individuals. We estimate that it will take each screener respondent approximately 5 minutes (0.083 hours) to complete the cognitive interview screener, for a total of 6 hours. We will conduct cognitive interviews with 18 participants. We estimate that it will take each participant approximately 1 hour to complete the interview, for a total of 18 hours. Prior to the administration of the surveys, the Agency plans to conduct a pretest to identify and resolve potential survey administration problems. The pretest will be conducted with 100 participants; we estimate that it will take each participant 20 minutes (0.33 hours) for the pretest for a total of 33 hours. We estimate that 5,000 eligible adults will participate in the survey with each taking 20 minutes (0.33 hours), for a total of 1,650 hours. Thus, the total estimated burden is 1,707 hours.

Dated: July 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16832 Filed 7–30–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3480]

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the fee rates and payment procedures for fiscal year (FY) 2025 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 2025.

DATES: The application fee rates apply to applications submitted on or after October 1, 2024, and will remain in effect through September 30, 2025.

FOR FURTHER INFORMATION CONTACT: Visit FDA's website at: *https://www.fda.gov/industry/fda-user-fee-programs/animal-drug-user-fee-act-adufa* 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.*

For questions relating to this notice: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 240–402–4989; or the User Fee Support Staff at *OO-OFBAP-OFM-UFFS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 740(a) 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 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. When certain conditions are met, FDA will waive or reduce fees per section 740(d) of the FD&C Act.

For FYs 2024 through 2028, section 740(b)(1) of the FD&C Act establishes the base revenue amount for each fiscal year. Per section 740(c)(2) and (3) of the FD&C Act, the base revenue amounts established for fiscal years after FY 2024 are subject to adjustment for inflation and workload. Beginning in FY 2025, the annual fee revenue amount is also subject to an operating reserve adjustment to allow FDA to adjust the fee revenue amount to maintain a specified operating reserve of carryover user fees, per section 740(c)(4) of the FD&C Act. 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.

Per section 740(b)(2) of the FD&C Act, 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. The target revenue amounts for each fee category for FY 2025 are as follows: for application fees, the target revenue amount is $5,701,000; for product fees, the target revenue amount is $7,697,000; for establishment fees, the target revenue amount is $7,412,000; and for sponsor fees, the target revenue amount is $7,697,000.

For FY 2025, the animal drug user fee rates are: (1) $581,735 for an animal drug application; (2) $290,867 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), 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; (3) $10,705 for the annual product fee; $157,702 for the annual establishment fee; and (4) $137,446 for the annual sponsor fee. FDA will issue invoices for FY 2025 product, establishment, and sponsor fees by December 31, 2024, and payment will be due by January 31, 2025. The application fee rates are effective for applications submitted on or after October 1, 2024, and will remain in effect through September 30, 2025. 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. Fee Revenue Amount for FY 2025

A. Statutory Fee Revenue Amounts

Section 740(b)(1) of the FD&C Act specifies that the base fee revenue amount for FY 2025 for all animal drug user fee categories totals $33,500,000.

B. Inflation Adjustment to Fee Revenue Amount

Section 740(c)(2)(A)(ii) and (iii) of the FD&C Act specifies that the annual fee revenue amount is to be adjusted for inflation increases for FY 2025 and subsequent fiscal years using two separate adjustments: one for personnel compensation and benefits (PC&B) and one for non-PC&B costs. Section 740(c)(2)(A)(ii) of the FD&C Act specifies 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 total PC&B cost per FTE 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 2025. The 3-year average is 3.8539 percent.

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

Fiscal year	2021	2022	2023	3-Year average
Total PC&B	$3,039,513,000	$3,165,477,000	$3,436,513,000	.....
Total FTEs	18,501	18,474	18,729	.....
PC&B per FTE	$164,289	$171,348	$183,486	.....
Percentage Change From Previous Year	0.1811%	4.2967%	7.0838%	3.8539%

Section 740(c)(2)(A)(ii) of the FD&C Act specifies that this 3.8539 percent should be multiplied by the proportion of PC&B costs to total FDA costs for the first 3 of the preceding 4 fiscal years for which data are available. Table 2 shows the amount of PC&B and the total amount obligated by FDA for the same 3 fiscal years.

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

Fiscal year	2021	2022	2023	3-Year average
Total PC&B	$3,039,513,000	$3,165,477,000	$3,436,513,000	.....
Total Costs	$6,049,798,000	$6,251,981,000	$6,654,058,000	.....
PC&B percent	50.2416%	50.6316%	51.6454%	50.8395%

The portion of the inflation adjustment relating to payroll costs is 3.8539 percent multiplied by 50.8359 percent, or 1.9593 percent.

Section 740(c)(2)(A)(iii) of the FD&C Act 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) (Washington-Arlington-Alexandria, DC-VA-MD-WV; not seasonally adjusted; all items less food and energy; annual index) for the first 3 years 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 years of the preceding 4 fiscal 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]

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENTAGE CHANGE IN CPI (LESS FOOD AND ENERGY) FOR WASHINGTON-ARLINGTON-ALEXANDRIA AREA

Fiscal year	2021	2022	2023	3-Year average
Annual CPI	287.144	302.608	313.315	.....
Annual Percent Change	3.1271%	5.3855%	3.5382%	4.0169%

Section 740(c)(2)(A)(iii) of the FD&C Act specifies to calculate the inflation adjustment for non-payroll costs, we multiply 4.0169 percent by the average proportion of all costs other than PC&B to total FDA costs for the first 3 years of the preceding 4 fiscal years. Since 50.8395 percent was obligated for PC&B as shown in table 2, 49.1605 percent is the portion of costs other than PC&B (100 percent minus the PC&B percentage of 50.8395). The portion of the inflation adjustment relating to non-payroll costs is 4.0169 percent multiplied by 49.1605 percent, or 1.9747 percent.

Next, we add the payroll component (1.9593 percent) to the non-payroll component (1.9747 percent), for an inflation adjustment of 3.9340 percent for FY 2025.

Section 740(c)(2)(B) of the FD&C Act provides for the inflation adjustment to be compounded each fiscal year after FY 2025. The inflation adjustment for FY 2025 (3.9340 percent) is compounded by adding 1 and then multiplying by 1 plus the inflation adjustment factor for FY 2024 (zero percent), which equals 1.0393 (rounded) (1.0393 multiplied 1.0). We then multiply the base revenue amount for FY 2025 ($33,500,000) by 1.0393, yielding an inflation adjusted amount of $34,817,890.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

Section 740(c)(3)(A) of the FD&C Act specifies that the annual fee revenue amounts in ADUFA V for FY 2025 and subsequent fiscal years are subject to adjustment to account for changes in FDA's review workload. The workload

[1] The data is published by the Bureau of Labor Statistics and can be found on its website at: *https://data.bls.gov/timeseries/CUURS35ASA0L1E.*

adjustment will be applied to the inflation adjusted fee revenue amount.

To determine whether a workload adjustment applies, per ADUFA V commitments FDA calculates the weighted average of the change in the total number of each of the five types of applications and submissions specified in the workload adjustment provision (animal drug applications, supplemental animal drug applications for which data with respect to safety or efficacy are required, manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational animal drug protocol submissions) received over the 5-year period that ended on September 30, 2023 (the base years; 2019 through 2023), and the average number of each of these types of applications and submissions over the most recent 5-year period that ended April 30, 2024.

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/submissions, reflecting how much of the total FDA 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 negative 4.4338 percent for FY 2025. This is the workload adjuster for FY 2025.

TABLE 4—WORKLOAD ADJUSTER CALCULATION

Application type	Column 1 5-Year average (base years)	Column 2 Latest 5-year average	Column 3 Percent change	Column 4 Weighting factor	Column 5 Weighted percent change
New Animal Drug Application (NADAs)	11.60	12.40	6.8966	0.0355	0.2447
Supplemental NADAs With Safety or Efficacy Data	8.20	7.60	−7.3171	0.0276	−0.2021
Manufacturing Supplements	367.20	359.20	−2.1786	0.2065	−0.4499
Investigational Study Submissions	164.20	159.00	−3.1669	0.5887	−1.8644
Investigational Protocol Submissions	216.20	183.20	−15.2636	0.1416	−2.1621
FY 2025 ADUFA V Workload Adjuster					−4.4338

Section 740(c)(3)(B) of the FD&C Act specifies that under no circumstances shall the workload adjustment result in fee revenues that are less than the base fee revenues for that fiscal year as adjusted for inflation. Additionally, section 740(c)(3)(A)(ii) states that the workload adjuster must be greater than 3 percent for a second fiscal year within ADUFA V before FDA can add the adjustment to the target revenue. For FY 2025 the workload adjuster is below the 3 percent statute threshold, therefore no workload adjustment shall be applied.

D. Operating Reserve Adjustment to Inflation and Workload Adjusted Fee Revenue Amount

Section 740(c)(4)(A) of the FD&C Act specifies that for FY 2025, 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 or decrease the fee revenue amount for such fiscal year, if necessary to provide for not more than 22 weeks of operating reserves.

To determine the dollar amounts for the 12-week and 22-week operating reserve thresholds, we divide the adjusted annual fee revenue amount (rounded) ($34,818,000) by 52 weeks to generate a 1-week operating reserve amount of $669,577. The 1-week operating reserve amount is then multiplied by 12 and 22. This results in a 12-week minimum threshold of $8,034,923 and a 22-week maximum threshold of $14,730,692.

To estimate the FY 2024 end-of-year operating reserve of carryover user fees, the Agency projected the user fee carryover amount at the end of July 2024 using forecasted obligations, collections, and estimated recoveries but not including carryover use fees that have not been appropriated. The operating reserve of carryover user fees is projected to be $21,041,545 or 31.43 weeks ($21,041,545 divided by $669,577).

Because the estimated FY 2024 end-of-year operating reserve of carryover user fees is not below the 12-week threshold amount of $8,034,923, FDA will not increase the fee revenue amount and fees for FY 2025.

However, because the estimated FY 2024 end-of-year operating reserve of carryover user fees of $21,041,545 exceeds the 22-week threshold of $14,730,692, FDA will apply an operating reserve adjustment of $6,310,853 to decrease the fee revenue and fees for FY 2025.

With respect to target revenue for FY 2025, subtracting the operating reserve adjustment amount of $6,310,853 from the adjusted fee revenue amount of $34,817,890 results in a total target revenue amount of $28,507,037 for FY 2025.

E. FY 2025 Fee Revenue Amounts

The fee revenue amount (rounded) for FY 2025 is $28,507,000. Section 740(b)(2) of the FD&C Act specifies that this revenue amount is to be divided as follows: 20 percent, or a total of $5,701,000 is to come from application fees; 27 percent, or a total of $7,697,000, is to come from product fees; 26 percent, or a total of $7,412,000 is to come from establishment fees; and 27 percent, or a total of $7,697,000 is to come from sponsor fees.

III. Animal Drug Application Fee Calculations for FY 2025

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

Section 740(a)(1)(A) of the FD&C Act states that each person that submits an animal drug application or a supplemental animal drug application shall be subject to an application fee, with limited exceptions. 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. 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 under the circumstances described in section 740(d)(1)(D) and 740(i) of the FD&C Act.

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.

The application fees are to be set so that they will generate $5,701,000 in fee revenue for FY 2025. 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.

To set animal drug application fees and supplemental animal drug application fees to realize $5,701,000 FDA must first make some assumptions about the number of fee-paying applications and supplemental applications the Agency will receive in FY 2025.

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 2025, FDA is assuming that the number of applications for which fees will be paid in FY 2025 will equal the average number of applications over the five most recently completed fiscal years of the ADUFA program (FY 2019 to FY 2023).

Over the 5 most recently completed fiscal years, the average number of animal drug applications subject to the full fee was 5.60. 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 8.40.

Based on the previous assumptions, FDA is estimating that it will receive a total of 9.80 fee-paying animal drug applications in FY 2025 (5.60 applications paying a full fee and 8.40 applications paying a half fee).

B. Application Fee Rates for FY 2025

FDA must set the fee rates for FY 2025 so that the estimated 9.80 applications that pay the fee will generate a total of $5,701,000. To generate this amount, the fee for an animal drug application, rounded to the nearest dollar, will have to be $581,735, 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 $290,867.

IV. Animal Drug Product Fee Calculations for FY 2025

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

Section 740(a)(2) of the FD&C Act specifies that 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. 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 (see section 739(3) of the FD&C Act). The product fees are to be set so that they will generate $7,697,000 in fee revenue for FY 2025.

To set animal drug product fees to realize $7,697,000, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2025. 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 a supplemental animal drug application pending after September 1, 2003. As of May 2024, FDA estimates that there are 734 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 734 products will be subject to this fee in FY 2025.

In estimating the fee revenue to be generated by animal drug product fees in FY 2025, FDA is assuming that 2 percent of the products invoiced, or 15, will not pay fees in FY 2025, due to fee waivers and reductions. FDA has made this estimate at 2 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 719 (734 minus 15) products will be subject to product fees in FY 2025.

B. Product Fee Rates for FY 2025

FDA must set the fee rates for FY 2025 so that the estimated 719 products for which fees are paid will generate a total of $7,697,000. To generate this amount will require the fee for an animal drug product, rounded to the nearest dollar, to be $10,705.

V. Animal Drug Establishment Fee Calculations for FY 2025

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

Section 740(a)(3) of the FD&C Act states that 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. 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 (see section 739(4) of the FD&C Act). The establishment fees are to be set so that they will generate $7,412,000 in fee revenue for FY 2025.

To set animal drug establishment fees to realize $7,412,000, FDA must make some assumptions about the number of establishments for which these fees will be paid in FY 2025. 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 2024, FDA estimates that there are a total of 50 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 50 establishments will be subject to this fee in FY 2025.

In estimating the fee revenue to be generated by animal drug establishment fees in FY 2025, FDA is assuming that 6 percent of the establishments invoiced, or three, will not pay fees in FY 2025 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 47 establishments (50 minus 3) will be subject to establishment fees in FY 2025.

B. Establishment Fee Rates for FY 2025

FDA must set the fee rates for FY 2025 so that the fees paid for the estimated 47 establishments will generate a total of $7,412,000. To generate this amount will require the fee for an animal drug establishment, rounded to the nearest dollar, to be $157,702.

VI. Animal Drug Sponsor Fee Calculations for FY 2025

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 sections 739(6) and 740(a)(4) of the FD&C Act). An animal drug sponsor is subject to only one such fee each fiscal year (see § 740(a)(4) of the FD&C Act). The sponsor fees are to be set so that they will generate $7,697,000 in fee revenue for FY 2025.

To set animal drug sponsor fees to realize $7,697,000, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2025. 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 2024, FDA estimates that a total of 176 sponsors will meet this definition in FY 2025.

In estimating the fee revenue to be generated by animal drug sponsor fees in FY 2025, FDA is assuming that 68 percent of the sponsors invoiced, or 120, will not pay sponsor fees in FY 2025 due to fee waivers and reductions. FDA has made this estimate at 68 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 56 sponsors (176 minus 120) will be subject to and pay sponsor fees in FY 2025.

B. Sponsor Fee Rates for FY 2025

FDA must set the fee rates for FY 2025 so that the estimated 56 sponsors that pay fees will generate a total of $7,697,000. To generate this amount will require the fee for an animal drug sponsor, rounded to the nearest dollar, to be $137,446.

VII. Fee Schedule for FY 2025

The fee rates for FY 2025 are summarized in table 5.

TABLE 5—FY 2025 FEE RATES

Animal drug user fee category	Fee rate for FY 2025
Animal Drug Application Fees:	
Animal Drug Application	$581,735
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.	290,867
Animal Drug Product Fee	10,705
Animal Drug Establishment Fee [1]	157,702
Animal Drug Sponsor Fee [2]	137,446

[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. After September 30, 2023, there is no longer an exemption for any person who submits to CVM 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.

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,'' [2] 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 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 based on 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 CPI for urban consumers (U.S. city average; not seasonally adjusted; all items; annual index), the inflation-adjusted level for FY 2025 will be $23,258,600; 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 2025. Requests for a waiver must be submitted in writing 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 one fiscal year. If a sponsor is not granted a waiver, they are liable for the fees.

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

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 (see section 740(d)(4) of the FD&C Act).

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 2025 Fees

A. Application Fees and Payment Instructions

The FY 2025 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, 2024. 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). 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. 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.* 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 South, 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 855–259–3064. 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 applying 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 the 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 is accurate and you have finalized the cover sheet, you will be able to transmit it electronically to the 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 above.

Step Four: Submit your application.

C. Product, Establishment, and Sponsor Fees

By December 31, 2024, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2025 using this fee schedule. Payment will be due by January 31, 2025. FDA will issue invoices in November 2025 for any products, establishments, and sponsors subject to fees for FY 2025 that qualify for fees after the December 2024 billing.

Dated: July 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–16894 Filed 7–30–24; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3481]

Animal Generic Drug User Fee Program Rates and Payment Procedures for Fiscal Year 2025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the fee rates and payment procedures for fiscal year (FY) 2025 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 (JINAD's), and for certain submissions related to JINAD files. This notice establishes the fee rates for FY 2025.

DATES: The application fee rates are effective for all abbreviated applications for a generic new animal drug submitted on or after October 1, 2024, and will remain in effect through September 30, 2025. 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, 2024, and will remain in effect through September 30, 2025.

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 the Center for Veterinary Medicine (CVM) at: *cvmagdufa@fda.hhs.gov.*

For questions relating to this notice: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 240–402–4989; or the User Fee Support Staff at *OO-OFBAP-OFM-UFFS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 741(a) of the FD&C Act (21 U.S.C. 379j–21(a)), establishes four different types of generic new animal drug user fees: (1) fees for certain abbreviated applications for generic new animal drugs; (2) annual fees for certain generic new animal drug products; (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs; and (4) JINAD file fees. When certain conditions are met, section 741(d) of the FD&C Act authorizes FDA to waive or reduce fees for generic new animal drugs intended solely to provide for a minor use or minor species indication.

Section 741(b)(1) of the FD&C Act establishes a base revenue amount for each fiscal year. Per section 741(c)(2) and (3) of the FD&C Act, the base revenue amounts established for fiscal years after FY 2024 are subject to adjustment for inflation and workload. Beginning FY 2026, the annual fee revenue amounts are also subject to adjustment to reduce workload-based increases by the amount of certain excess collections. Section 741(b) of the FD&C Act establishes fees each year so that the percentage allocations for each of the fee categories is as follows: 20 percent shall be derived from fees for abbreviated applications for a generic new animal drug and JINAD file fees; 40 percent shall be derived from fees for generic new animal drug products; and 40 percent shall be derived from fees for generic new animal drug sponsors. The target revenue amounts for each fee category for FY 2025 are as follows: for application and/or JINAD file fees, the target revenue amount is $5,196,700; for product fees, the target revenue amount is $10,393,400; and for sponsor fees, the target revenue amount is $10,393,400.

For FY 2025, the AGDUFA rates are: $161,907 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)); $80,954 for each abbreviated application for a generic new animal drug subject to the criteria in section 512(d)(4) of the FD&C Act; $50,000 for each JINAD file request or certain submissions to established JINAD files; $16,139 for each generic new animal drug product; $270,204 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; $202,653 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and $135,102 for each generic new animal drug sponsor paying 50 percent of the sponsor fee. FDA will