four years. CDC requests information from states regarding children's cavity risk, one-year sealant retention rate, sealant program services delivered, and school sealant program cost and quantity of resources used at each school event. This data will allow CDC and states to monitor the performance and efficiency of their school sealant programs, which will improve and extend program delivery to more children.

CDC requests OMB approval for a Reinstatement of a previously approved data collection. The total estimated annualized burden hours requested are 1,388. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
State Sealant Administrator	Add Program and Add User	18	1	45/60
SSP Local Administrator	Add User and Add School	162	1	43/60
SSP Local Administrator	Program Options and Cost Options	162	1	46/60
SSP Local Administrator	Add Event	162	20	21/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4488]

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2024

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the fee rates and payment procedures for fiscal year (FY) 2024 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Drug User Fee Amendments of 2023 (ADUFA V), authorizes FDA to collect user fees for certain animal drug applications and supplemental animal drug applications, for certain animal drug products, for certain establishments where such products are made, and for certain sponsors of such animal drug applications and/or investigational animal drug submissions. This notice establishes the fee rates for FY 2024.

DATES: The application fee rates are effective for applications submitted on or after October 1, 2023, and will remain in effect through September 30, 2024.

FOR FURTHER INFORMATION CONTACT: Visit FDA's website at *https://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/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: *cvmadufa@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

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

For FYs 2024 through 2028, the FD&C Act establishes the base revenue amount for each fiscal year (21 U.S.C. 379j–12(b)(1)). Beginning in FY 2025, the base revenue amount is subject to adjustment for inflation and workload (21 U.S.C. 379j–12(c)(2) and (3)). Also beginning in FY 2025, ADUFA V provides for an operating reserve adjustment to allow FDA to adjust the fee revenue amount to maintain a specified operating reserve of carryover user fees (21 U.S.C. 379j–12(c)(4)). FDA may increase the fee revenue amount to maintain a 12-week minimum. If FDA has an excess operating reserve, FDA will decrease the fee revenue amount so that FDA has 22 weeks of operating reserve for FY 2025, 20 weeks for FY 2026, 18 weeks for FY 2027, and 16 weeks for FY 2028.

Fees for applications, establishments, 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) revenue from application fees shall be 20 percent of total fee revenue; (2) revenue from product fees shall be 27 percent of total fee revenue; (3) revenue from establishment fees shall be 26 percent of total fee revenue; and (4) revenue from sponsor fees shall be 27 percent of total fee revenue (21 U.S.C. 379jndash;12(b)(2)). The fee revenue amount for FY 2024 is $33,500,000 (21 U.S.C. 379j–12(b)(1)). The target revenue amounts for each fee category for FY 2024 are as follows: for application fees, the target revenue amount is $6,700,000; for product fees, the target revenue amount is $9,045,000; for establishment fees, the target revenue amount is $8,710,000; and for sponsor fees, the target revenue amount is $9,045,000.

For FY 2024, the animal drug user fee rates are: $683,673 for an animal drug application; $341,837 for a supplemental animal drug application for which safety or effectiveness data are required, for an animal drug application subject to the criteria set forth in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)), and for an application for conditional approval under section 571 of the FD&C Act (21 U.S.C. 360ccc) for which an animal drug application submitted under section 512(b)(1) of the FD&C Act has been previously approved under section 512(d)(1) of the FD&C Act for another intended use; $12,459 for the annual product fee; $174,200 for the annual establishment fee; and $153,305 for the annual sponsor fee. FDA will issue invoices for FY 2024 product, establishment, and sponsor fees by December 31, 2023, and payment will be due by January 31, 2024. The application fee rates are effective for applications submitted on or after October 1, 2023, and will remain in effect through September 30, 2024.

Applications will not be accepted for review until FDA has received full payment of application fees and any other animal drug user fees owed under the ADUFA program.

II. Revenue Amount for FY 2024

A. Statutory Fee Revenue Amounts

ADUFA V, Title III of Public Law 118–15, specifies that the aggregate base fee revenue amount for FY 2024 for all animal drug user fee categories is $33,500,000 (21 U.S.C. 379j–12(b)(1)).

B. Inflation Adjustment to Fee Revenue Amount

ADUFA V specifies that the annual fee revenue amount is to be adjusted for inflation increases for FY 2025 and subsequent fiscal years (21 U.S.C. 379j–12(c)(2)). Since ADUFA V does not adjust for inflation until FY 2025, there is no inflation adjustment for FY 2024.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

The fee revenue amounts established in ADUFA V for FY 2025 and subsequent fiscal years are also subject to adjustment to account for changes in FDA's review workload (21 U.S.C. 379j–12(c)(3)). Since ADUFA V does not adjust for workload until FY 2025, there is no workload adjustment for FY 2024.

D. Operating Reserve Adjustment

For fiscal year 2025 and each subsequent fiscal year, after the fee revenue amount established under section 740(b) of the FD&C Act is adjusted for inflation and workload, the Secretary shall increase the fee revenue amount for such fiscal year, if necessary to provide an operating reserve of not less than 12 weeks. If the operating reserve is in excess of the number of weeks specified in section 740(c)(4)(C) of the FD&C Act for that fiscal year, the Secretary shall decrease the fee revenue amount to provide not more than the number of weeks specified for that fiscal year. Since ADUFA V does not adjust for the operating reserve until FY 2025, there is no adjustment for FY 2024.

E. FY 2024 Fee Revenue Amounts

The fee revenue amount for FY 2024 is $33,500,000. ADUFA V specifies that this revenue amount is to be divided as follows: 20 percent, or a total of $6,700,000, is to come from application fees; 27 percent, or a total of $9,045,000, is to come from product fees; 26 percent, or a total of $8,710,000 is to come from establishment fees; and 27 percent, or a total of $9,045,000 is to come from sponsor fees (21 U.S.C. 379j–12(b)).

III. Application Fee Calculations for FY 2024

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

Each person that submits an animal drug application or a supplemental animal drug application shall be subject to an application fee, with limited exceptions (see 21 U.S.C. 379j–12(a)(1)). The term ''animal drug application'' means an application for approval of any new animal drug submitted under section 512(b)(1) of the FD&C Act or an application for conditional approval of a new animal drug submitted under section 571 of the FD&C Act (see section 739(1) of the FD&C Act (21 U.S.C. 379j–11(1)). A ''supplemental animal drug application'' is defined as a request to FDA to approve a change in an approved animal drug application, or a request to FDA to approve a change to an application approved under section 512(c)(2) of the FD&C Act for which data with respect to safety or effectiveness are required. Such applications are subject to ADUFA fees, except those fees may be waived if the application is intended solely to provide for a minor use or minor species (MUMS) indication (see 21 U.S.C. 379j–12(d)(1)(D)).

Furthermore, ADUFA V continues to provide an exception from application fees for animal drug applications submitted under section 512(b)(1) of the FD&C Act by a sponsor who previously applied for conditional approval under section 571 of the FD&C Act for the same product and paid an application fee at the time they applied for conditional approval. The purpose of this exception is to prevent sponsors of conditionally approved products from having to pay a second application fee at the time they apply for full approval of their products under section 512(b)(1) of the FD&C Act, provided the sponsor's application for full approval is filed consistent with the timeframes established in section 571(h) of the FD&C Act (see 21 U.S.C. 379j–12(a)(1)(C)(ii)).

The application fees are to be set so that they will generate $6,700,000 in fee revenue for FY 2024. The fee for a supplemental animal drug application for which safety or effectiveness data are required, for an animal drug application subject to criteria set forth in section 512(d)(4) of the FD&C Act, and for an application for conditional approval under section 571 of the FD&C Act of a new animal drug for which an animal drug application submitted under section 512(b)(1) of the FD&C Act has been previously approved under section 512(d)(1) for another intended use is to be set at 50 percent of the animal drug application fee (21 U.S.C. 379j–12(a)(1)(A)(ii)).

To set animal drug application fees and supplemental animal drug application fees to realize $6,700,000, FDA must first make some assumptions about the number of fee-paying applications and supplemental applications the Agency will receive in FY 2024.

The Agency knows the number of applications that have been submitted in previous fiscal years. That number fluctuates annually. In estimating the fee revenue to be generated by animal drug application fees in FY 2024, FDA is assuming that the number of applications for which fees will be paid in FY 2024 will equal the average number of applications over the 5 most recently completed fiscal years of the ADUFA program (FY 2018 to FY 2022).

Over the 5 most recently completed fiscal years, the average number of animal drug applications subject to the full fee was 5.20. Over this same period, the average number of supplemental applications for which safety or effectiveness data are required, applications subject to the criteria set forth in section 512(d)(4) of the FD&C Act, and applications for conditional approval of a new animal drug for which a section 512(b)(1) application has been previously approved for another intended use subject to half of the full fee was 9.20.

Based on the previous assumptions, FDA is estimating that it will receive a total of 9.80 fee-paying animal drug applications in FY 2024 (5.20 applications paying a full fee and 9.20 applications paying a half fee).

B. Application Fee Rates for FY 2024

FDA must set the fee rates for FY 2024 so that the estimated 9.80 applications that pay the fee will generate a total of $6,700,000. To generate this amount, the fee for an animal drug application, rounded to the nearest dollar, will have to be $683,673, and the fee for a supplemental animal drug application for which safety or effectiveness data are required, for applications subject to the criteria set forth in section 512(d)(4) of the FD&C Act, and for an application for conditional approval under section 571 of the FD&C Act of a new animal drug for which an animal drug application submitted under section 512(b)(1) of the FD&C Act has been previously approved under section 512(d)(1) for another intended use will have to be $341,837.

IV. Animal Drug Product Fee Calculations for FY 2024

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

The animal drug product fee must be paid annually by the person named as the applicant in a new animal drug application or supplemental new animal drug application for an animal drug product submitted for listing under section 510 of the FD&C Act (21 U.S.C. 360) and who had an animal drug application or supplemental animal drug application pending at FDA after September 1, 2003 (21 U.S.C. 379j–12(a)(2)). The term ''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 animal drug application or a supplemental animal drug application has been approved (21 U.S.C. 379j–11(3)). The product fees are to be set so that they will generate $9,045,000 in fee revenue for FY 2024.

To set animal drug product fees to realize $9,045,000, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2024. FDA developed data on all 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 an animal drug application or supplemental animal drug application pending after September 1, 2003. As of May 2023, FDA estimates that there are 733 products submitted for listing by persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. Based on this, FDA estimates that a total of 733 products will be subject to this fee in FY 2024.

In estimating the fee revenue to be generated by animal drug product fees in FY 2024, FDA is assuming that 1 percent of the products invoiced, or seven, will not pay fees in FY 2024, due to fee waivers and reductions. FDA has made this estimate at 1 percent this year, based on historical data over the past 5 completed fiscal years of the ADUFA program.

Accordingly, the Agency estimates that a total of 726 (733 minus 7) products will be subject to product fees in FY 2024.

B. Product Fee Rates for FY 2024

FDA must set the fee rates for FY 2024 so that the estimated 726 products for which fees are paid will generate a total of $9,045,000. To generate this amount will require the fee for an animal drug product, rounded to the nearest dollar, to be $12,459.

V. Animal Establishment Fee Calculations for FY 2024

A. Establishment Fee Revenues and Numbers of Fee-Paying Establishments

The animal drug establishment fee must be paid annually by the person who: (1) owns or operates, directly or through an affiliate, an animal drug establishment; (2) is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product submitted for listing under section 510 of the FD&C Act; (3) had an animal drug application or supplemental animal drug application pending at FDA after September 1, 2003; and (4) whose establishment engaged in the manufacture of the animal drug product during the fiscal year (see 21 U.S.C. 379j–12(a)(3)). An establishment subject to animal drug establishment fees is assessed only one such fee per fiscal year. The term ''animal drug establishment'' is defined as a foreign or domestic place of business at one general physical location, consisting of one or more buildings, all of which are within 5 miles of each other, at which one or more animal drug products are manufactured in final dosage form (21 U.S.C. 379j–11(4)). The establishment fees are to be set so that they will generate $8,710,000 in fee revenue for FY 2024.

To set animal drug establishment fees to realize $8,710,000, FDA must make some assumptions about the number of establishments for which these fees will be paid in FY 2024. FDA developed data on all animal drug establishments and matched this to the list of all persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. As of May 2023, FDA estimates that there are a total of 53 establishments owned or operated by persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. Based on this, FDA believes that 53 establishments will be subject to this fee in FY 2024.

In estimating the fee revenue to be generated by animal drug establishment fees in FY 2024, FDA is assuming that 6 percent of the establishments invoiced, or three, will not pay fees in FY 2024 due to fee waivers and reductions. FDA has made this estimate at 6 percent this year, based on historical data over the past 5 completed fiscal years.

Accordingly, the Agency estimates that a total of 50 establishments (53 minus 3) will be subject to establishment fees in FY 2024.

B. Establishment Fee Rates for FY 2024

FDA must set the fee rates for FY 2024 so that the fees paid for the estimated 50 establishments will generate a total of $8,710,000. To generate this amount will require the fee for an animal drug establishment, rounded to the nearest dollar, to be $174,200.

VI. Animal Drug Sponsor Fee Calculations for FY 2024

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

The animal drug sponsor fee must be paid annually by each person who: (1) is named as the applicant in an animal drug application, 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 animal drug submission that has not been terminated or otherwise rendered inactive and (2) had an animal drug application, supplemental animal drug application, or investigational animal drug submission pending at FDA after September 1, 2003 (see 21 U.S.C. 379j–11(6) and 379j–12(a)(4)). An animal drug sponsor is subject to only one such fee each fiscal year (see 21 U.S.C. 379j–12(a)(4)). The sponsor fees are to be set so that they will generate $9,045,000 in fee revenue for FY 2024.

To set animal drug sponsor fees to realize $9,045,000, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2024. FDA developed data on all animal drug sponsors and matched this to the list of all sponsors who had pending submissions and applications after September 1, 2003. As of May, 2023, FDA estimates that a total of 179 sponsors will meet this definition in FY 2024.

In estimating the fee revenue to be generated by animal drug sponsor fees in FY 2024, FDA is assuming that 67 percent of the sponsors invoiced, or 120, will not pay sponsor fees in FY 2024 due to fee waivers and reductions. FDA has made this estimate at 67 percent this year, based on historical data over the past 5 completed fiscal years of the ADUFA program.

Accordingly, the Agency estimates that a total of 59 sponsors (179 minus 120) will be subject to and pay sponsor fees in FY 2024.

B. Sponsor Fee Rates for FY 2024

FDA must set the fee rates for FY 2024 so that the estimated 59 sponsors that pay fees will generate a total of $9,045,000. To generate this amount will require the fee for an animal drug sponsor, rounded to the nearest dollar, to be $153,305.

VII. Fee Schedule for FY 2024

The fee rates for FY 2024 are summarized in table 1.

TABLE 1—FY 2024 FEE RATES

Animal drug user fee category	Fee rate for FY 2024
Animal Drug Application Fees:	
Animal Drug Application	$683,673
Supplemental Animal Drug Application for Which Safety or Effectiveness Data are Required, Animal Drug Application Subject to the Criteria Set Forth in Section 512(d)(4) of the FD&C Act, or Application for Conditional Approval Under Section 571 of the FD&C Act for Which an Animal Drug Application Submitted Under Section 512(b)(1) of the FD&C Act Has Been Previously Approved Under Section 512(d)(1) for Another Intended Use	341,837
Animal Drug Product Fee	12,459
Animal Drug Establishment Fee [1]	174,200
Animal Drug Sponsor Fee [2]	153,305

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

VIII. Fee Waiver or Reduction; Exemption From Fees

The types of fee waivers, fee reductions, and exemptions from fees that applied during ADUFA IV still exist in ADUFA V, with one exception. No longer available is the exemption for a supplemental animal drug application relating to a new animal drug application 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 503(w) of the FD&C Act (21 U.S.C. 352(w)).

Remaining waivers and reductions apply for the following: barriers to innovation; where fees will exceed the cost to review the animal drug application; if the application is related to certain free-choice medicated feeds; if the application is solely for a MUMS indication; or if the sponsor is a small business submitting its first animal drug application. See section 740(d)(1) of the FD&C Act.

A. Barrier to Innovation Waivers or Fee Reductions

Under section 740(d)(1)(A) of the FD&C Act, an animal drug applicant may qualify for a waiver or reduction of one or more ADUFA fees if the fee would present a significant barrier to innovation because of limited resources available to the applicant or other circumstances. CVM's guidance for industry (GFI) #170, entitled ''Animal Drug User Fees and Fee Waivers and Reductions,'' [1] states that the Agency interprets this provision to mean that a waiver or reduction is appropriate when: (1) the product for which the waiver is being requested is innovative, or the requestor is otherwise pursuing innovative animal drug products or technology, and (2) the fee would be a significant barrier to the applicant's ability to develop, manufacture, or market the innovative product or technology. Only those applicants that meet both of these criteria will qualify for a waiver or reduction in user fees under this provision (see GFI #170 at pp. 6–8). For purposes of determining whether the second criterion would be met on the basis of limited financial resources available to the applicant, FDA has determined an applicant with financial resources of less than $20,000,000 (including the financial resources of the applicant's affiliates), adjusted annually for inflation, has limited resources available. Using the Consumer Price Index for urban consumers (U.S. city average; not seasonally adjusted; all items; annual index), the inflation-adjusted level for FY 2024 will be $22,796,000; this level represents the financial resource ceiling that will be used to determine if there are limited resources available to an applicant requesting a Barrier to Innovation waiver on financial grounds for FY 2024. Requests for a waiver need to be submitted to FDA each fiscal year not later than 180 days from when the fees are due. A waiver granted on Barrier to Innovation grounds (or any of the other grounds listed in section 740(d)(1) of the FD&C Act) is only valid for 1 fiscal year. If a sponsor is not granted a waiver, they are liable for the fees.

B. Exemption or Exception From Fees

In addition to the waivers and fee reductions described above, one fee exemption and two exceptions still apply in ADUFA V.

If an animal drug application, supplemental animal drug application, or investigational submission involves the intentional genomic alteration of an animal that is intended to produce a human medical product, any person who is the named applicant or sponsor of that application or submission will not be subject to sponsor, product, or establishment fees under ADUFA based solely on that application or submission (21 U.S.C. 379j–12(d)(4)).

There is an exception from application fees for animal drug applications submitted under section 512(b)(1) of the FD&C Act by a sponsor who previously applied for conditional approval under section 571 of the FD&C Act for the same product and paid an application fee at the time they applied for conditional approval, provided the sponsor has submitted the application under section 512(b)(1) of the FD&C Act within the timeframe specified in section 571(h) of the FD&C Act. There is also an exception from application fees for previously filed applications that were not approved or were withdrawn (without waiver or refund). Both exceptions are detailed in section 740(a)(1)(C) of the FD&C Act.

IX. Procedures for Paying the FY 2024 Fees

A. Application Fees and Payment Instructions

The FY 2024 fee established in the new fee schedule must be paid for an animal drug application or supplement subject to fees under ADUFA V that is submitted on or after October 1, 2023. The payment must be made in U.S. currency from a U.S. bank by one of the following methods: wire transfer,

[1] CVM's GFI #170 is located at: *https://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052494.pdf.*

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 search for and find your invoice, select ''Pay Now'' to be redirected to *www.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 AD, on the upper right-hand corner of your completed Animal Drug User Fee Cover Sheet. Also write the 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 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: U.S. Bank, Attn: Government Lockbox 979033, 3180 Rider Trail S., Earth City, MO 63045. (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 application arrives at FDA's CVM. FDA records the official 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 receipt of an electronic or wire transfer 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 on to the ADUFA website at *https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/animal-drug-user-fee-cover-sheet* and, under Application Submission Information, click on ''Create ADUFA 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 Drug User Fee Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your username and password, complete the steps required to create an Animal Drug User Fee Cover Sheet. One cover sheet is needed for each animal drug application or supplement. 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 IX.A.

Step Four: Submit your application.

C. Product, Establishment, and Sponsor Fees

By December 31, 2023, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2024 using this fee schedule. Payment will be due by January 31, 2024. FDA will issue invoices in November 2024 for any products, establishments, and sponsors subject to fees for FY 2024 that qualify for fees after the December 2023 billing.

Dated: October 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–23373 Filed 10–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–4468]

Animal Generic Drug User Fee Program Rates and Payment Procedures for Fiscal Year 2024

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the fee rates and payment procedures for fiscal year (FY) 2024 generic new animal drug program user fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Generic Drug User Fee Amendments of 2023 (AGDUFA IV), authorizes FDA to collect user fees for certain abbreviated applications for generic new animal drugs, for certain generic new animal drug products, for certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs, and for certain submissions related to generic investigational new animal drug (JINAD) files. This notice establishes the fee rates for FY 2024.

DATES: The application fee rates are effective for all abbreviated applications for a generic new animal drug submitted on or after October 1, 2023, and will remain in effect through September 30, 2024. The fee rates for requests to establish a JINAD file, and for certain submissions to JINAD files established prior to October 1, 2023, are effective on October 1, 2023, and will remain in effect through September 30, 2024.

FOR FURTHER INFORMATION 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,* or visit FDA's website at *https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm.* For general questions, you may also email the Center for Veterinary