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Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–1607]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the fee rates and payment procedures for fiscal year (FY) 2023 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Drug User Fee Amendments of 2018 (ADUFA IV), 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 2023.

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

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

SUPPLEMENTARY INFORMATION:

I. Background

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

For FYs 2019 through 2023, the FD&C Act establishes the base revenue amount for each fiscal year (21 U.S.C. 379j–12(b)(1)). Base revenue amounts are subject to adjustment for inflation and workload (21 U.S.C. 379j–12(c)(2) and (3)). Beginning with FY 2021, the annual fee revenue amounts are also subject to adjustment to reduce workload-based increases by the amount of certain excess collections or to account for certain collection shortfalls (21 U.S.C. 379j–12(c)(3) and (g)(5)). Fees for applications, products, establishments, and sponsors are to be established each year by FDA so that the percentages of the total revenue that are derived from each type of user fee will be as follows: (1) revenue from application fees shall be 20 percent of total fee revenue; (2) revenue from product fees shall be 27 percent of total fee revenue; (3) revenue from establishment fees shall be 26 percent of total fee revenue; and (4) revenue from sponsor fees shall be 27 percent of total fee revenue (21 U.S.C. 379j–12(b)(2)). The target revenue amounts for each fee category for FY 2023, are as follows: for application fees, the target revenue amount is $6,428,800; for product fees, the target revenue amount is $8,678,880; for establishment fees, the target revenue amount is $8,357,440 and for sponsor fees, the target revenue amount is $8,678,880.

For FY 2023, the animal drug user fee rates are: $659,364 for an animal drug application; $329,682 for a supplemental animal drug application for which safety or effectiveness data are required and for an animal drug application subject to the criteria set forth in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)); $11,375 for the annual product fee; $167,149 for the annual establishment fee; and $149,636 for an annual sponsor fee. FDA will issue invoices for FY 2023 product, establishment, and sponsor fees by December 31, 2022, and payment will be due by January 31, 2023. The application fee rates are effective for applications submitted on or after October 1, 2022, and will remain in effect through September 30, 2023. Applications will not be accepted for review until FDA has received full payment of application fees and any other animal drug user fees owed under the ADUFA program.

II. Revenue Amount for FY 2023

A. Statutory Fee Revenue Amounts

ADUFA IV, Title I of Public Law 115–234, specifies that the aggregate base fee revenue amount for FY 2023 for all animal drug user fee categories is $29,931,240 (21 U.S.C. 379j–12(b)(1)(B)).

B. Inflation Adjustment to Fee Revenue Amount

ADUFA IV specifies that the annual fee revenue amount is to be adjusted for inflation increases for FY 2020 and subsequent fiscal years, using two separate adjustments—one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (21 U.S.C. 379j–12(c)(2)(A)(ii) and (iii)). The component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all PC&B paid per full-time equivalent position (FTE) at FDA for the first 3 of the 4 preceding fiscal years of available data, multiplied by the average proportion of PC&B costs to total FDA costs for the first 3 of the 4 preceding fiscal years of available data. The data on total PC&B paid and numbers of FTE paid, from which the average cost per FTE can be derived, are published in FDA's Justification of Estimates for Appropriations Committees.

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

TABLE 1—FDA PC&B EACH YEAR AND PERCENT CHANGE

	FY 2019	FY 2020	FY 2021	3-Year average
Total PC&B	$2,620,052,000	$2,875,592,000	$3,039,513,000	
Total FTE	17,144	17,535	18,501	
PC&B per FTE	152,826	163,992	164,289	

TABLE 1—FDA PC&B EACH YEAR AND PERCENT CHANGE—Continued

	FY 2019	FY 2020	FY 2021	3-Year average
Percent Change From Previous Year	−3.3120%	7.3063%	0.1811%	1.3918%

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

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

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

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

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

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

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

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

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

ADUFA IV provides for the inflation adjustment to be compounded each fiscal year after FY 2020 (see 21 U.S.C. 379j–12(c)(2)(B)). The inflation adjustment for FY 2023 (1.5911 percent) is compounded by adding 1 and then multiplying by 1 plus the inflation adjustment factor for FY 2022 (5.7121 percent), as published in the **Federal Register** on July 28, 2021 (86 FR 40595), which equals 1.0739 (rounded) (1.0159 × 1.0571) for FY 2023. We then multiply the base revenue amount for FY 2023 ($29,931,240) by 1.0739, yielding an inflation adjusted amount of $32,144,386.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

The fee revenue amounts established in ADUFA IV for FY 2020 and subsequent fiscal years are also subject to adjustment to account for changes in FDA's review workload. A workload adjustment will be applied to the inflation adjusted fee revenue amount (21 U.S.C. 379j–12(c)(3)).

To determine whether a workload adjustment applies, FDA calculates the weighted average of the change in the total number of each of the 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, 2018 (the base years), and the average number of each of these types of applications and submissions over the most recent 5-year period that ended May 31, 2022.

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

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 4.5044 percent for FY 2023. This is the workload adjuster for FY 2023.

TABLE 4—WORKLOAD ADJUSTER CALCULATION

Application type	Column 1	Column 2	Column 3	Column 4	Column 5
	Year average (base years)	Latest 5-year average	Percent change	Weighting factor	Weighted percent change
New Animal Drug Application (NADAs)	16.40	12.80	−21.9512	0.04	−0.9235
Supplemental NADAs With Safety or Efficacy Data	11.60	9.00	−22.4138	0.03	−0.5627
Manufacturing Supplements	353.20	367.80	4.1336	0.19	0.7751
Investigational Study Submissions	183.20	170.40	−6.9869	0.57	−3.9856
Investigational Protocol Submissions	236.40	239.00	1.0998	0.17	0.1923
FY 2023 ADUFA IV Workload Adjuster					−4.5044

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 (21 U.S.C. 379j–12(c)(3)). FDA will not adjust the FY 2023 fee revenue amount for workload changes because the workload adjuster was less than 1 percent.[2]

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

Under section 740(c)(3)(B) of the FD&C Act, for FYs 2021 through 2023, if application of the workload adjustment increases the amount of fee revenues established for the fiscal year, as adjusted for inflation, the fee revenue increase will be reduced by the amount of any excess collections for the second preceding fiscal year, up to the amount of the fee revenue increase for workload. Since there is no workload-based increase in FY 2023, this provision does not apply.

E. Recovery of Collection Shortfalls

Under section 740(g)(5)(A)(iii) of the FD&C Act, for FY 2023, the amount of fees otherwise authorized to be collected shall be increased by the cumulative amount, if any, by which the amount collected and appropriated for FY 2021 and FY 2022 (including estimated collections for FY 2022) falls below the cumulative amount of fees authorized for FYs 2021 and 2022.

In FY 2021, the total revenue amount authorized was $33,339,000 and the total amount of fees collected for FY 2021 as of May 31, 2022, was $33,811,815. The total revenue amount authorized for FY 2022 is $31,641,000 and the estimated collections for FY 2022 is projected to be $30,570,000. The cumulative amount of fees collected and estimated for FYs 2021 and 2022 is below the total authorized revenue amount by $1,071,000. Therefore, the recovery of collection shortfalls provision of section 740(g)(5)(A)(iii) is invoked. The next section details the reduction of the shortfall-based fee increase by prior year excess collections.

F. Reduction of Shortfall-Based Fee Increase by Prior Year Excess Collections

Under section 740(g)(5)(B) of the FD&C Act, where FDA's calculations under section 740(g)(5)(A) would result in a fee increase for that fiscal year to recover a collection shortfall in a prior year, FDA must reduce the increase by the amount of any excess collections for preceding fiscal years (after FY 2018) that have not already been applied to reduce workload-based fee increases. FDA's calculations under section 740(g)(5)(A) would result in a fee increase for FY 2023 to recover a collection shortfall of $1,071,000. FDA also calculates that it had $795,666 of excess collections in FY 2020 and $329,934 of excess collections in FY 2021 that have not previously been applied to reduce workload-based fee increases, for a total of $1,125,600 in excess collections. Because the FYs 2020 and 2021 excess collections not previously applied to a workload-based fee increase exceed the projected shortfall in FY 2022, there is a reduction of the shortfall-based fee increase under section 740(g)(5)(B). Therefore, no recovery of collections shortfall will be added to the FY 2023 target revenue.

G. Final Year Adjustment

For FY 2023, FDA may, in addition to other adjustments under section 740(c) of the FD&C Act, further increase the fees, if such an adjustment is necessary, to provide for up to 3 months of operating reserves of carryover user fees for the process for the review of animal drug applications for the first 3 months of FY 2024. If FDA has carryover balances for the process for the review of animal drug applications in excess of 3 months of such operating reserves, then this adjustment will not be made. (See 21 U.S.C. 379j–12(c)(4).) Since FDA currently has an excess of 3 months of such operating reserves, this adjustment will not be made for FY 2023.

H. FY 2023 Fee Revenue Amounts

The fee revenue amount for FY 2023, after considering the possible adjustments under sections 740(c) and (g)(5) of the FD&C Act, is $32,144,000 (rounded to the nearest thousand dollars). ADUFA IV specifies that this revenue amount is to be divided as follows: 20 percent, or a total of $6,428,800, is to come from application fees; 27 percent, or a total of $8,678,880, is to come from product fees; 26 percent, or a total of $8,357,440, is to come from establishment fees; and 27 percent, or a total of $8,678,880, is to come from sponsor fees (21 U.S.C. 379j–12(b)).

III. Application Fee Calculations for FY 2023

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

Each person who submits an animal drug application or a supplemental

[2] CVM increases the fee revenue amount established for the fiscal year to reflect changes in workload only if the workload adjuster is equal to or greater than 1 percent.

animal drug application shall be subject to an application fee, with limited exceptions (see 21 U.S.C. 379j–12(a)(1)). The term ''animal drug application'' means an application for approval of any new animal drug submitted under section 512(b)(1) of the FD&C Act or an application for conditional approval of a new animal drug submitted under section 571 of the FD&C Act (21 U.S.C. 360ccc) (see section 739(1) of the FD&C Act (21 U.S.C. 379j–11(1))). As the expanded definition of ''animal drug application'' includes applications for conditional approval submitted under section 571 of the FD&C Act, such applications are now subject to ADUFA fees, except that those fees may be waived if the drug is intended solely to provide for a minor use or minor species (MUMS) indication (see 21 U.S.C. 379j–12(d)(1)(D)).

Prior to ADUFA IV, FDA only had authority to grant conditional approval for drugs intended for a MUMS indication. Under amendments made to section 571 of the FD&C Act by ADUFA IV, FDA retains authority to grant conditional approval for drugs intended for MUMS indications but also will be able to grant conditional approval for certain drugs not intended for a MUMS indication provided certain criteria are met. Beginning with FY 2019, ADUFA IV provides 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.

A ''supplemental animal drug application'' is defined as a request to the Secretary of Health and Human Services (Secretary) to approve a change in an animal drug application that has been approved, or a request to the Secretary 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 (21 U.S.C. 379j–11(2)). The application fees are to be set so that they will generate $6,428,800 in fee revenue for FY 2023. The fee for a supplemental animal drug application for which safety or effectiveness data are required and for an animal drug application subject to criteria set forth in section 512(d)(4) of the FD&C Act is to be set at 50 percent of the animal drug application fee (21 U.S.C. 379j–12(a)(1)(A)(ii)).

To set animal drug application fees and supplemental animal drug application fees to realize $6,428,800, FDA must first make some assumptions about the number of fee-paying applications and supplemental applications the Agency will receive in FY 2023.

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 2023, FDA is assuming that the number of applications for which fees will be paid in FY 2023 will equal the average number of applications over the 4 most recent completed fiscal years of the ADUFA program (FY 2018 to FY 2021). FDA decided to use a 4-year average for the FY 2023 fee rate calculation rather than a 5-year average. FDA made this adjustment because in the past 5 FY, 1 FY had an abnormally low number of applications. Thus, FDA used a 4-year average to remove this outlier from the forecast method, which resulted in a lower application fee rate.

Over the 4 most recent completed fiscal years, the average number of animal drug applications that would have been subject to the full fee was 5.25. Over this same period, the average number of supplemental applications for which safety or effectiveness data are required and applications subject to the criteria set forth in section 512(d)(4) of the FD&C Act that would have been subject to half of the full fee was 9.0.

Based on the previous assumptions, FDA is estimating that it will receive a total of 9.75 fee-paying animal drug applications in FY 2023 (5.25 applications paying a full fee and 9.00 applications paying a half fee).

B. Application Fee Rates for FY 2023

FDA must set the fee rates for FY 2023 so that the estimated 9.75 applications that pay the fee will generate a total of $6,428,800. To generate this amount, the fee for an animal drug application, rounded to the nearest dollar, will have to be $659,364, and the fee for a supplemental animal drug application for which safety or effectiveness data are required and for applications subject to the criteria set forth in section 512(d)(4) of the FD&C Act will have to be $329,682.

IV. Animal Drug Product Fee Calculations for FY 2023

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

The animal drug product fee must be paid annually by the person named as the applicant in a new animal drug application or supplemental new animal drug application for an animal drug product submitted for listing under section 510 of the FD&C Act (21 U.S.C. 360) and who had an animal drug application or supplemental animal drug application pending at FDA after September 1, 2003 (21 U.S.C. 379j–12(a)(2)). The term ''animal drug product'' means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the National Drug Code, and for which an animal drug application or a supplemental animal drug application has been approved (21 U.S.C. 379j–11(3)). The product fees are to be set so that they will generate $8,678,880 in fee revenue for FY 2023.

To set animal drug product fees to realize $8,678,880, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2023. FDA gathered data on all animal drug products that have been submitted for listing under section 510 of the FD&C Act and matched this to the list of all persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. As of May 2022, FDA estimates that there is a total of 779 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 779 products will be subject to this fee in FY 2023.

In estimating the fee revenue to be generated by animal drug product fees in FY 2023, FDA is assuming that 2 percent of the products invoiced, or 16, will not pay fees in FY 2023 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 763 (779 minus 16) products will be subject to product fees in FY 2023.

B. Product Fee Rates for FY 2023

FDA must set the fee rates for FY 2023 so that the estimated 763 products for

which fees are paid will generate a total of $8,678,880. To generate this amount will require the fee for an animal drug product, rounded to the nearest dollar, to be $11,375.

V. Animal Drug Establishment Fee Calculations for FY 2023

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

The animal drug establishment fee must be paid annually by the person who: (1) owns or operates, directly or through an affiliate, an animal drug establishment; (2) is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product submitted for listing under section 510 of the FD&C Act; (3) had an animal drug application or supplemental animal drug application pending at FDA after September 1, 2003; and (4) whose establishment engaged in the manufacture of the animal drug product during the fiscal year (see 21 U.S.C. 379j–12(a)(3)). An establishment subject to animal drug establishment fees is assessed only one such fee per fiscal year. The term ''animal drug establishment'' is defined as a foreign or domestic place of business at one general physical location, consisting of one or more buildings, all of which are within 5 miles of each other, at which one or more animal drug products are manufactured in final dosage form (21 U.S.C. 379j–11(4)). The establishment fees are to be set so that they will generate $8,357,440 in fee revenue for FY 2023.

To set animal drug establishment fees to realize $8,357,440, FDA must make some assumptions about the number of establishments for which these fees will be paid in FY 2023. FDA gathered 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 2022, FDA estimates that there is a total of 54 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 54 establishments will be subject to this fee in FY 2023.

In estimating the fee revenue to be generated by animal drug establishment fees in FY 2023, FDA is assuming that 7 percent of the establishments invoiced, or four establishments, will not pay fees in FY 2023 due to fee waivers and reductions. FDA has made this estimate at 7 percent this year, based on historical data over the past 5 completed fiscal years.

Accordingly, the Agency estimates that a total of 50 (54 minus 4) establishments will be subject to establishment fees in FY 2023.

B. Establishment Fee Rates for FY 2023

FDA must set the fee rates for FY 2023 so that the fees paid for the estimated 50 establishments will generate a total of $8,357,440. To generate this amount will require the fee for an animal drug establishment, rounded to the nearest dollar, to be $167,149.

VI. Animal Drug Sponsor Fee Calculations for FY 2023

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

The animal drug sponsor fee must be paid annually by each person who: (1) is named as the applicant in an animal drug application, except for an approved application for which all subject products have been removed from listing under section 510 of the FD&C Act, or has submitted an investigational animal drug submission that has not been terminated or otherwise rendered inactive and (2) had an animal drug application, supplemental animal drug application, or investigational animal drug submission pending at FDA after September 1, 2003 (see 21 U.S.C. 379j–11(6) and 379j–12(a)(4)). An animal drug sponsor is subject to only one such fee each fiscal year (see 21 U.S.C. 379j–12(a)(4)). The sponsor fees are to be set so that they will generate $8,678,880 in fee revenue for FY 2023.

To set animal drug sponsor fees to realize $8,678,880, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2023. FDA estimates that a total of 182 sponsors will meet this definition in FY 2023.

In estimating the fee revenue to be generated by animal drug sponsor fees in FY 2023, FDA is assuming that 68 percent of the sponsors invoiced, or 124, will not pay sponsor fees in FY 2023 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 58 (182 minus 124) sponsors will be subject to and pay sponsor fees in FY 2023.

B. Sponsor Fee Rates for FY 2023

FDA must set the fee rates for FY 2023 so that the estimated 58 sponsors that pay fees will generate a total of $8,678,880. To generate this amount will require the fee for an animal drug sponsor, rounded to the nearest dollar, to be $149,636.

VII. Fee Schedule for FY 2023

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

TABLE 5—FY 2023 FEE RATES

Animal drug user fee category	Fee rate for FY 2023
Animal Drug Application Fees:	
Animal Drug Application	$659,364
Supplemental Animal Drug Application for Which Safety or Effectiveness Data are Required or Animal Drug Application Subject to the Criteria Set Forth in Section 512(d)(4) of the FD&C Act	329,682
Animal Drug Product Fee	11,375
Animal Drug Establishment Fee [1]	167,149
Animal Drug Sponsor Fee [2]	149,636

[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

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,'' [3] states that the Agency interprets this provision to mean that a waiver or reduction is appropriate when: (1) the product for which the waiver is being requested is innovative, or the requestor is otherwise pursuing innovative animal drug products or technology and (2) the fee would be a significant barrier to the applicant's ability to develop, manufacture, or market the innovative product or technology. Only those applicants that meet both of these criteria will qualify for a waiver or reduction in user fees under this provision (see GFI #170 at pp. 6–8). For purposes of determining whether the second criterion would be met on the basis of limited financial resources available to the applicant, FDA has determined an applicant with financial resources of less than $20,000,000 (including the financial resources of the applicant's affiliates), adjusted annually for inflation, has limited resources available. Using the CPI for urban consumers (U.S. city average; not seasonally adjusted; all items; annual index), the inflation-adjusted level for FY 2023 will be $22,364,520; 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 2023. Requests for a waiver need to be submitted to FDA each fiscal year not later than 180 days from when the fees are due. A waiver granted on Barrier to Innovation grounds (or any of the other grounds listed in section 740(d)(1) of the FD&C Act) is only valid for 1 fiscal year. If a sponsor is not granted a waiver, they are liable for the fees.

B. Exemptions From Fees

The types of fee waivers and reductions that applied during ADUFA III still exist for FY 2023. In addition, ADUFA IV established two new exemptions and one new exception from fees, as described below:

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

Fees will not apply to any person who not later than September 30, 2023, 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 502(w)(3) of the FD&C Act (21 U.S.C. 352(w)(3)), if that person otherwise would be subject to user fees under ADUFA based only on the submission of the supplemental application (21 U.S.C. 379j–12(d)(4)(A)).

There is also 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 (see 21 U.S.C. 379j–12(a)(1)(C)(ii)).

IX. Procedures for Paying the FY 2023 Fees

A. Application Fees and Payment Instructions

The FY 2023 fee established in the new fee schedule must be paid for an animal drug application or supplement subject to fees under ADUFA IV that is submitted on or after October 1, 2022. The payment must be made in U.S. currency from a U.S. bank by one of the following methods: wire transfer, electronically, check, bank draft, or U.S. postal money order made payable to the Food and Drug Administration. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay,* or the *Pay.gov* payment option is available to you after you submit a cover sheet. (Note: only full payments are accepted. No partial payments can be made online.) Once you search for and find your invoice, select ''Pay Now'' to be redirected to *www.pay.gov.* Electronic payment options are based on the balance due. Payment by credit card is available only for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

When paying by check, bank draft, or U.S. postal money order, please write your application's unique Payment Identification Number (PIN), beginning with the letters AD, on the upper right-hand corner of your completed Animal Drug User Fee Cover Sheet. Also write the FDA 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, Attn: Government Lockbox 979033, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery.)

It is important that the fee arrives at the bank at least a day or two before the 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

[3] CVM's GFI #170 can be accessed at: *https://www.fda.gov/media/69918/download.*

CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U.S. Department of the Treasury notifies FDA of receipt of an electronic or wire transfer payment. U.S. Bank and the U.S. Department of the Treasury are required to notify FDA within 1 working day, using the PIN described previously.

The tax identification number of FDA is 53–0196965.

B. Application Cover Sheet Procedures

Step One: Create a user account and password. Log on to the ADUFA website at *https://www.fda.gov/industry/animal-drug-user-fee-act-adufa/animal-drug-user-fee-cover-sheet* and, under Application Submission Information, click on ''Create ADUFA User Fee Cover Sheet.'' For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

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

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

Step Four: Submit your application.

C. Product, Establishment, and Sponsor Fees

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

Dated: July 22, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–16176 Filed 7–27–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information (RFI): Inviting Comments and Suggestions on an ODS Strategic Plan 2022–2026

AGENCY: National Institutes of Health, HHS.

ACTION: Request for information.

SUMMARY: Since its inception in 1994, the National Institutes of Health (NIH), Office of Dietary Supplements (ODS) has used a structured planning process to develop five-year strategic plans. ODS is committed to engaging its stakeholders including representatives of the scientific community, industry, other federal agencies, and the public in the strategic planning process by soliciting their comments on the draft ODS Strategic Plan for Fiscal Years (FY) 2022–2026. Considering comments from representative stakeholder groups, and the general public will help ODS assess the outcomes of its investments and prioritize plans for the next five years.

DATES: The RFI is open for public comments and must be received by 11:59:59 p.m. (ET) on August 31, 2022, to ensure consideration.

ADDRESSES: All comments must be submitted electronically to *odsplan@od.nih.gov.*

FOR FURTHER INFORMATION CONTACT: Please direct all inquiries to: Barbara Cohen at *ODSplan@od.nih.gov* or (301) 435–2920.

SUPPLEMENTARY INFORMATION: This notice is in accordance with the 21st Century Cures Act, wherein NIH institutes are required to regularly update their strategic plans. The purpose of the FY 2022–2026 ODS Strategic Plan (*https://ods.od.nih.gov/About/StrategicPlan.aspx*) is to communicate how ODS will advance its mission to support, coordinate, and disseminate the results of scientific research, and provide leadership to help expand the knowledge, scientific evidence, and understanding of dietary supplements, thus fostering an enhanced quality of life and health for the U.S. population. The plan articulates ODS' priorities in five key areas (goals):

(1) Expand the scientific knowledge base on dietary supplements by stimulating and supporting a full range of biomedical research and by developing and contributing to relevant initiatives, workshops, meetings, and conferences;

(2) Enhance the dietary supplement research workforce through training and career development and simultaneously support the development of programs for diverse researchers who are underrepresented in science;

(3) Foster development and dissemination of research resources and tools to enhance the quality of dietary supplement research;

(4) Translate dietary supplement research findings into useful information for consumers, health professionals, researchers, and policymakers; and

(5) Coordinate and support the development of collaborative initiatives to address gaps in dietary supplement research.

ODS has completed a draft of its Five-Year Strategic Plan for FY 2022–2026 (*https://ods.od.nih.gov/About/StrategicPlan.aspx*) and is interested in receiving feedback from all interested parties on the following:

- Are there additional emerging public health issues that ODS can help address?
- Are there existing knowledge gaps that ODS can help address (not included in the current plan)?
- What can ODS do better to meet the needs of its stakeholders?

ODS encourages organizations to submit a single response reflective of the views of the organization as a whole.

Responses to this RFI are voluntary and may be submitted anonymously. Please do not include any personally identifiable information or any information that you do not wish to make public. Proprietary, classified, confidential, or sensitive information should not be included in your response. The NIH will use the information submitted in response to this RFI at its discretion. The NIH reserves the right to use any submitted information on public websites, in reports, in summaries of the state of the science, in any possible resultant solicitation(s), grant(s), or cooperative agreement(s), or in the development of future funding opportunity announcements. This RFI is for informational and planning purposes only and is not a solicitation for applications or an obligation on the part of the Government to provide support for any ideas identified in response to it. Please note that the Government will not pay for the preparation of any information submitted or for use of that information.

We look forward to your input and hope that you will share this RFI opportunity with your colleagues.