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]

BILLING CODE 4164–01–P

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

issue invoices for FY 2025 product and sponsor fees by December 31, 2024, and payment will be due by January 31, 2025. 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 rate for requests to establish a JINAD file, and for certain submissions to JINAD files established prior to October 1, 2023, is effective on 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 fees owed under the AGDUFA program. Similarly, a request to establish a JINAD file or a submission to an existing JINAD file will not be accepted for action by FDA until FDA has received full payment of all fees owed under the AGDUFA program.

II. Fee Revenue Amount for FY 2025

A. Statutory Fee Revenue Amounts

Section 741(b)(1) of the FD&C Act specifies that the base fee revenue amount for FY 2025 for all generic animal drug user fee categories totals $25,000,000.

B. Inflation Adjustment to Fee Revenue Amount

Section 741(c)(2)(A) 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 factors—one for personnel compensation and benefits (PC&B) costs and one for non-PC&B costs.

Section 741(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, per full-time equivalent (FTE) position of the FDA, for the first 3 of the preceding 4 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 costs per FTE for the specified fiscal years, provides the percentage change from the previous fiscal year, and provides the average percentage 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 PERCENT 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	.....
Percent Change from Previous Year	0.1811%	4.2967%	7.0838%	3.8539%

Section 741(c)(2)(A)(ii) of the FD&C Act specifies that the 3.8539 percent should be multiplied by the average 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 costs obligated by FDA for the same 3 fiscal years.

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

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 741(c)(2)(A)(iii) of the FD&C Act specifies that the non-payroll costs adjustment factor is calculated by multiplying the average annual percentage change that occurred in the Consumer Price Index for Urban Consumers (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 by the average proportion of all non-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 percentage change in the specified CPI for the Washington-Arlington-Alexandria area.[1]

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT 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%

[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.*

Section 741(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 741(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 × 1.0). We then multiply the base revenue amount for FY 2025 ($25,000,000) by 1.0393, yielding an inflation adjusted amount of $25,983,500.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

Section 741(c)(3)(A) of the FD&C Act specifies that fee revenue amounts for FY 2025 and subsequent fiscal years are subject to adjustment to account for changes in FDA's review workload. The workload adjustment would be applied to the inflation adjusted fee revenue amount.

To determine whether a workload adjustment applies, per AGDUFA IV commitments FDA calculates the weighted average of the change in the total number of each of the six 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, investigational generic new animal drug protocol submissions, generic investigational new animal drug file requests, and generic investigational new animal drug meeting requests) 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/submission, 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 negative 0.9977 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
Abbreviated Application for a Generic New Animal Drug (ANADAs)	28.00	31.60	12.8571	0.0902	1.1600
Manufacturing Supplements ANADAs	249.40	249.20	−0.0802	0.2321	−0.0186
Generic Investigational Study Submissions	171.80	167.00	−2.7939	0.4759	−1.3296
Generic Investigational Protocol Submissions	58.00	54.60	−5.8621	0.1068	−0.6263
Generic Investigational New Animal Drug File Requests (JINAD)	49.20	47.20	−4.0650	0.0183	−0.0744
Generic Investigational New Animal Drug Meeting Requests (JINAD)	28.20	27.80	−1.4184	0.0767	−0.1087
FY 2025 AGDUFA IV Workload Adjuster					−0.9977

Per section 741(c)(3)(C) of the FD&C Act 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. For FY 2025 the workload adjustment would result in fee revenues less than the base fee revenues as adjusted for inflation, therefore no workload adjustment shall be applied.

E. FY 2025 Fee Revenue Amounts

AGDUFA IV specifies that the revenue amount of $25,983,500 for FY 2025 is to be divided as follows: 20 percent, or a total of $5,196,700, is to come from application and/or JINAD file fees; 40 percent, or a total of $10,393,400, is to come from product fees; and 40 percent, or a total of $10,393,400 is to come from sponsor fees (See section 741(b) of the FD&C Act).

III. Abbreviated Application Fee and Generic Investigational New Animal Drug (JINAD) File Fee Calculations for FY 2025

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

Section 741(a)(1)(A) of the FD&C Act states that each person who submits an abbreviated application for a generic new animal drug shall be subject to an application fee, with limited exceptions. 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. FDA will assess fees related to JINAD files under section 741(a)(4)(A)(i) of the FD&C Act when a person submits a request to establish a new JINAD file. FDA will assess a fee under section 741(a)(4)(A)(ii) and (iii) of the FD&C Act for a person's first submission, as described below, to a JINAD file on or after October 1, 2023, where the JINAD file had been established prior to that date. The JINAD file fee is set in accordance with

section 741(c)(1)(C) of the FD&C Act at $50,000. FDA will set the abbreviated application fee so that such fees combined with the JINAD file fees will generate a combined total of $5,196,700 in fee revenue for FY 2025.

To set fees for abbreviated applications for generic new animal drugs, FDA must first make some assumptions about the number of fee-paying abbreviated applications it will receive during FY 2025, the number of requests to establish new JINAD files it will receive during FY 2025, and the number of existing (prior to October 1, 2023) JINAD files to which it will receive submissions during FY 2025.

Regarding the fee for a person's first submission to an existing (prior to October 1, 2023) JINAD file on or after October 1, 2023, FDA intends to assess a fee only for the first data (or ''P'') submission to the Bioequivalence (BE) or Chemistry, Manufacturing, and Controls (CMC) technical sections of the JINAD file. The Agency has selected P submissions to the BE or CMC technical sections as the basis for assessing this fee because P submissions to these sections consistently entail the substantial use of FDA review hours during the phased review process.

The Agency knows the numbers of applications and submissions that have been submitted in previous years. Those numbers fluctuate annually. In estimating the fee revenue to be generated by application and submission fees in FY 2025, FDA is assuming that the number of applications and submissions for which fees will be paid in FY 2025 will equal the average number of applications and submissions over the 5 most recently completed fiscal years of the AGDUFA program (FY 2019–FY 2023).

In addition, under section 741(a)(1)(C)(ii) of the FD&C Act an abbreviated application for a generic new animal 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.

The average number of original submissions of abbreviated applications for generic new animal drugs over the 5 most recently completed fiscal years is 15 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 18.20 anticipated full fees.

Based on the previous assumptions, FDA is estimating that it will receive a total of 18.20 fee-paying generic new animal drug applications in FY 2025 (15.0 original applications paying a full fee and 6.4 applications paying a half fee).

For estimating the number of requests to establish a new JINAD file and the number of P submissions to the BE or CMC section of an existing (prior to October 1, 2023) JINAD file the Agency will receive in FY 2025, FDA took the number of new JINAD file requests and P submissions to the BE or CMC section of an existing JINAD file received in FY 2024. The number of requests to establish new JINAD files and P submissions to the BE or CMC section of existing JINAD files during FY 2024 as of June is 45.

Based on the previous assumptions, FDA is estimating that it will receive a total of 45 fee-paying JINAD file submissions in FY 2025 (including both requests to establish new JINAD files and first P submissions to the BE or CMC section of existing (prior to October 1, 2023) JINAD files).

B. Application Fee Rates for FY 2025

FDA must set the fee rates for FY 2025 so that the estimated 18.20 abbreviated application fees and 45 JINAD file fees will generate a total of $5,196,700. The fee for a new JINAD file request or the first submission to an existing (prior to October 1, 2023) JINAD file is $50,000 under section 741(c)(1)(C) of the FD&C Act. Therefore, the JINAD fees will generate a total of $2,250,000. Abbreviated application fees will have to generate a total of $2,946,700.

To generate this amount, the fee for a generic new animal drug application will be $161,907 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 $80,954.

IV. Generic New Animal Drug Product Fee Calculations For FY 2025

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 (21 U.S.C. 379j–21(a)(2)). Section 741(k)(6) of FD&C Act defines ''generic new animal drug product'' as a 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. The product fees are to be set so that they will generate $10,393,400 in fee revenue for FY 2025.

To set generic new animal drug product fees to realize $10,393,400, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2025. 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 FDA estimated would have a generic new animal drug application or supplemental abbreviated application pending after September 1, 2008. As of May 2024, FDA estimates that there is a total of 651 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 651 products will be subject to this fee in FY 2025.

Per section 741(d) of the FD&C Act in estimating the fee revenue to be generated by generic new animal drug product fees in FY 2025, FDA is estimating that 1 percent of the products invoiced, or 7 products, will not pay fees in FY 2025, 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 AGDUFA program.

Accordingly, the Agency estimates that a total of 644 (651 minus 7) 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 644 products for which fees are paid will generate a total of $10,393,400. To generate this amount will require the fee for a generic new animal drug product, rounded to the nearest dollar, to be $16,139.

V. Generic New Animal Drug Sponsor Fee Calculations for FY 2025

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 section 741(k)(7) and (a)(3) of the FD&C Act.

Per section 741(a)(3)(C) of the FD&C Act, a generic new animal drug sponsor is subject to only one such fee each fiscal year. Applicants with more than 6 approved abbreviated applications will pay 100 percent of the sponsor fee; applicants with more than 1 and fewer than 7 approved abbreviated applications will pay 75 percent of the sponsor fee; and applicants with 1 or fewer approved abbreviated applications will pay 50 percent of the sponsor fee. The sponsor fees are to be set so that they will generate $10,393,400 in fee revenue for FY 2025.

To set generic new animal drug sponsor fees to realize $10,393,400, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2025. FDA developed data on all generic new animal drug sponsors and matched this to the list of all sponsors who had pending submissions and applications after September 1, 2008. As of May, 2024, FDA estimates that in FY 2025, 15 sponsors will pay 100 percent fees, 15 sponsors will pay 75 percent fees, and 26 sponsors will pay 50 percent fees. The total of these figures is the equivalent of 39.25 full sponsor fees (15 times 100 percent or 15, plus 15 times 75 percent or 11.25 plus 26 times 50 percent or 13).

FDA estimates that about 2 percent of all of these sponsors, or 0.79, will not pay fees in FY 2025, due to fee waivers and reductions. 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 fiscal years of the AGDUFA program. See section 741(d) of the FD&C Act.

Accordingly, the Agency estimates that the equivalent of 38.47 full sponsor fees (39.25 minus 0.78) are likely to be paid in FY 2025.

B. Sponsor Fee Rates for FY 2025

FDA must set the fee rates for FY 2025 so that the estimated equivalent of 38.47 full sponsor fees will generate a total of $10,393,400. To generate this amount will require the 100 percent fee for a generic new animal drug sponsor, rounded to the nearest dollar, to be $270,204. Accordingly, the fee for those paying 75 percent of the full sponsor fee will be $202,653, and the fee for those paying 50 percent of the full sponsor fee will be $135,102.

VI. Fee Schedule for FY 2025

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

TABLE 5—FY 2025 FEE RATES

User fee category	Fee rate for FY 2025
Abbreviated Application Fee for Generic New Animal Drug except those subject to the criteria in section 512(d)(4)	$161,907
Abbreviated Application Fee for Generic New Animal Drug subject to the criteria in section 512(d)(4)	80,954
Generic Investigational New Animal Drug File Fee (JINAD)	50,000
Generic New Animal Drug Product Fee	16,139
100% Generic New Animal Drug Sponsor Fee [1]	270,204
75% Generic New Animal Drug Sponsor Fee [1]	202,653
50% Generic New Animal Drug Sponsor Fee [1]	135,102

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

VIII. Fee Waiver or Reduction; Exemption From Fees

Per section 741(d)(1), of the FD&C Act the types of fees waivers and reductions that applied last fiscal year still exist for FY 2025. However, after September 30, 2023, there is no longer an exemption for any person who 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)).

Waivers or reductions remain available for abbreviated applications for generic new animal drugs intended solely for a minor use/minor species indication; see section 741(d) of the FD&C Act.

IX. Procedures for Paying FY 2025 Fees

A. Abbreviated Application Fees, JINAD File Fees, and Payment Instructions

The FY 2025 fees established in the new fee schedule must be paid for the following applications/submissions that are subject to fees under AGDUFA IV and submitted on or after October 1, 2024: a generic new animal drug application, a submission requesting to establish a JINAD file, or the first BE or CMC submission to a JINAD file that was established prior to 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, 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 find your invoice, select ''Pay Now'' to be redirected to *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 ''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 or JINAD file submission.

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 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 abbreviated application or JINAD submission arrives at FDA's CVM. FDA records the official abbreviated application or JINAD submission receipt date as the later of the following: the date the application or submission 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 and JINAD File Submission 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'' and follow the directions. For security reasons, each firm submitting an application and/or a JINAD file submission 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 username 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 or JINAD file submission. 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 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 or JINAD file submission as described in section IX.A.

Step Four: Submit your application or JINAD file submission.

C. Product and Sponsor Fees

By December 31, 2024, FDA will issue invoices and payment instructions for product 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 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. 2024–16885 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–3005]

Outsourcing Facility Fee Rates for Fiscal Year 2025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2025 rates for the establishment and reinspection fees related to entities that compound human drugs and elect to register as outsourcing facilities under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FD&C Act authorizes FDA to assess and collect an annual establishment fee from outsourcing facilities, as well as a reinspection fee for each reinspection of an outsourcing facility. This document establishes the FY 2025 rates for the small business establishment fee ($6,488), the non-small business establishment fee ($21,534), and the reinspection fee ($19,465) for outsourcing facilities; provides information on how the fees for FY 2025 were determined; and describes the payment procedures outsourcing facilities should follow.

DATES: These fee rates are effective October 1, 2024, and will remain in effect through September 30, 2025.

FOR FURTHER INFORMATION CONTACT: For more information on human drug compounding and outsourcing facility fees, visit FDA's website at: *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding.*

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-UFSS-Government@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under section 503B of the FD&C Act (21 U.S.C. 353b), a human drug compounder can register with FDA as an ''outsourcing facility.'' Outsourcing facilities, as defined in section 503B(d)(4), are facilities that meet all the conditions described in section 503B(a), including registering with FDA as an outsourcing facility and paying an annual establishment fee. If the conditions of section 503B are met, a