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 (*Pay.gov*) 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 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16171 Filed 7–27–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1620]

Animal Generic Drug User Fee Rates and Payment Procedures for Fiscal Year 2023

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the fee rates and payment procedures for fiscal year (FY) 2023 generic new animal drug user fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Generic Drug User Fee Amendments of 2018 (AGDUFA III), authorizes FDA to collect user fees for certain abbreviated applications for generic new animal drugs, for certain generic new animal drug products, and for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs. This notice establishes the fee rates for FY 2023.

DATES: The application fee rates are effective for all abbreviated applications for a generic new animal drug submitted on or after October 1, 2022, and will remain in effect through September 30, 2023.

FOR FURTHER INFORMATION CONTACT: Visit FDA's website at *https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm* or contact Lisa Kable, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–6888, *Lisa.Kable@fda.hhs.gov.* For general questions, you may also email FDA's Center for Veterinary Medicine (CVM) at: *cvmagdufa@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 741 of the FD&C Act (21 U.S.C. 379j–21) as amended by AGDUFA III, establishes three different types of user fees: (1) fees for certain types of abbreviated applications for generic new animal drugs; (2) annual fees for certain generic new animal drug products; and (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (21 U.S.C. 379j–21(a)). When certain conditions are met, FDA will waive or reduce fees for generic new animal drugs intended solely to provide for a minor use or minor species indication (21 U.S.C. 379j–21(d)).

For FYs 2019 through 2023, the FD&C Act establishes the base revenue amount for each fiscal year (21 U.S.C. 379j–21(b)(1)). Base revenue amounts are subject to adjustment for inflation and workload (21 U.S.C. 379j–21(c)(2) and (3)). Beginning with FY 2021, the annual fee revenue amounts are also subject to adjustment to reduce workload-based increases by the amount of certain excess collections (21 U.S.C. 379j–21(c)(3)(B)). Fees for applications, products, and sponsors are to be established each year by FDA so that the percentages of the total revenue that are derived from each type of user fee will be as follows: (1) 25 percent shall be derived from fees for abbreviated applications for a generic new animal drug; (2) 37.5 percent shall be derived from fees for generic new animal drug products; and (3) 37.5 percent shall be derived from fees for generic new animal drug sponsors (21 U.S.C. 379j–

21(b)(2)). The target revenue amounts for each fee category for FY 2023, are as follows: for application fees, the target revenue amount is $7,325,750; for product fees, the target revenue amount is $10,988,625; and for sponsor fees, the target revenue amount is $10,988,625.

For FY 2023, the generic new animal drug user fee rates are: $494,983 for each abbreviated application for a generic new animal drug other than those subject to the criteria in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)); $247,492 for each abbreviated application for a generic new animal drug subject to the criteria in section 512(d)(4) of the FD&C Act; $18,881 for each generic new animal drug product; $283,870 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; $212,903 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and $141,935 for each generic new animal drug sponsor paying 50 percent of the sponsor fee. FDA will issue invoices for FY 2023 product and sponsor fees by December 31, 2022, and payment will be due by January 31, 2023. The application fee rates are effective for all abbreviated applications for a generic new animal drug submitted on or after October 1, 2022, and will remain in effect through September 30, 2023. Applications will not be accepted for review until FDA has received full payment of application fees and any other fees owed under the AGDUFA program.

II. Revenue Amount for FY 2023

A. Statutory Fee Revenue Amount

AGDUFA III, Title II of Public Law 115–234, specifies that the aggregate base fee revenue amount for FY 2023 for all generic new animal drug user fee categories is $18,336,340 (21 U.S.C. 379j–21(b)(1)).

B. Inflation Adjustment to Fee Revenue Amount

AGDUFA III specifies that the annual fee revenue amount is to be adjusted for inflation increases for FY 2020 and subsequent fiscal years, using two separate adjustments—one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see 21 U.S.C. 379j–21(c)(2)). The component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all PC&B paid per full-time equivalent position (FTE) at FDA for the first 3 of the 4 preceding fiscal years of available data, multiplied by the average proportion of PC&B costs to total FDA costs for the first 3 of the 4 preceding fiscal years of available data. The data on total PC&B paid and numbers of FTE paid, from which the average cost per FTE can be derived, are published in FDA's Justification of Estimates for Appropriations Committees.

Table 1 summarizes the actual cost and FTE data for the specified fiscal years, provides the percent change from the previous fiscal year, and provides the average percent change over the first 3 of the 4 fiscal years preceding FY 2023. The 3-year average is 1.3918 percent.

TABLE 1—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGE

	FY 2019	FY 2020	FY 2021	3-year average
Total PC&B	$2,620,052,000	$2,875,592,000	$3,039,513,000	.....
Total FTE	17144	17535	18501	.....
PC&B per FTE	$152,826	$163,992	$164,829	.....
Percent Change From Previous Year	−3.3120%	7.3063%	0.1811%	1.3918%

The statute specifies that this 1.3918 percent should be multiplied by the proportion of PC&B costs to total FDA costs. Table 2 shows the amount of PC&B and the total amount obligated by FDA for the same 3 FYs.

TABLE 2—PC&B AS A PERCENT OF TOTAL COSTS AT FDA

	FY 2019	FY 2020	FY 2021	3-year average
Total PC&B	$2,620,052,000	$2,875,592,000	$3,039,513,000	.....
Total Costs	$5,663,389,000	$6,039,321,000	$6,049,798,000	.....
PC&B Percent	46.2630%	47.6145%	50.2416%	48.0397%

The portion of the inflation adjustment relating to payroll costs is 1.3918 percent multiplied by 48.0397 percent, or 0.6686 percent.

The statute specifies that the portion of the inflation adjustment for non-payroll costs is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Baltimore, DC-MD-VA-WV; not seasonally adjusted; all items less food and energy; annual index) for the first 3 of the preceding 4 years of available data multiplied by the average proportion of all costs other than PC&B costs to total FDA costs for the first 3 of the 4 preceding fiscal years. As a result of a geographical revision made by the Bureau of Labor Statistics in January 2018,[1] the ''Washington-Baltimore, DC-MD-VA-WV'' index was discontinued and replaced with two separate indices (*i.e.,* ''Washington-Arlington-Alexandria, DC-VA-MD-WV'' and ''Baltimore-Columbia-Towson, MD''). To continue applying a CPI that best reflects the geographic region in which FDA is headquartered and that provides the most current data available, FDA is using the Washington-Arlington-Alexandria index, less food and energy, in calculating the relevant adjustment factors for FY 2020 and subsequent years. Table 3 provides the summary data for the percent change in the specified CPI for the Washington-Arlington-Alexandria area. The data from the Bureau of Labor Statistics are shown in table 3.

[1] Available at: *https://www.bls.gov/cpi/additional-resources/geographic-revision-2018.htm.*

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN WASHINGTON-ARLINGTON-ALEXANDRIA AREA CPI, LESS FOOD AND ENERGY

	FY 2019	FY 2020	FY 2021	3-Year average
Annual CPI	275.84	278.44	287.14	.....
Annual Percent Change	1.2580%	0.9411%	3.1271%	1.7754%

To calculate the inflation adjustment for non-payroll costs, we multiply 1.7754 percent by the proportion of all costs other than PC&B to total FDA costs. Since 48.0397 percent was obligated for PC&B as shown in table 2, 51.9603 percent is the portion of costs other than PC&B (100 percent minus 48.0397 percent equals 51.9603 percent). The portion of the inflation adjustment relating to non-payroll costs is 1.7754 percent times 51.9603 percent, or 0.9225 percent.

Next, we add the payroll component (0.6686 percent) to the non-payroll component (0.9225 percent), for an inflation adjustment of 1.5911 percent for FY 2023.

AGDUFA III provides for the inflation adjustment to be compounded each fiscal year after FY 2020 (see 21 U.S.C. 379j–21(c)(2)). The inflation adjustment for FY 2023 (1.5911 percent) is compounded by adding 1 and then multiplying by 1 plus the inflation adjustment factor for FY 2022 (5.7121 percent), as published in the **Federal Register** on July 23, 2021 (86 FR 39028), which equals 1.0739 (rounded) (1.0159 times 1.0571) for FY 2023. We then multiply the base revenue amount for FY 2023 ($18,336,340) by 1.073941, yielding an inflation adjusted amount of $19,692,147.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

The fee revenue amounts established in AGDUFA III for FY 2020 and subsequent fiscal years are also subject to adjustment to account for changes in FDA's review workload. A workload adjustment will be applied to the inflation adjusted fee revenue amount (21 U.S.C. 379j–21(c)(3)).

To determine whether a workload adjustment applies, FDA calculates the weighted average of the change in the total number of each of the four types of applications and submissions specified in the workload adjustment provision (abbreviated applications for generic new animal drugs, manufacturing supplemental abbreviated applications for generic new animal drugs, investigational generic new animal drug study submissions, and investigational generic new animal drug protocol submissions) received over the 5-year period that ended on September 30, 2018 (the base years), and the average number of each of these types of applications and submissions over the most recent 5-year period that ended May 31, 2022.

The results of these calculations are presented in the first two columns of table 4. Column 3 reflects the percent change in workload over the two 5-year periods. Column 4 shows the weighting factor for each type of application, reflecting how much of the total FDA generic new animal drug review workload was accounted for by each type of application or submission in the table during the most recent 5 years. Column 5 is the weighted percent change in each category of workload and was derived by multiplying the weighting factor in each line in column 4 by the percent change from the base years in column 3. At the bottom right of the table the sum of the values in column 5 is calculated, reflecting a total change in workload of 77.5221 percent for FY 2023. This is the workload adjuster for FY 2023.

TABLE 4—WORKLOAD ADJUSTER CALCULATION

Application type	Column 1	Column 2	Column 3	Column 4	Column 5
	5-year average (base years)	Latest 5-year average	Percent change	Weighting factor	Weighted percent change
Abbreviated Application for a Generic New Animal Drug (ANADAs)	24.00	27.00	12.5000	0.15	1.8953
Manufacturing Supplements ANADAs	169.40	219.60	29.6340	0.24	7.2536
Generic Investigational Study Submissions	69.20	155.40	124.5665	0.46	57.2176
Generic Investigational Protocol Submissions	34.40	61.00	77.3256	0.14	11.1556
FY 2023 AGDUFA III Workload Adjuster	.....	.....	.....	.....	77.52221

The statutory revenue amount after the inflation adjustment ($19,692,147) must now be increased by 77.5221 percent to reflect the changes in review workload (workload adjustment), for a workload and inflation-adjusted amount of $34,957,913.

D. Reduction of Workload-Based Increase by Amount of Certain Excess Collections

Under section 741(c)(3)(B) of the FD&C Act, for FYs 2021 through 2023, if application of the workload adjustment increases the amount of fee revenues established for the fiscal year, as adjusted for inflation, the fee revenue increase will be reduced by the amount of any excess collections for the second preceding fiscal year, up to the amount of the fee revenue increase for workload. The workload and inflation-adjusted amount ($34,957,913) is subtracted by the inflation adjusted amount ($19,692,147) to get the workload adjustment amount ($15,265,766). Then the excess fees collected from FY 2021 as of May 31, 2022 ($5,655,218) are subtracted from the workload adjustment amount ($15,265,766) to get a reduced workload adjustment amount of $9,610,548. Next, the reduced workload adjustment amount ($9,610,548) is added to the inflation-adjusted revenue amount ($19,692,147), for a total fee revenue target of $29,303,000 (rounded to the nearest thousand dollars).

E. Final Year Adjustment

For FY 2023, FDA may, in addition to other adjustments under section 741(c) of the FD&C Act, further increase the fees, if such an adjustment is necessary, to provide for up to 3 months of

operating reserves of carryover user fees for the process for the review of generic animal drug applications for the first 3 months of FY 2024. If FDA has carryover balances for the process for the review of generic new animal drug applications in excess of 3 months of such operating reserves, then this adjustment will not be made (see 21 U.S.C. 379j–21(c)(4)). Since FDA currently has an excess of 3 months of such operating reserves, this adjustment will not be made for FY 2023.

F. FY 2023 Fee Revenue Amounts

AGDUFA III specifies that the revenue amount of $29,303,000 for FY 2023 is to be divided as follows: 25 percent, or a total of $7,325,750, is to come from application fees; 37.5 percent, or a total of $10,988,625, is to come from product fees; and 37.5 percent, or a total of $10,988,625, is to come from sponsor fees (21 U.S.C. 379j–21(b)).

III. Abbreviated Application Fee Calculations for FY 2023

A. Application Fee Revenues and Numbers of Fee-Paying Applications

Each person who submits an abbreviated application for a generic new animal drug shall be subject to an application fee, with limited exceptions (21 U.S.C. 379j–21(a)(1)). The term ''abbreviated application for a generic new animal drug'' means an abbreviated application for the approval of any generic new animal drug submitted under section 512(b)(2) of the FD&C Act (21 U.S.C. 379j–21(k)(1)). The application fees are to be set so that they will generate $7,325,750 in fee revenue for FY 2023.

To set fees for abbreviated applications for generic new animal drugs to realize $7,325,750, FDA must first make some assumptions about the number of fee-paying abbreviated applications it will receive during FY 2023.

The Agency knows the number of applications that have been submitted in previous years. That number fluctuates annually. In estimating the fee revenue to be generated by generic new animal drug applications in FY 2023, FDA is assuming that the number of applications for which fees will be paid in FY 2023 will equal the average number of applications over the 5 most recently completed fiscal years of the AGDUFA program (FY 2017–FY 2021).

Also, under AGDUFA III, an abbreviated application for an animal generic drug subject to the criteria in section 512(d)(4) of the FD&C Act and submitted on or after October 1, 2013, shall be subject to 50 percent of the fee applicable to all other abbreviated applications for a generic new animal drug (21 U.S.C. 379j–21(a)(1)(C)(ii)).

The average number of original submissions of abbreviated applications for generic new animal drugs over the 5 most recently completed fiscal years is 11.6 applications not subject to the criteria in section 512(d)(4) of the FD&C Act and 6.4 submissions subject to the criteria in section 512(d)(4). Each of the submissions described under section 512(d)(4) of the FD&C Act pays 50 percent of the fee paid by the other applications and will be counted as one half of a fee. Adding all of the applications not subject to the criteria in section 512(d)(4) of the FD&C Act and 50 percent of the number that are subject to such criteria results in a total of 14.80 anticipated full fees.

Based on the previous assumptions, FDA is estimating that it will receive a total of 14.80 fee-paying generic new animal drug applications in FY 2023 (11.6 original applications paying a full fee and 6.4 applications paying a half fee).

B. Application Fee Rates for FY 2023

FDA must set the fee rates for FY 2023 so that the estimated 14.80 abbreviated applications that pay the fee will generate a total of $7,325,750. To generate this amount, the fee for a generic new animal drug application will have to be $494,983 and for those applications that are subject to the criteria set forth in section 512(d)(4) of the FD&C Act, 50 percent of that amount, or $247,492.

IV. Generic New Animal Drug Product Fee Calculations for FY 2023

A. Product Fee Revenues and Numbers of Fee-Paying Products

The generic new animal drug product fee must be paid annually by the person named as the applicant in an abbreviated application or supplemental abbreviated application for a generic new animal drug product submitted for listing under section 510 of the FD&C Act (21 U.S.C. 360) and who had an abbreviated application or supplemental abbreviated application for a generic new animal drug product pending at FDA after September 1, 2008 (see 21 U.S.C. 379j–21(a)(2)). The term ''generic new animal drug product'' means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the National Drug Code, and for which an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug has been approved (21 U.S.C. 379j–21(k)(6)). The product fees are to be set so that they will generate $10,988,625 in fee revenue for FY 2023.

To set generic new animal drug product fees to realize $10,988,625, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2023. FDA gathered data on all generic new animal drug products that have been submitted for listing under section 510 of the FD&C Act and matched this to the list of all persons who had a generic new animal drug application or supplemental abbreviated application pending after September 1, 2008. As of May 2022, FDA estimates that there is a total of 588 products submitted for listing by persons who had an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug pending after September 1, 2008. Based on this, FDA believes that a total of 588 products will be subject to this fee in FY 2023.

In estimating the fee revenue to be generated by generic new animal drug product fees in FY 2023, FDA is estimating that 1 percent of the products invoiced, or 6 products, will qualify for a minor use/minor species fee waiver (see 21 U.S.C. 379j–21(d)). FDA has made this estimate at 1 percent this year, based on historical data over the past 5 completed fiscal years of the AGDUFA program.

Accordingly, the Agency estimates that a total of 582 (588 minus 6) products will be subject to product fees in FY 2023.

B. Product Fee Rates for FY 2023

FDA must set the fee rates for FY 2023 so that the estimated 582 products for which fees are paid will generate a total of $10,988,625. To generate this amount will require the fee for a generic new animal drug product, rounded to the nearest dollar, to be $18,881.

V. Generic New Animal Drug Sponsor Fee Calculations for FY 2023

A. Sponsor Fee Revenues and Numbers of Fee-Paying Sponsors

The generic new animal drug sponsor fee must be paid annually by each person who: (1) is named as the applicant in an abbreviated application for a generic new animal drug, except for an approved application for which all subject products have been removed from listing under section 510 of the FD&C Act, or has submitted an

investigational submission for a generic new animal drug that has not been terminated or otherwise rendered inactive and (2) had an abbreviated application for a generic new animal drug, supplemental abbreviated application for a generic new animal drug, or investigational submission for a generic new animal drug pending at FDA after September 1, 2008 (see 21 U.S.C. 379j–21(k)(7) and 379j–21(a)(3)). A generic new animal drug sponsor is subject to only one such fee each fiscal year (see 21 U.S.C. 379j–21(a)(3)(C)). Applicants with more than six approved abbreviated applications will pay 100 percent of the sponsor fee; applicants with more than one and fewer than seven approved abbreviated applications will pay 75 percent of the sponsor fee; and applicants with one or fewer approved abbreviated applications will pay 50 percent of the sponsor fee (see 21 U.S.C. 379j–21(a)(3)(C)). The sponsor fees are to be set so that they will generate $10,988,625 in fee revenue for FY 2023.

To set generic new animal drug sponsor fees to realize $10,988,625, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2023. FDA estimates that in FY 2023, 12 sponsors will pay 100 percent fees, 18 sponsors will pay 75 percent fees, and 28 sponsors will pay 50 percent fees. That results in the equivalent of 39.5 full sponsor fees (12 times 100 percent or 12, plus 18 times 75 percent or 13.5, plus 28 times 50 percent or 14).

FDA estimates that about 2 percent of all of these sponsors, or 0.79, may qualify for a minor use/minor species fee waiver (see 21 U.S.C. 379j–21(d)). FDA has made the estimate of the percentage of sponsors that will not pay fees at 2 percent this year, based on historical data over the past 5 completed FYs of the AGDUFA program.

Accordingly, the Agency estimates that the equivalent of 38.71 full sponsor fees (39.5 minus 0.79) are likely to be paid in FY 2023.

B. Sponsor Fee Rates for FY 2023

FDA must set the fee rates for FY 2023 so that the estimated equivalent of 38.71 full sponsor fees will generate a total of $10,988,625. To generate this amount will require the 100 percent fee for a generic new animal drug sponsor, rounded to the nearest dollar, to be $283,870. Accordingly, the fee for those paying 75 percent of the full sponsor fee will be $212,903, and the fee for those paying 50 percent of the full sponsor fee will be $141,935.

VI. Fee Schedule for FY 2023

The fee rates for FY 2023 are summarized in table 5.

TABLE 5—FY 2023 FEE RATES

Generic new animal drug user fee category	Fee rate for FY 2023
Abbreviated Application Fee for Generic New Animal Drug except those subject to the criteria in section 512(d)(4)	$494,983
Abbreviated Application Fee for Generic New Animal Drug subject to the criteria in section 512(d)(4)	247,492
Generic New Animal Drug Product Fee	18,881
100% Generic New Animal Drug Sponsor Fee [1]	283,870
75% Generic New Animal Drug Sponsor Fee [1]	212,903
50% Generic New Animal Drug Sponsor Fee [1]	141,935

[1] An animal drug sponsor is subject to only one such fee each fiscal year.

VII. Fee Waiver or Reduction; Exemption From Fees

The types of fee waivers and reductions that applied last fiscal year still exist for FY 2023. In AGDUFA III, a new exemption from fees was established as follows: Fees will not apply to any person who not later than September 30, 2023, submits to CVM a supplemental abbreviated application relating to a generic new animal drug approved under section 512 of the FD&C Act, solely to add the application number to the labeling of the drug in the manner specified in section 502(w)(3) of the FD&C Act (21 U.S.C. 352(w)(3)), if that person otherwise would be subject to user fees under AGDUFA based only on the submission of the supplemental abbreviated application (21 U.S.C. 379j–21(d)(2)).

VIII. Procedures for Paying FY 2023 Fees

A. Abbreviated Application Fees and Payment Instructions

The FY 2023 fee established in the new fee schedule must be paid for a generic new animal drug application subject to fees under AGDUFA III that is submitted on or after October 1, 2022. 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 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* or the *Pay.gov* payment option is available to you after you submit a cover sheet. (Note: only full payments are accepted. No partial payments can be made online.) Once you find 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 that are 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 write your application's unique Payment Identification Number (PIN), beginning with the letters ''AG'', on the upper right-hand corner of your completed Animal Generic Drug User Fee Cover Sheet. Also write FDA's post office box number (P.O. Box 979033) and PIN on the enclosed check, bank draft, or money order. Mail the payment and a copy of the completed Animal Generic Drug User Fee Cover Sheet to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000. Note: In no case should the payment for the fee be submitted to FDA with the application.

When paying by wire transfer, the invoice number or PIN needs to be included. Without the invoice number or PIN, the payment may not be applied, and the invoice amount would be referred to collections. 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. Use the following account information when sending a payment by wire

transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account Number: 75060099, U.S. Department of the Treasury routing/transit number: 021030004, SWIFT Number: FRNYUS33.

To send a check by a courier such as FedEx, the courier must deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 979033, 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 telephone number is only for questions about courier delivery.)

It is important that the fee arrives at the bank at least a day or two before the abbreviated application arrives at FDA's CVM. FDA records the official abbreviated application receipt date as the later of the following: the date the application was received by CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U.S. Department of the Treasury notifies FDA of payment. U.S. Bank and the U.S. Department of the Treasury are required to notify FDA within 1 working day, using the PIN described previously.

The tax identification number of FDA is 53–0196965.

B. Application Cover Sheet Procedures

Step One: Create a user account and password. Log onto the AGDUFA website at *https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm137049.htm* and, under Application Submission Information, click on ''Create AGDUFA User Fee Cover Sheet.'' For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two: Create an Animal Generic Drug User Fee Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your user name and password, complete the steps required to create an Animal Generic Drug User Fee Cover Sheet. One cover sheet is needed for each abbreviated application for a generic new animal drug. Once you are satisfied that the data on the cover sheet are accurate and you have finalized the cover sheet, you will be able to transmit it electronically to FDA, and you will be able to print a copy of your cover sheet showing your unique PIN.

Step Three: Send the payment for your application as described in section VIII.A.

Step Four: Submit your application.

C. Product and Sponsor Fees

By December 31, 2022, FDA will issue invoices and payment instructions for product and sponsor fees for FY 2023 using this fee schedule. Payment will be due by January 31, 2023. FDA will issue invoices in November 2023 for any products and sponsors subject to fees for FY 2023 that qualify for fees after the December 2022 billing.

Dated: July 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1590]

Food Safety Modernization Act Voluntary Qualified Importer Program User Fee Rate for Fiscal Year 2023

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2023 annual fee rate for importers approved to participate in the Voluntary Qualified Importer 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).

DATES: This fee is effective on August 1, 2022, and will remain in effect through September 30, 2023.

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 (Pub L. 111–353), Voluntary Qualified Importer Program (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 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 FY (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 FY, to begin receiving benefits for that VQIP fiscal year.

The FY 2023 VQIP user fee will support benefits from October 1, 2022, through September 30, 2023.

II. Estimating the Average Cost of a Supported Direct FDA Work Hour for FY 2023

FDA is required to estimate 100 percent of its costs for each activity in order to establish fee rates for FY 2023. 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 2023

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 2023 cost. The FY 2023 FDA-wide average