identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2026–N–2526 for ''Butylated Hydroxytoluene (BHT); Request for Information.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: John Steele, Office of Food Chemical Safety, Dietary Supplements, and Innovation, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 301–796–1976; or Lauren Kleinman, Office of Policy and International Engagement, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 13, 2026 (91 FR 27054), FDA published a notice with a 60-day comment period to request information on the current uses and safety data for BHT in human food and as a food contact substance. We originally gave interested persons until July 13, 2026, to provide data and information.

Following publication of the notice, FDA received a request to allow interested parties additional time to comment. The request asserted that 60 days was insufficient to allow impacted stakeholders to develop a complete and scientifically robust submission, particularly due to supply chain communications. We have considered this request, and, because the request came too late for us to extend the comment period before it expired, we are reopening the comment period for 30 days. FDA believes that these additional 30 days will allow time for interested parties to submit data and other information to support our post-market assessment of the safety of BHT in food and as a food contact substance.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–15429 Filed 7–29–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–7558]

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2027

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the fee rates and payment procedures for fiscal year (FY) 2027 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 2027.

DATES: The application fee rates apply to applications submitted on or after October 1, 2026, and will remain in effect through September 30, 2027.

FOR FURTHER INFORMATION CONTACT: Visit FDA's website at: *https://www.fda.gov/industry/fda-user-fee-programs/animal-drug-user-fee-act-adufa.* 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, 301–796–7900; or *FDAUserFees@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 2027 are as follows: for application fees, the target revenue amount is $6,465,600; for product fees, the target revenue amount is $8,728,560; for establishment fees, the target revenue amount is $8,405,280; and for sponsor fees, the target revenue amount is $8,728,560.

For FY 2027, the animal drug user fee rates are: (1) $621,692 for an animal drug application; (2) $310,846 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) $12,294 for the annual product fee; (4) $215,513 for the annual establishment fee; and (5) $145,476 for the annual sponsor fee. FDA will issue invoices for FY 2027 product, establishment, and sponsor fees by December 31, 2026, and payment will be due by January 31, 2027. The application fee rates are effective for applications submitted on or after October 1, 2026, and will remain in effect through September 30, 2027. 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 2027

A. Statutory Fee Revenue Amounts

Section 740(b)(1) of the FD&C Act specifies that the base fee revenue amount for FY 2027 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 2027. The 3-year average is 5.7330 percent.

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

Fiscal year	2023	2024	2025	3-Year average
Total PC&B	$3,436,513,000	$3,791,729,000	$3,875,940,000	
Total FTEs	18,729	19,687	19,139	
PC&B per FTE	$183,486	$192,601	$202,515	
Percentage Change from Previous Year	7.0838%	4.9677%	5.1474%	5.7330%

Section 740(c)(2)(A)(ii) of the FD&C Act specifies that this 5.7330 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	2023	2024	2025	3-Year average
Total PC&B	$3,436,513,000	$3,791,729,000	$3,875,940,000	
Total Costs	$6,654,058,000	$6,976,495,000	$6,809,369,000	
PC&B percent	51.6454%	54.3501%	56.9207%	54.3054%

The portion of the inflation adjustment relating to payroll costs is 5.7330 percent multiplied by 54.3054 percent, or 3.1133 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	2023	2024	2025	3-Year average
Annual CPI	313.315	324.560	332.041	
Annual Percent Change	3.5382%	3.5890%	2.3050%	3.1441%

Section 740(c)(2)(A)(iii) of the FD&C Act specifies to calculate the inflation adjustment for non-payroll costs, we multiply 3.1441 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 54.3054 percent was obligated for PC&B as shown in table 2, 45.6946 percent is the portion of costs other than PC&B (100 percent minus the PC&B percentage of 54.3054). The portion of the inflation adjustment relating to non-payroll costs is 3.1441 percent multiplied by 45.6946 percent, or 1.4367 percent.

Next, we add the payroll component (3.1133 percent) to the non-payroll component (1.4367 percent), for an inflation adjustment of 4.5500 percent for FY 2027.

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 2027 (4.5500 percent) is compounded by adding 1 and then multiplying by 1 plus the inflation adjustment factor for FY 2026 (1.0896), which equals 1.1392 (rounded) (1.0896 multiplied by 1.0455). We then multiply the base revenue amount for FY 2027 ($33,500,000) by 1.1392, yielding an inflation adjusted amount of $38,163,368.

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 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, 2025 (the base years; 2021 through 2025), and the average number of each of these types of applications and submissions over the most recent 5-year period that ended April 30, 2026.

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 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 4.8810 percent for FY 2027. This is the workload adjuster for FY 2027.

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)	11.80	12.0	1.6949	0.0434	0.0735
Supplemental NADAs With Safety or Efficacy Data	8.40	9.0	7.1429	0.0291	0.2077
Manufacturing Supplements	369.20	349.2	−5.4171	0.2117	−1.1466
Investigational Study Submissions	143.60	134.2	−6.5460	0.5911	−3.8692
Investigational Protocol Submissions	136.40	134.8	−1.1730	0.1248	−0.1464
FY 2027 ADUFA V Workload Adjuster					−4.8810

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 2027 the workload adjuster is below the 3 percent statute threshold; therefore, no workload adjustment shall be applied.

[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.*

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 2027, 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 18 weeks of operating reserves.

To determine the dollar amounts for the 12-week and 18-week operating reserve thresholds, we divide the adjusted annual fee revenue amount ($38,163,368) by 52 weeks to generate a 1-week operating reserve amount of $733,911. The 1-week operating reserve amount is then multiplied by 12 and 18. This results in a 12-week minimum threshold of $8,806,932 and a 18-week maximum threshold of $13,210,398.

To estimate the FY 2026 end-of-year operating reserve of carryover user fees, the Agency projected the user fee carryover amount at the end of July 2026 using forecasted obligations, collections, and estimated recoveries but not including carryover user fees that have not been appropriated. The operating reserve of carryover user fees is projected to be $19,048,886 or 25.96 weeks ($19,048,886 divided by $733,911).

Because the estimated FY 2026 end-of-year operating reserve of carryover user fees is not below the 12-week threshold amount of $8,806,932, FDA will not increase the fee revenue amount and fees for FY 2027.

However, because the estimated FY 2026 end-of-year operating reserve of carryover user fees of $19,048,886 exceeds the 18-week threshold of $13,210,398, FDA will apply an operating reserve adjustment of $5,834,940 to decrease the fee revenue and fees for FY 2027.

With respect to target revenue for FY 2027, subtracting the operating reserve adjustment amount of $5,834,940 from the adjusted fee revenue amount of $38,163,368 results in a total target revenue amount of $32,328,000 (rounded) for FY 2027.

E. FY 2027 Fee Revenue Amounts

The fee revenue amount for FY 2027 is $32,328,000 (rounded). 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 $6,465,600 is to come from application fees; 27 percent, or a total of $8,728,560, is to come from product fees; 26 percent, or a total of $8,405,280 is to come from establishment fees; and 27 percent, or a total of $8,728,560 is to come from sponsor fees.

III. Animal Drug Application Fee Calculations for FY 2027

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 sections 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 $6,465,600 in fee revenue for FY 2027. 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 $6,465,600, FDA must first make some assumptions about the number of fee-paying applications and supplemental applications the Agency will receive in FY 2027.

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 2027, FDA is assuming that the number of applications for which fees will be paid in FY 2027 will equal the average number of applications over the five most recently completed fiscal years of the ADUFA program (FY 2021 to FY 2025).

Over the 5 most recently completed fiscal years, the average number of animal drug applications subject to the full fee was 5.80. 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 10.40 fee-paying animal drug applications in FY 2027 (5.80 applications paying a full fee and 9.20 applications paying a half fee).

B. Application Fee Rates for FY 2027

FDA must set the fee rates for FY 2027 so that the estimated 10.40 applications that pay the fee will generate a total of $6,465,600. To generate this amount, the fee for an animal drug application, rounded to the nearest dollar, will have to be $621,692, 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 $310,846.

IV. Animal Drug Product Fee Calculations for FY 2027

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 $8,728,560 in fee revenue for FY 2027.

To set animal drug product fees to realize $8,728,560, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2027. 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 2025, FDA estimates that there are 724 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 724 products will be subject to this fee in FY 2027.

In estimating the fee revenue to be generated by animal drug product fees in FY 2027, FDA is assuming that 2 percent of the products invoiced, or 14, will not pay fees in FY 2027, 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 710 (724 minus 14) products will be subject to product fees in FY 2027.

B. Product Fee Rates for FY 2027

FDA must set the fee rates for FY 2027 so that the estimated 710 products for which fees are paid will generate a total of $8,728,560. To generate this amount will require the fee for an animal drug product, rounded to the nearest dollar, to be $12,294.

V. Animal Drug Establishment Fee Calculations for FY 2027

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 $8,405,280 in fee revenue for FY 2027.

To set animal drug establishment fees to realize $8,405,280, FDA must make some assumptions about the number of establishments for which these fees will be paid in FY 2027. 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 2026, FDA estimates that there are a total of 41 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 41 establishments will be subject to this fee in FY 2027.

In estimating the fee revenue to be generated by animal drug establishment fees in FY 2027, FDA is assuming that 5 percent of the establishments invoiced, or two, will not pay fees in FY 2027 due to fee waivers and reductions. FDA has made this estimate at 5 percent this year, based on historical data over the past 5 completed fiscal years.

Accordingly, the Agency estimates that a total of 39 establishments (41 minus 2) will be subject to establishment fees in FY 2027.

B. Establishment Fee Rates for FY 2027

FDA must set the fee rates for FY 2027 so that the fees paid for the estimated 39 establishments will generate a total of $8,405,280. To generate this amount will require the fee for an animal drug establishment, rounded to the nearest dollar, to be $215,520.

VI. Animal Drug Sponsor Fee Calculations for FY 2027

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 section 740(a)(4) of the FD&C Act). The sponsor fees are to be set so that they will generate $8,728,560 in fee revenue for FY 2027.

To set animal drug sponsor fees to realize $8,728,560, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2027. 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 2026, FDA estimates that a total of 198 sponsors will meet this definition in FY 2027.

In estimating the fee revenue to be generated by animal drug sponsor fees in FY 2027, FDA is assuming that 70 percent of the sponsors invoiced, or 138, will not pay sponsor fees in FY 2027 due to fee waivers and reductions. FDA has made this estimate at 70 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 60 sponsors (198 minus 138) will be subject to and pay sponsor fees in FY 2027.

B. Sponsor Fee Rates for FY 2027

FDA must set the fee rates for FY 2027 so that the estimated 60 sponsors that pay fees will generate a total of $8,728,560. To generate this amount will require the fee for an animal drug sponsor, rounded to the nearest dollar, to be $145,476.

VII. Fee Schedule for FY 2027

The fee rates for FY 2027 are summarized in table 5.

TABLE 5—FY 2027 FEE RATES

Animal drug user fee category	Fee rate for FY 2027
Animal Drug Application Fees:	
Animal Drug Application	$621,692
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.	310,846
Animal Drug Product Fee	12,294
Animal Drug Establishment Fee [1]	215,520
Animal Drug Sponsor Fee [2]	145,476

[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 2027 will be $25,493,000; 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 2027. 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.

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 2027 Fees

A. Application Fees and Payment Instructions

The FY 2027 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, 2026. Payments made to FDA must be made in U.S. currency drawn on a U.S. bank

[2] CVM's GFI #170 is located at: *https://www.fda.gov/media/69918/download.*

by electronic check, credit card, or wire transfer. The preferred method for payments to FDA is online using electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). FDA has partnered with the U.S. Department of the Treasury to utilize *Pay.gov*, a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website upon receipt of an invoice or after completing the User Fee Cover Sheet and generating the user fee ID number.

Secure electronic payments to FDA can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay.* (*Note:* Only full payments are accepted; no partial payments can be made online.) Once an invoice or cover sheet is located, ''Pay Now'' should be selected to be redirected to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

For payments made by wire transfer, include the unique user fee ID or invoice number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID or invoice number, the payment may not be applied. The originating financial institution may charge a wire transfer fee. Include applicable wire transfer fees with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The following account information should be used to send payments by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account No: 75060099, Routing No: 021030004, SWIFT: FRNYUS33.

FDA's tax identification number is 53–0196965. If a fee is not paid in full, the fee will be treated as a claim of the U.S. Government (see section 740(h) of the FD&C Act and 45 CFR part 30), meaning the invoice balance due amount is referred to collections.

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, 2026, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2027 using this fee schedule. Payment will be due by January 31, 2027. FDA will issue invoices in November 2027 for any products, establishments, and sponsors subject to fees for FY 2027 that qualify for fees after the December 2026 billing.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–7492]

Medical Device User Fee Rates for Fiscal Year 2027

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the fee rates and payment procedures for medical device user fees for fiscal year (FY) 2027. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Medical Device User Fee Amendments of 2022 (MDUFA V), authorizes FDA to collect user fees for certain medical device submissions and annual fees both for certain periodic reports and for establishments subject to registration. This notice establishes the fee rates for FY 2027, which apply from October 1, 2026, through September 30, 2027, and provides information on how the fees for FY 2027 were determined, the payment procedures you should follow, and how you may qualify for reduced small business fees.

FOR FURTHER INFORMATION CONTACT: Olufunmilayo Ariyo, Office of Financial Management, Food and Drug Administration, 301–796–7900; or *FDAUserFees@fda.hhs.gov. For information on Medical Device User Fees: https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa. For questions relating to the MDUFA Small Business Program, please visit the Center for Devices and Radiological Health's website: https://www.fda.gov/medical-devices/premarket-submissions/reduced-medical-device-user-fees-small-business-determination-sbd-program.*

SUPPLEMENTARY INFORMATION:

I. Background

The FD&C Act, as amended by MDUFA V, authorizes FDA to collect user fees for certain medical device submissions and annual fees both for certain periodic reports and for establishments subject to registration. Section 738 of the FD&C Act (21 U.S.C. 379j) establishes fees for certain medical device applications, submissions, supplements, notices, and requests (for simplicity, this document refers to these collectively as ''submissions'' or ''applications''); for periodic reporting on class III devices; and for the registration of certain establishments.

Under the FD&C Act, the fee rate for each type of submission is set at a specified percentage of the standard fee for a premarket application (a premarket application is a premarket approval application (PMA), a product development protocol (PDP), or a biologics license application (BLA)). The FD&C Act specifies the base fee for a premarket application for each year from FY 2023 through FY 2027; the base fee for a premarket application received by FDA during FY 2027 is $470,000. From this starting point, this document establishes FY 2027 fee rates for certain types of submissions, and for periodic reporting, by applying criteria specified in the FD&C Act. Under statutorily defined conditions, a qualified applicant may receive a fee waiver or may pay a lower small business fee (see sections 738(a)(3)(B), 738(d) and 738(e) of the FD&C Act). For more information on fee waivers, please see Section IX. Small Business Fee Reductions and Fee Waivers.