reflect an increase in annual submissions, as reflected in table 1, row 6.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
MDR Procedures—803.17	1,799	1	1,799	3.3	5,937
MDR Files—803.18	1,799	1	1,799	1.5	2,699
Total					8,636

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The number of respondents in table 2 is based on the MDRs reported to FDA's internal databases recently. We believe that the majority of respondents (manufacturers, user facilities, and importers) have already established written procedures and MDR files to document complaints and information to meet the MDR requirements as part of their internal quality control system.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]
Importer Reporting, Death and Serious Injury—803.40 and 803.42.	112	25	2,800	0.35 (21 minutes).	980

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Number has been rounded.

The number of respondents for each CFR section in table 3 was identified from the MDRs reported to FDA's internal databases during the period recently.

Since the publication of the 60 day notice we have adjusted our burden estimate. Our estimated burden for the information collection reflects an increase of 155,360 total burden hours and a corresponding increase of 1,566,458 total annual responses. This increase corresponds with data obtained from our database.

Dated: July 21, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16034 Filed 7–27–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0706]

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2022

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) 2022 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 2022.

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) 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 aggregate yearly base revenue amounts 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, establishments, products, and sponsors are to be established each year by FDA so that the percentages of the total revenue that are derived from each type of user fee will be as follows: (1) Revenue from application fees shall be 20 percent of total fee revenue; (2) revenue from product fees shall be 27 percent of total fee revenue; (3) revenue from establishment fees shall be 26 percent of

total fee revenue; and (4) revenue from sponsor fees shall be 27 percent of total fee revenue (21 U.S.C. 379j–12(b)(2)).

For FY 2022, the animal drug user fee rates are: $580,569 for an animal drug application; $290,284 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)); $10,787 for an annual product fee; $155,220 for an annual establishment fee; and $137,791 for an annual sponsor fee. FDA will issue invoices for FY 2022 product, establishment, and sponsor fees by December 31, 2021, and payment will be due by January 31, 2022. The application fee rates are effective for applications submitted on or after October 1, 2021, and will remain in effect through September 30, 2022. 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 Animal Drug User Fee Act program (ADUFA program).

II. Revenue Amount for FY 2022

A. Statutory Fee Revenue Amounts

ADUFA IV, Title I of Public Law 115–234, specifies that the aggregate base fee revenue amount for FY 2022 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. 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 that actual cost and FTE data for the specified fiscal years, and provides the percent change from the previous fiscal year and the average percent change over the first 3 of the 4 fiscal years preceding FY 2022. The 3-year average is 2.7383 percent.

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

Fiscal year	2018	2019	2020	3-Year average
Total PC&B	$2,690,678,000	$2,620,052,000	$2,875,592,000	.....
Total FTE	17,023	17,144	17,535	.....
PC&B per FTE	$158,061	$152,826	$163,992	.....
Percent Change from Previous Year	4.2206%	−3.3120%	7.3063%	2.7383%

The statute specifies that this 2.7383 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

Fiscal year	2018	2019	2020	3-Year average
Total PC&B	$2,690,678,000	$2,620,052,000	$2,875,592,000	.....
Total Costs	$5,370,935,000	$5,663,389,000	$6,039,321,000	.....
PC&B Percent	50.0970%	46.2630%	47.6145%	47.9915%

The portion of the inflation adjustment relating to payroll costs is 2.7383 percent multiplied by 47.9915 percent, or 1.3142 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.

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

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

Year	2018	2019	2020	3-Year average
Annual CPI	272.414	275.841	278.437	.....
Annual Percent Change	2.0671%	1.2580%	0.9411%	1.4221%

To calculate the inflation adjustment for non-payroll costs, we multiply 1.4221 percent by the proportion of all costs other than PC&B to total FDA costs. Since 47.9915 percent was obligated for PC&B as shown in table 2, 52.0085 percent is the portion of costs other than PC&B (100 percent minus 47.9915 percent equals 52.0085 percent). The portion of the inflation adjustment relating to non-payroll costs is 1.4221 percent times 52.0085 percent, or 0.7396 percent.

Next, we add the payroll component (1.3142 percent) to the non-payroll component (0.7396 percent), for an inflation adjustment of 2.0538 percent for FY 2022.

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 2022 (2.0538 percent) is compounded by adding 1 and then multiplying by 1 plus the inflation adjustment factor for FY 2021 (3.5847 percent), as published in the **Federal Register** on August 3, 2020 (85 FR 46635), which equals 1.057121 (rounded) (1.020538×1.035847) for FY 2022. We then multiply the base revenue amount for FY 2022 ($29,931,240) by 1.057121, yielding an inflation adjusted amount of $31,640,942.

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, 2021.

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, which 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 added, reflecting a total change in workload of 0.6187 percent for FY 2022. This is the workload adjuster for FY 2022.

TABLE 4—WORKLOAD ADJUSTER CALCULATION

Application type	Column 1	Column 2	Column 3	Column 4	Column 5
	5-Year average (base years)	Latest 5-year average	Percent change (%)	Weighting factor	Weighted percent change (%)
New Animal Drug Applications (NADAs)	16.4	14.6	−10.9756	0.0442	−0.4852
Supplemental NADAs with Safety or Efficacy Data	11.6	9.0	−22.4138	0.0241	−0.5392
Manufacturing Supplements	353.2	382.4	8.2673	0.1826	1.5093
Investigational Study Submissions	183.2	175.2	−4.3668	0.5544	−2.4208
Investigational Protocol Submissions	236.4	267.4	13.1134	0.1948	2.5547
FY 2022 ADUFA IV Workload Adjuster	.....	.....	.....	.....	0.6187

Under no circumstances will 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 2022 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. Because there is no workload-based increase in FY 2022, this provision does not apply.

E. Recovery of Collection Shortfalls

Under section 740(g)(5)(A) of the FD&C Act, for FY 2022, the amount of fees otherwise authorized to be

[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.

collected shall be increased by the amount, if any, by which the amount collected and appropriated for FY 2020 falls below the amount of fees authorized for FY 2020.

In FY 2020, the total revenue amount was $30,611,000 and the total amount of fees collected as of May 31, 2021, was $31,261,667. Because the amount of fees collected exceeded the total revenue amount, there was no collection shortfall in FY 2020 and therefore no increase in fees will be made under section 740(g)(5)(A).

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) result in a fee increase for that fiscal year to recover a collection shortfall, 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 for purposes of reducing workload-based fee increases. Because FDA's calculations under section 740(g)(5)(A) do not result in a fee increase for FY 2022 to recover a collection shortfall, there will be no reduction of a shortfall-based increase under section 740(g)(5)(B).

G. FY 2022 Fee Revenue Amounts

The fee revenue amount for FY 2022, after considering the possible adjustments under sections 740(c) and (g)(5) of the FD&C Act, is $31,641,000 (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 $6,328,200, is to come from application fees; 27 percent, or a total of $8,543,070, is to come from product fees; 26 percent, or a total of $8,226,660 is to come from establishment fees; and 27 percent, or a total of $8,543,070 is to come from sponsor fees (21 U.S.C. 379j–12(b)).

III. Application Fee Calculations for FY 2022

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

Each person that submits an animal drug application or a supplemental animal drug application shall be subject to an application fee, with limited exceptions (see 21 U.S.C. 379j–12(a)(1)). The term ''animal drug application'' means an application for approval of any new animal drug submitted under section 512(b)(1) of the FD&C Act or an application for conditional approval of a new animal drug submitted under section 571 of the FD&C Act (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 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 $6,328,200 in fee revenue for FY 2022. 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 $6,328,200, FDA must first make some assumptions about the number of fee-paying applications and supplemental applications the Agency will receive in FY 2022.

The Agency knows the number of applications that have been submitted in previous years, which fluctuates annually. In estimating the fee revenue to be generated by animal drug application fees in FY 2022, FDA is assuming that the number of applications for which fees will be paid in FY 2022 will equal the average number of submissions over the 5 most recent completed fiscal years of the ADUFA program (FY 2016 to FY 2020).

Over the 5 most recent completed fiscal years, the average number of animal drug applications that would have been subject to the full fee was 6.4. 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.

B. Application Fee Rates for FY 2022

FDA must set the fee rates for FY 2022 so that the estimated 6.4 applications for which the full fee will be paid and the estimated 9.0 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 for which half of the full fee will be paid will generate a total of $6,328,200. To generate this amount, the fee for an animal drug application, rounded to the nearest dollar, will have to be $580,569, 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 $290,284.

IV. Product Fee Calculations for FY 2022

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 $8,543,070 in fee revenue for FY 2022.

To set animal drug product fees to realize $8,543,070, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2022. FDA developed data on all animal drug products that have been submitted for listing under section 510 of the FD&C Act and matched this to the list of all persons who had an animal drug application or supplemental animal drug application pending after September 1, 2003. As of May 2021, FDA estimates that there are a total of 808 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 808 products will be subject to this fee in FY 2022.

In estimating the fee revenue to be generated by animal drug product fees in FY 2022, FDA is assuming that 2 percent of the products invoiced, or 16, will not pay fees in FY 2022 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 792 (808 minus 16) products will be subject to product fees in FY 2022.

B. Product Fee Rates for FY 2022

FDA must set the fee rates for FY 2022 so that the estimated 792 products for which fees are paid will generate a total of $8,543,070. To generate this amount will require the fee for an animal drug product, rounded to the nearest dollar, to be $10,787.

V. Establishment Fee Calculations for FY 2022

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 $8,226,660 in fee revenue for FY 2022.

To set animal drug establishment fees to realize $8,226,660, FDA must make some assumptions about the number of establishments for which these fees will be paid in FY 2022. 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 2021, FDA estimates that there are a total of 58 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 58 establishments will be subject to this fee in FY 2022.

In estimating the fee revenue to be generated by animal drug establishment fees in FY 2022, FDA is assuming that 8 percent of the establishments invoiced, or five, will not pay fees in FY 2022 due to fee waivers and reductions. FDA has made this estimate at 8 percent this year, based on historical data over the past 5 completed fiscal years.

Accordingly, the Agency estimates that a total of 53 establishments (58 minus 5) will be subject to establishment fees in FY 2022.

B. Establishment Fee Rates for FY 2022

FDA must set the fee rates for FY 2022 so that the fees paid for the estimated 53 establishments will generate a total of $8,226,660. To generate this amount will require the fee for an animal drug establishment, rounded to the nearest dollar, to be $155,220.

VI. Sponsor Fee Calculations for FY 2022

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 $8,543,070 in fee revenue for FY 2022.

To set animal drug sponsor fees to realize $8,543,070, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2022. FDA estimates that a total of 187 sponsors will meet this definition in FY 2022.

In estimating the fee revenue to be generated by animal drug sponsor fees in FY 2022, FDA is assuming that 67 percent of the sponsors invoiced, or 125, will not pay sponsor fees in FY 2022 due to fee waivers and reductions. FDA has made this estimate at 67 percent this year, based on historical data over the past 5 completed fiscal years of the ADUFA program.

Accordingly, the Agency estimates that a total of 62 sponsors (187 minus 125) will be subject to and pay sponsor fees in FY 2022.

B. Sponsor Fee Rates for FY 2022

FDA must set the fee rates for FY 2022 so that the estimated 62 sponsors that pay fees will generate a total of $8,543,070. To generate this amount will require the fee for an animal drug sponsor, rounded to the nearest dollar, to be $137,791.

VII. Fee Schedule for FY 2022

The fee rates for FY 2022 are summarized in table 5.

TABLE 5—FY 2022 FEE RATES

Animal drug user fee category	Fee rate for FY 2022
Animal Drug Application Fees:	
Animal Drug Application	$580,569
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	290,284
Animal Drug Product Fee	10,787
Animal Drug Establishment Fee [1]	155,220
Animal Drug Sponsor Fee [2]	137,791

[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 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 2022 will be $21,896,240; 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 2022. 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 one 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 2022. 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 (21 U.S.C. 379j–12(a)(1)(C)(ii)).

IX. Procedures for Paying the FY 2022 Fees

A. Application Fees and Payment Instructions

The appropriate application 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, 2021. The payment must be made in U.S. currency 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 *https://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

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

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, FDA Deposit 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 Federal Express, 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 CVM. FDA records the official application receipt date as the later of the following: The date the application was received by CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U.S. Treasury notifies FDA of receipt of an electronic or wire transfer payment. U.S. Bank and the U.S. 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 user name 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—Please submit your application and a copy of the completed Animal Drug User Fee Cover Sheet to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV–199), 7500 Standish Pl., Rockville, MD 20855.

C. Product, Establishment, and Sponsor Fees

By December 31, 2021, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2022 using this fee schedule. Payment will be due by January 31, 2022. FDA will issue invoices in November 2022 for any products, establishments, and sponsors subject to fees for FY 2022 that qualify for fees after the December 2021 billing.

Dated: July 20, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16043 Filed 7–27–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Biomedical Sensing, Measurement and Instrumentation.

Date: August 12, 2021.

Time: 1:00 p.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Yordan V. Kostov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20817, 301–867–5309, *kostovyv@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 22, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–15990 Filed 7–27–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council on Alcohol Abuse and Alcoholism. The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*).

A portion of the meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material,