identified with Docket No. FDA–2020–N–2366 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at *https://www.regulations.gov* or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

Dated: July 19, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16044 Filed 7–27–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0704]

Food Safety Modernization Act Voluntary Qualified Importer Program User Fee Rate for Fiscal Year 2022

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2022 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 August 1, 2021, and will remain in effect through September 30, 2022.

FOR FURTHER INFORMATION CONTACT: Donald Prater, Office of Food Policy and Response, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 3202, Silver Spring, MD 20993, 301–348–3007.

SUPPLEMENTARY INFORMATION:

I. Background

Section 302 of FSMA, Voluntary Qualified Importer Program, 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 the 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 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 must be paid before October 1, the start of the VQIP fiscal year, to begin receiving benefits for that VQIP fiscal year.

The FY 2022 VQIP user fee will support benefits from October 1, 2021, through September 30, 2022.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2022

FDA is required to estimate 100 percent of its costs for each activity in order to establish fee rates for FY 2022. 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 of the remaining funds (operating funds) available to FDA are used to support FDA employees for paying rent, travel, utility, information technology (IT), and other operating costs.

A. Estimating the Full Cost per Direct Work Hour in FY 2022

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 2022 cost. The FY 2022 FDA-wide average cost for payroll (salaries and benefits) is $171,228; non-payroll—including equipment, supplies, IT, general and administrative overhead—is $101,625; and rent, including cost allocation analysis and adjustments for other rent and rent-related costs, is $23,597 per paid staff year, excluding travel costs.

Summing the average cost of an FTE for payroll, non-payroll, and rent, brings the FY 2022 average fully supported cost to $296,450 per FTE, excluding travel costs. FDA will use this base unit fee in determining the hourly fee rate for VQIP fees for FY 2022 prior to including domestic or foreign travel costs as applicable for the activity.

To calculate an hourly rate, FDA must divide the FY 2022 average fully supported cost of $296,450 per FTE by the average number of supported direct FDA work hours in FY 2020—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 2020

Total number of hours in a paid staff year	2,080
Less:	
10 paid holidays	−80
20 days of annual leave	−160
10 days of sick leave	−80
12.5 days of training	−100
23 days of general administration	−184
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 2022 ($296,450) by the total number of supported direct work hours available for assignment in FY 2020 (1,160) results in an average fully supported cost of $256 (rounded to the nearest dollar), excluding inspection travel costs, per supported direct work hour in FY 2022.

B. Adjusting FY 2020 Travel Costs for Inflation To Estimate FY 2022 Travel Costs

To adjust the hourly rate for FY 2022, FDA must estimate the cost of inflation in each year for FY 2021 and FY 2022. 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 2021 inflation rate to be 1.3493 percent; this rate was published in the FY 2021 PDUFA user fee rates notice in the **Federal Register** (August 3, 2020, 85 FR 46651). Utilizing the method set forth in section 736(c)(1) of the FD&C Act, FDA has calculated an inflation rate of 1.3493 percent for FY

2021 and 2.2013 percent for FY 2022, and FDA intends to use these inflation rates to make inflation adjustments for FY 2022; the derivation of this rate will be published in the **Federal Register** in the FY 2022 notice for the PDUFA user fee rates. The compounded inflation rate for FYs 2021 and 2022, therefore, is 1.035803 (or 3.5803 percent) (calculated as 1 plus 1.3493 percent times 1 plus 2.2013 percent).

The average fully supported cost per supported direct FDA work hour, excluding travel costs, of $256 already takes into account inflation as the calculation above is based on FY 2022 predicted costs. FDA will use this base unit fee in determining the hourly fee rate for VQIP fees for FY 2022 prior to including domestic or foreign travel costs as applicable for the activity.

In FY 2020, FDA's Office of Regulatory Affairs (ORA) spent a total of $3,831,758 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 4,399 CFSAN and CVM domestic inspections, which averages a total of $871 per inspection. These inspections average 42.65 hours per inspection. Dividing $871 per inspection by 42.65 hours per inspection results in a total and an additional cost of $20 (rounded to the nearest dollar) per hour spent for domestic inspection travel costs in FY 2020. To adjust for the $20 per hour additional domestic cost inflation increases for FY 2021 and FY 2022, FDA must multiply the FY 2021 PDUFA inflation rate adjustor (1.013493) by the FY 2022 PDUFA inflation rate adjustor (1.022013) times the $20 additional domestic cost, which results in an estimated cost of $21 (rounded to the nearest dollar) per paid hour in addition to $256 for a total of $277 per paid hour ($256 plus $21) for each direct hour of work requiring domestic inspection travel. FDA will use these rates in charging fees in FY 2022 when domestic travel is required.

In FY 2020, ORA spent a total of $1,449,058 on 171 foreign inspection trips related to FDA's CFSAN and CVM field activities programs, which averaged a total of $8,474 per foreign inspection trip. These trips averaged 3 weeks (or 120 paid hours) per trip. Dividing $8,474 per trip by 120 hours per trip results in a total and an additional cost of $71 (rounded to the nearest dollar) per paid hour spent for foreign inspection travel costs in FY 2020. To adjust $71 for inflationary increases in FY 2021 and FY 2022, FDA must multiply it by the same inflation factors mentioned previously in this document (1.013493 and 1.022013), which results in an estimated cost of $74 (rounded to the nearest dollar) per paid hour in addition to $256 for a total of $330 per paid hour ($256 plus $74) for each direct hour of work requiring foreign inspection travel. FDA will use these rates in charging fees in FY 2022 when foreign travel is required.

TABLE 2—FSMA FEE SCHEDULE FOR FY 2022

Hourly rate without travel	$256
Hourly rate if domestic travel is required	277
Hourly rate if foreign travel is required	330

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 2022.

TABLE 3—FSMA VQIP USER FEE SCHEDULE FOR FY 2022

Fee category	Fee rates for FY 2022
VQIP User Fee	$15,938

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 previously published a set of 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 did receive some comments in response, they did not address the questions posed, *i.e.,* 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. We plan on monitoring costs and collecting data to determine if, in future fiscal years, we will provide for a small business fee reduction. Consistent with section 743(b)(2)(B)(iii) of the FD&C Act, 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). Additional costs include maintenance and support costs of information technology of administering benefits of the program. These costs are estimated to be $7,000 per VQIP importer.

Based on updated data, FDA anticipates that there may be up to three returning VQIP applicants and up to one new applicant 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, $256/hour, to calculate the portion of the user fee attributable to those activities: $256/hour × (39 hours) = $9,984. FDA employees are likely to review returning VQIP applications from their worksites, so we use the fully supported FTE hourly rate excluding travel, $256/hour, to calculate the portion of the user fee attributable to those activities: $256/hour × (28 hours) = $7,168.

FDA employees will 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. A VQIP importer may be located inside or outside of the United States. However, this fiscal year, all VQIP importers will be located inside the United States. One new applicant may have an associated VQIP inspection.

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, $256/hour, to calculate the portion of the user fee attributable to those activities: $256/hour × (8 hours) = $2,048. 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, $277/hour, to calculate the portion of the user fee attributable to those activities: $277/hour × 8 hours (*i.e.,* one fully supported FTE × (1 day onsite × 8 hours)) = $2,216. Therefore, the total cost of conducting the domestic performance evaluation of a VQIP importer is determined to be $2,216 + $2,048 = $4,264.

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, $256/hour, to calculate the portion of the user fee attributable to those activities: $256/hour × (10 hours) = $2,560. 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, $330/hour, to calculate the portion of the user fee attributable to those activities: $330/hour × 24 hours (*i.e.,* one fully supported FTE × ((2 travel days × 8 hours) + (1 day onsite × 8 hours))) = $7,920. Therefore, the total cost of conducting the foreign performance evaluation of a VQIP importer is determined to be $2,560 + $7,920 = $10,480.

Therefore, the estimated average cost of the work FDA performs in total for approving an application for a VQIP importer in FY22 based on these figures would be $7,000 + ($9,984 × 0.25) + ($7,168 × 0.75) + ($4,264 × 0.25) = $15,938

IV. How must the fee be paid?

An invoice will be sent to VQIP importers approved to participate in the program. Payment must be made prior to October 1, 2021, to be eligible for VQIP participation for the benefit year beginning October 1, 2021. FDA will not refund the VQIP user fee for any reason.

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 in the check stub. 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.)

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

The consequences of not paying these fees are outlined in Section J of ''FDA's Voluntary Qualified Importer Program; Guidance for Industry'' document (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, 2021, 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, 2021. 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 20, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16053 Filed 7–27–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0661]

Generic Drug User Fee Rates for Fiscal Year 2022

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Federal Food, Drug, and Cosmetic Act (FD&C Act or statute), as amended by the Generic Drug User Fee Amendments of 2017 (GDUFA II), authorizes the Food and Drug Administration (FDA, Agency, or we) to assess and collect fees for abbreviated new drug applications (ANDAs); drug master files (DMFs); generic drug active pharmaceutical ingredient (API) facilities, finished dosage form (FDF) facilities, and contract manufacturing organization (CMO) facilities; and generic drug applicant program user fees. In this document, FDA is announcing fiscal year (FY) 2022 rates for GDUFA II fees.

FOR FURTHER INFORMATION CONTACT: Lola Olajide, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61077B, Beltsville, MD 20705–4304, 240–402–4244.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 744A and 744B of the FD&C Act (21 U.S.C. 379j–41 and 379j–42) establish fees associated with human generic drug products. Fees are assessed on: (1) Certain types of applications for