutrition (CFSAN) and Center for Veterinary Medicine (CVM) field activities programs. The total ORA domestic travel costs spent is then divided by the 7,851 CFSAN and CVM domestic inspections, which averages a total of $955 per inspection. These inspections average 45.09 hours per inspection. Dividing $955 per inspection by 45.09 hours per inspection results in a total and an additional cost of $21 (rounded to the nearest dollar) per hour spent for domestic inspection travel costs in FY 2024. To adjust for the $21 per hour additional domestic cost inflation increases for FY 2025 and FY 2026, FDA multiplies the FY 2025 PDUFA inflation rate adjustor (1.041167) by the FY 2026 PDUFA inflation rate adjustor (1.050313) times the $21 additional domestic cost, which results in an estimated cost of $23 (rounded to the nearest dollar) per paid hour in addition to $316 for a total of $339 per paid hour ($316 plus $23) for each direct hour of work requiring domestic inspection travel. FDA will use these rates in charging fees in FY 2026 when domestic travel is required.

In FY 2024, ORA spent a total of $3,209,026 on 487 foreign inspection trips related to FDA's CFSAN and CVM field activities programs, which averaged a total of $6,589 per foreign inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing $6,589 per trip by 120 hours per trip results in a total and an additional cost of $55 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2024. To adjust $55 for inflationary increases in FY 2025 and FY 2026, FDA multiplies it by the same inflation factors mentioned previously in this document (1.041167 and 1.050313), which results in an estimated cost of $60 (rounded to the nearest dollar) for each direct hour of work requiring foreign

inspection travel. FDA will use these rates in charging fees in FY 2026 when foreign travel is required.

Table 2.--FSMA Fee Schedule for FY 2026

Fee Category	Fee Rates for FY 2026
Hourly rate without travel	$316
Hourly rate if domestic travel is required	$339
Hourly rate if foreign travel is required	$376

III. Fees for Importers Approved to Participate in the Voluntary Qualified Importer Program Under Section 743 of the FD&C Act

FDA assesses fees for VQIP annually. Table 3 provides an overview of the fees for FY 2026.

Table 3.--FSMA VQIP User Fee Schedule for FY 2026

Fee Category	Fee Rates for FY 2026
VQIP User Fee	$9,620

Section 743 of the FD&C Act requires that each importer participating in VQIP pay a fee to cover FDA's costs of administering the program. This fee represents the estimated average cost of the work FDA performs in reviewing and evaluating a VQIP importer. At this time, FDA is not offering an adjusted fee for small businesses. As required by section 743(b)(2)(B)(iii) of the FD&C Act, FDA published guidelines in consideration of the burden of the VQIP fee on small businesses and provided for a period of public comment on the guidelines (80 FR 32136, June 5, 2015). While we received some comments, the comments did not address the questions posed (that is, how a small business fee reduction should be structured, what percentage of fee reduction would be appropriate, or what alternative structures FDA might consider to indirectly reduce fees for small businesses by charging different fee amounts to different VQIP participants). Consistent with section 743(b)(2)(B)(iii) of the FD&C Act, if we determine to provide for a small business fee reduction, we will adjust the fee schedule for small businesses only through notice and comment rulemaking.

The fee is based on the fully supported FTE hourly rates and estimates of the number of hours it would take FDA to perform relevant activities. These estimates represent FDA's current thinking, and as the program evolves, FDA will reconsider the estimated hours. We estimate that it would take, on average, 39 person-hours to review a new VQIP application (including communication provided through the VQIP Importer's Help Desk), 28 person-hours to review a returning VQIP application (including communication provided through the VQIP Importer's Help Desk), 16 person-hours for an onsite performance evaluation of a domestic VQIP importer (including travel and other steps necessary for a fully supported FTE to complete and document an onsite assessment), and 34 person-hours for an onsite performance evaluation of a foreign VQIP importer (including travel and other steps necessary for a fully supported FTE to complete and document an onsite assessment).

Based on updated data, FDA anticipates that there may be up to seven returning VQIP applicants and up to two new applicants this fiscal year. FDA employees are likely to review new VQIP applications from their worksites, so we use the fully supported FTE hourly rate excluding travel, $316/hour, to calculate the portion of the user fee attributable to those activities: $316/hour × (39 hours) = $12,324. FDA employees are likely to review returning VQIP applications from their worksites, so we use the fully supported FTE hourly rate excluding travel, $316/hour, to calculate the portion of the user fee attributable to those activities: $316/hour × (28 hours) = $8,848.

FDA employees may conduct a VQIP inspection to verify the eligibility criteria and full implementation of the food safety and food defense systems established in the Quality Assurance Program. For FY 2026, FDA does not anticipate conducting dedicated VQIP inspections and will instead use existing inspection programs (such as the Foreign Supplier Verification Program and Hazard Analysis and Critical Control Point regulations) for program participants.

FDA employees are likely to prepare for and report on the performance evaluation of a domestic VQIP importer at an FTE's worksite, so we use the fully supported FTE hourly rate

excluding travel, $316/hour, to calculate the portion of the user fee attributable to those activities: $316/hour × (8 hours) = $2,528. For the portion of the fee covering onsite evaluation of a domestic VQIP importer, we use the fully supported FTE hourly rate for work requiring domestic travel, $339/hour, to calculate the portion of the user fee attributable to those activities: $339/hour × 8 hours (i.e., one fully supported FTE × (1 day onsite × 8 hours)) = $2,712. Therefore, the total cost of conducting the domestic performance evaluation of a VQIP importer is determined to be $2,528 + $2,712 = $5,240.

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, $316/hour, to calculate the portion of the user fee attributable to those activities: $316/hour × (10 hours) = $3,160. 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, $376/hour, to calculate the portion of the user fee attributable to those activities: $376/hour ×24 hours (i.e., one fully supported FTE × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) = $9,024. Therefore, the total cost of conducting the foreign performance evaluation of a VQIP importer is determined to be $3,160 + $9,024 = $12,184.

Therefore, the estimated average cost of the work FDA performs in total for approving an application for a VQIP importer in FY 2026 based on these figures would be ($12,324 × 2/9) + ($8,848 × 7/9) = $9,620.

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, 2025, to be eligible for VQIP participation for the benefit year beginning October 1, 2025. FDA will not refund the VQIP user fee for any reason.

The payments are to be made in U.S. currency drawn on a U.S. bank by electronic check, credit card, or wire transfer. The preferred payment method is online using an electronic check (via the U.S. Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments 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 you have found your invoice, select "Pay Now" to be redirected to Pay.gov. Electronic payment options are based on the balance due. Payment by credit card is available only for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments are to be made using U.S. bank accounts as well as U.S. credit cards.

When paying by wire transfer, the invoice number should be included; without the invoice number the payment may not be applied. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, the fee should be added to the payment to ensure that the invoice is paid in full. For international wire transfers, please inquire with the financial institutions prior to submitting the payment. Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account No.: 75060099, Routing No.: 021030004, Swift No.: FRNYUS33.

The tax identification number of FDA 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, 2025, 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, 2025. 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.

Dated: July 25, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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