and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Megha Reddy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2568, Silver Spring, MD 20993–0002, 240–402–2980.

SUPPLEMENTARY INFORMATION:

I. Background

The opioid overdose crisis is a serious and complex challenge facing the United States. The Agency has already taken significant steps to decrease unnecessary exposure to opioids, prevent new cases of opioid use disorder (OUD) and support the treatment of people with OUD. The Center for Devices and Radiological Health (CDRH) is committed to helping to end this national crisis. This guidance provides recommendations for the design of pivotal clinical studies for devices intended to treat OUD (hereafter ''OUD device studies'') and used to support marketing submissions. These recommendations are applicable to the design and development of clinical studies to provide a reasonable assurance of safety and effectiveness for a device intended to treat OUD. OUD device studies designed using the recommendations set out in this guidance may advance the treatment of OUD by providing scientific evidence that aids FDA in determining whether there is a reasonable assurance that a device intended to treat OUD is safe and effective. These recommendations may change as more information becomes available, and the research community gains experience with different designs in relation to OUD device studies.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all CDRH guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products*. This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*. Persons unable to download an electronic copy of ''Clinical Considerations for Studies of Devices Intended to Treat Opioid Use Disorder'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00019017 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA guidance have been approved by OMB as listed in the following table:

Guidance	Topic	OMB control No.
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions ..	0910–0756

Dated: July 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–15968 Filed 7–27–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2897]

Food Safety Modernization Act Third-Party Certification Program User Fee Rate for Fiscal Year 2024

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the fiscal year (FY) 2024 annual fee rate for recognized accreditation bodies and accredited certification bodies, and the initial and renewal fee rate for accreditation bodies applying to be recognized in the third-party certification program that is authorized by the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the FDA Food Safety Modernization Act (FSMA). We are also announcing the fee rate for certification bodies that are applying to be directly accredited by FDA.

DATES: This fee is effective on October 1, 2023, and will remain in effect through September 30, 2024.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo (Funmi) Ariyo, Food and Drug Administration, 404 Powder Mill Rd., Beltsville, MD 20705–4304, 240–402–4989; or the FSMA Fee Staff, Office of Food Policy and Response, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, *FSMAFeeStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 307 of FSMA (Pub. L. 111–353), Accreditation of Third-Party Auditors, amended the FD&C Act to create a new provision, section 808, under the same name. Section 808 of the FD&C Act (21 U.S.C. 384d) directs FDA to establish a program for accreditation of third-party certification bodies [1] conducting food safety audits and issuing food and facility certifications to eligible foreign entities (including registered foreign food facilities) that meet our applicable requirements. Under this provision, we established a system for FDA to recognize accreditation bodies to accredit certification bodies, except for limited circumstances in which we may directly

[1] For the reasons explained in the third-party certification final rule (80 FR 74570 at 74578–74579, November 27, 2015), and for consistency with the implementing regulations for the third-party certification program in 21 CFR parts 1, 11, and 16, this notice uses the term ''third-party certification body'' rather than the term ''third-party auditor'' used in section 808(a)(3) of the FD&C Act.

accredit certification bodies to participate in the third-party certification program.

Section 808(c)(8) of the FD&C Act directs FDA to establish a reimbursement (user fee) program by which we assess fees and require reimbursement for the work FDA performs to establish and administer the third-party certification program under section 808 of the FD&C Act. The user fee program for the third-party certification program was established by a final rule entitled ''Amendments to Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications To Provide for the User Fee Program'' (81 FR 90186, December 14, 2016).

The FSMA FY 2024 third-party certification program user fee rate announced in this notice is effective on October 1, 2023 and will remain in effect through September 30, 2024.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2024

FDA must estimate its costs for each activity in order to establish fee rates for FY 2024. In each year, the costs of salary (or personnel compensation) and benefits for FDA employees account for between 50 and 60 percent of the funds available to, and used by, FDA. Almost all the remaining funds (operating funds) available to FDA are used to support FDA employees for paying rent, travel, utility, information technology, and other operating costs.

A. Estimating the Full Cost per Direct Work Hour in FY 2024

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 Agency-wide total cost per FTE requires three primary cost elements: payroll, non-payroll, and rent.

We have used an average of past year cost elements to predict the FY 2024 cost. The FY 2024 FDA-wide average cost for payroll (salaries and benefits) is $192,848; non-payroll (including equipment, supplies, information technology, general and administrative overhead) is $99,316; and rent (including cost allocation analysis and adjustments for other rent and rent-related costs) is $23,239 per paid staff year, excluding travel costs.

Summing the average cost of an FTE for payroll, non-payroll, and rent, brings the FY 2024 average fully supported cost to $315,403 [2] per FTE, excluding travel costs. FDA will use this base unit fee in determining the hourly fee rate for third-party certification user fees for FY 2024 prior to including travel costs as applicable for the activity.

To calculate an hourly rate, FDA must divide the FY 2024 average fully supported cost of $315,403 per FTE by the average number of supported direct FDA work hours in FY 2022 (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 2022

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 2024 ($315,403) by the total number of supported direct work hours available for assignment in FY 2022 (1,160) results in an average fully supported cost of $272 (rounded to the nearest dollar), excluding travel costs, per supported direct work hour in FY 2024.

B. Adjusting FY 2022 Travel Costs for Inflation To Estimate FY 2024 Travel Costs

To adjust the hourly rate for FY 2024, FDA must estimate the cost of inflation in each year for FY 2023 and FY 2024. 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) (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 2023 inflation rate to be 1.6404 percent; this rate was published in the FY 2023 PDUFA user fee rates notice in the **Federal Register** (October 7, 2022, 87 FR 61063). Utilizing the method set forth in section 736(c)(1) of the FD&C Act, FDA has calculated an inflation rate of 1.6404 percent for FY 2023 and 3.8896 percent for FY 2024. FDA intends to use this inflation rate to make inflation adjustments for FY 2024; the derivation of this rate will be published in the **Federal Register** in the FY 2024 notice for the PDUFA user fee rates. The compounded inflation rate for FYs 2023 and 2024, therefore, is 1.055938 (or 5.5938 percent) (calculated as 1 plus 1.6404 percent times 1 plus 3.8896 percent).

The average fully supported cost per supported direct FDA work hour, excluding travel costs, of $272 already takes into account inflation as the calculation above is based on FY 2024 predicted costs. FDA will use this base unit fee in determining the hourly fee rate for third-party certification program fees for FY 2024 prior to including travel costs as applicable for the activity. For the purpose of estimating the fee, we are using the travel cost rate for foreign travel because we anticipate that the vast majority of onsite assessments made by FDA under this program will require foreign travel. In FY 2022, the Office of Regulatory Affairs spent a total of $802,057 on 175 foreign inspection trips related to FDA's Center

[2] Total includes rounding.

for Food Safety and Applied Nutrition and Center for Veterinary Medicine field activities programs, which averaged a total of $4,583 per foreign inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing $4,583 per trip by 120 hours per trip results in an additional cost of $38 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2022. To adjust $38 for inflationary increases in FY 2023 and FY 2024, FDA must multiply it by the same inflation factor mentioned previously in this document (1.055938 or 5.5938 percent), which results in an estimated cost of $40 per paid hour in addition to $272 for a total of $312 per paid hour ($272 plus $40) for each direct hour of work requiring foreign inspection travel. FDA will use this rate in charging fees in FY 2024 when travel is required for the third-party certification program.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2024

Fee category	Fee rates for FY 2024
Hourly rate without travel	$272
Hourly rate if travel is required	312

III. Fees for Accreditation Bodies and Certification Bodies in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

The third-party certification program assesses application fees and annual fees. In FY 2024, the only fees that could be collected by FDA under section 808(c)(8) of the FD&C Act are the initial application fee for accreditation bodies seeking recognition, the annual fee for recognized accreditation bodies, the annual fee for certification bodies accredited by a recognized accreditation body, the initial application fee for a certification body seeking direct accreditation from FDA, and the renewal application fee for recognized accreditation bodies. Table 3 provides an overview of the fees for FY 2024.

TABLE 3—FSMA THIRD-PARTY CERTIFICATION PROGRAM USER FEE SCHEDULE FOR FY 2024

Fee category	Fee rates for FY 2024
Initial Application Fee for Accreditation Body Seeking Recognition	$45,440
Annual Fee for Recognized Accreditation Body	2,131
Annual Fee for Accredited Certification Body	2,664
Initial Application Fee for a Certification Body Seeking Direct Accreditation from FDA	45,440
Renewal Application Fee for Recognized Accreditation Body	27,888

A. Application Fee for Accreditation Bodies Applying for Recognition in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

Section 1.705(a)(1) (21 CFR 1.705(a)(1)) establishes an application fee for accreditation bodies applying for initial recognition that represents the estimated average cost of the work FDA performs in reviewing and evaluating initial applications for recognition of accreditation bodies.

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 continue to reconsider the estimated hours. Based on data we have acquired since starting the program, we estimate that it would take, on average, 80 person-hours to review an accreditation body's submitted application, 48 person-hours for an onsite performance evaluation of the applicant (including travel and other steps necessary for a fully supported FTE to complete an onsite assessment), and 32 person-hours to prepare a written report documenting the onsite assessment.

FDA employees review applications and prepare reports from their worksites, so we use the fully supported FTE hourly rate excluding travel, $272 per hour, to calculate the portion of the user fee attributable to those activities: $272/hour × (80 hours (application review) + 32 hours (written report)) = $30,464. FDA employees will likely travel to foreign countries for the onsite performance evaluations because most accreditation bodies are anticipated to be located in foreign countries. For this portion of the fee, we use the fully supported FTE hourly rate for work requiring travel, $312 per hour, to calculate the portion of the user fee attributable to those activities: $312/hour × 48 hours (*i.e.,* two fully supported FTEs × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) = $14,976. The estimated average cost of the work FDA performs in total for reviewing an initial application for recognition for an accreditation body based on these figures would be $30,464 + $14,976 = $45,440. Therefore, the application fee for accreditation bodies applying for recognition in FY 2024 will be $45,440.

B. Annual Fee for Accreditation Bodies Participating in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

To calculate the annual fee for each recognized accreditation body, FDA takes the estimated average cost of work FDA performs to monitor performance of a single recognized accreditation body and annualizes that over the average term of recognition. At this time, we assume an average term of recognition of 5 years. We also assume that FDA will monitor 10 percent of recognized accreditation bodies onsite. As the program proceeds, we will adjust the term of recognition as appropriate. We estimate that for one performance evaluation of a recognized accreditation body, it would take, on average (taking into account that not all recognized accreditation bodies would be monitored onsite), 22 hours for FDA to conduct records review, 8 hours to prepare a report detailing the records review and onsite performance evaluation, and 8 hours of onsite performance evaluation. Using the fully supported FTE hourly rates in table 2, the estimated average cost of the work FDA performs to monitor performance of a single recognized accreditation

body would be $8,160 ($272/hour × (22 hours (records review) + 8 hours (written report))) plus $2,496 ($312/hour × 8 hours (onsite evaluation)), which is $10,656. Annualizing this amount over 5 years would lead to an annual fee for recognized accreditation bodies of $2,131 for FY 2024.

C. Annual Fee for Certification Bodies Accredited by a Recognized Accreditation Body in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

To calculate the annual fee for a certification body accredited by a recognized accreditation body, FDA takes the estimated average cost of work FDA performs to monitor performance of a single certification body accredited by a recognized accreditation body and annualizes that over the average term of accreditation. At this time, we assume an average term of accreditation of 4 years. This 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. We estimate that FDA would conduct, on average, the same activities, for the same amount of time to monitor certification bodies accredited by a recognized accreditation body as we would to monitor an accreditation body recognized by FDA. Using the fully supported FTE hourly rates in table 2, the estimated average cost of the work FDA performs to monitor performance of a single accredited certification body would be $8,160 ($272/hour × (22 hours (records review) + 8 hours (written report))) plus $2,496 ($312/hour × 8 hours (onsite evaluation)), which is $10,656. Annualizing this amount over 4 years would lead to an annual fee for accredited certification bodies of $2,664 for FY 2024.

D. Initial Application Fee for Certification Bodies Seeking Direct Accreditation From FDA in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

Section 1.705(a)(3) establishes an application fee for certification bodies applying for direct accreditation from FDA that represents the estimated average cost of the work FDA performs in reviewing and evaluating initial applications for direct accreditation of certification bodies.

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, 80 person-hours to review a certification body's submitted application, 48 person-hours for an onsite performance evaluation of the applicant (including travel and other steps necessary for a fully supported FTE to complete an onsite assessment), and 32 person-hours to prepare a written report documenting the onsite assessment.

FDA employees are likely to review applications and prepare reports from their worksites, so we use the fully supported FTE hourly rate excluding travel, $272 per hour, to calculate the portion of the user fee attributable to those activities: $272/hour × (80 hours (application review) + 32 hours (written report)) = $30,464. FDA employees will likely travel to foreign countries for the onsite performance evaluations because most certification bodies are anticipated to be located in foreign countries. For this portion of the fee, we use the fully supported FTE hourly rate for work requiring travel, $312 per hour, to calculate the portion of the user fee attributable to those activities: $312/hour × 48 hours (*i.e.,* two fully supported FTEs × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) = $14,976. The estimated average cost of the work FDA performs in total for reviewing an initial application for direct accreditation of a certification body based on these figures would be $30,464 + $14,976 = $45,440. Therefore, the application fee for certification bodies applying for direct accreditation from FDA in FY 2024 will be $45,440.

E. Renewal Application Fee for Accreditation Bodies Participating in the Third-Party Certification Program Under Section 808(c)(8) of the FD&C Act

Section 1.705(a)(2) establishes a renewal application fee for recognized accreditation bodies that represents the estimated average cost of the work FDA performs in reviewing and evaluating renewal applications for recognition of accreditation bodies.

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, 43 person-hours to review an accreditation body's submitted renewal application, 24 person-hours for an onsite performance evaluation of the applicant (including travel and other steps necessary for a fully supported FTE to complete an onsite assessment), and 32 person-hours to prepare a written report documenting the onsite assessment.

FDA employees are likely to review renewal applications and prepare reports from their worksites, so we use the fully supported FTE hourly rate excluding travel, $272 per hour, to calculate the portion of the user fee attributable to those activities: $272/hour × (43 hours (application review) + 32 hours (written report)) = $20,400. FDA employees will likely travel to foreign countries for the onsite performance evaluations because most certification bodies are anticipated to be located in foreign countries. For this portion of the fee, we use the fully supported FTE hourly rate for work requiring travel, $312 per hour, to calculate the portion of the user fee attributable to those activities: $312/hour × 24 hours (*i.e.,* fully supported FTE × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) = $7,488. The estimated average cost of the work FDA performs in total for reviewing a renewal application for recognition of an accreditation body based on these figures would be $20,400 + $7,488 = $27,888. Therefore, the renewal application fee for recognized accreditation bodies in FY 2024 will be $27,888.

IV. Estimated Fees for Accreditation Bodies and Certification Bodies in Other Fee Categories for FY 2024

Section 1.705(a) also establishes application fees for certification bodies applying for renewal of direct accreditation. Section 1.705(b) also establishes annual fees for certification bodies directly accredited by FDA.

Although we will not be collecting these other fees in FY 2024, for transparency and planning purposes, we have provided an estimate of what these fees would be for FY 2024 based on the fully supported FTE hourly rates for FY 2024 and estimates of the number of hours it would take FDA to perform relevant activities as outlined in the Final Regulatory Impact Analysis for the Third-Party Certification Regulation. Table 4 provides an overview of the estimated fees for other fee categories.

TABLE 4—ESTIMATED FEE RATES FOR OTHER FEE CATEGORIES UNDER THE FSMA THIRD-PARTY CERTIFICATION PROGRAM

Fee category	Estimated fee rates for FY 2024
Renewal application fee for directly accredited certification body	$27,888
Annual fee for certification body directly accredited by FDA	21,184

V. How must the fee be paid?

Accreditation bodies seeking initial recognition must submit the application fee with the application. For recognized accreditation bodies and accredited certification bodies, an invoice will be sent annually. Payment must be made within 30 days of the receipt invoice date. The payment must be made in U.S. currency from a U.S. bank by one of the following methods: wire transfer, electronically, check, bank draft, or U.S. postal money order made payable to the Food and Drug Administration. The preferred payment method is online using an electronic check (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 must be made using U.S. bank accounts as well as U.S. credit cards. When paying by check, bank draft, or U.S. postal money order, please include the invoice number. Also write the FDA post office box number (P.O. Box 979108) on the enclosed check, bank draft, or money order. Mail the payment, including the invoice number on the check stub, to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000.

When paying by wire transfer, it is required that the invoice number is 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, it is required to add that amount 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.

To send a check by a courier such as Federal Express, the courier must deliver the check to: U.S. Bank, Attn: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (Note: this address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314–418–4013. This phone number is only for questions about courier delivery.) The tax identification number of FDA is 53–0196965. (Note: invoice copies do not need to be submitted to FDA with the payments.)

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

The consequences of not paying these fees are outlined in 21 CFR 1.725. If FDA does not receive an application fee with an application for recognition, the application will be considered incomplete, and FDA will not review the application. If a recognized accreditation body fails to submit its annual user fee within 30 days of the due date, we will suspend its recognition. If the recognized accreditation body fails to submit its annual user fee within 90 days of the due date, we will revoke its recognition. If an accredited certification body fails to pay its annual fee within 30 days of the due date, we will suspend its accreditation. If the accredited certification body fails to pay its annual fee within 90 days of the due date, we will withdraw its accreditation.

Dated: July 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–15921 Filed 7–27–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2898]

Food Safety Modernization Act Voluntary Qualified Importer Program User Fee Rate for Fiscal Year 2024

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2024 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, 2023 and will remain in effect through September 30, 2024.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo Ariyo, FSMA Fee Staff, Office of Food Policy and Response, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 240–402–4989, *FSMAFeeStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 302 of FSMA, VQIP, amended the FD&C Act to create a new provision, section 806, under the same name. 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. The fee