ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Pediatric	Pediatric Pain Questionnaire (PPQ)	3	1	15/60	1
Pediatric	Visual Analogue Scale	3	1	8/60	0
Pediatric	Hospital Anxiety and Depression Scale	3	1	7/60	0
Pediatric	Pediatric Daytime Sleepiness Scale	3	1	3/60	0
Pediatric	Social Participation Form Pediatric	3	1	10/60	0
Pediatric	Sociability Form	3	1	5/60	0
Pediatric	Saliva Collection Form	3	1	5/60	0
Adult	CogState Practice Section	109	1	17/60	31
Adult	CogState Baseline Section	109	1	27/60	49
Adult	WAIS IV DS F+B, TOPF	109	1	10/60	18
Adult	Exercise (Bike) Testing	64	1	30/60	32
Adult	CogState Time 1 Section	109	1	22/60	40
Adult	CogState Time 2 Section	109	1	12/60	22
Adult	CogState Time 3 Section	109	1	12/60	22
Adult	CogState Time 4 Section	109	1	12/60	22
Adult	Visual Analogue Scale for CFS Symptoms	60	1	8/60	8
Adult	EQ–5D–Y Health Questionnaire	60	1	6/60	6
Adult	PROMIS SF v1—Physical Function	60	1	5/60	5
Adult	Physical Fitness and Exercise Activity Levels of Scale	60	1	2/60	2
Adult	International Physical Activity Questionnaire (Self-Administered Long Form).	60	1	5/60	5
Adult	Physical Activity Readiness Questionnaire	60	1	5/60	5
Adult	Visual Analogue Scale for CFS Symptoms	49	1	8/60	6
Adult	EQ–5D–Y Health Questionnaire	49	1	6/60	5
Adult	PROMIS SF v1—Physical Function	49	1	5/60	4
Adult	Physical Fitness and Exercise Activity Levels of Scale	49	1	2/60	2
Adult	International Physical Activity Questionnaire (Self-Administered Long Form).	49	1	5/60	4
Adult	Physical Activity Readiness Questionnaire	49	1	5/60	4
Total		715			

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0806]

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2021

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fee rates and payment procedures for fiscal year (FY) 2021 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 supplements, 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 2021.

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 the 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 supplements; (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 2021, the animal drug user fee rates are: $574,810 for an animal drug application; $287,405 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)); $12,230 for an annual product fee; $166,695 for an annual establishment fee; and $142,881 for an annual sponsor fee. FDA will issue invoices for FY 2021 product, establishment, and sponsor fees by December 31, 2020, and payment will be due by January 31, 2021. The application fee rates are effective for applications submitted on or after October 1, 2020, and will remain in effect through September 30, 2021. 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 2021

A. Statutory Fee Revenue Amounts

ADUFA IV, Title I of Public Law 115–234, specifies that the aggregate base fee revenue amount for FY 2021 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 2021. The 3-year average is 1.2644 percent.

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

Fiscal year	2017	2018	2019	3-Year average
Total PC&B	$2,581,551,000	$2,690,678,000	$2,620,052,000	
Total FTE	17,022	17,023	17,144	
PC&B per FTE	$151,660	$158,061	$152,826	
Percent Change from Previous Year	2.8845%	4.2206%	–3.3120%	1.2644%

The statute specifies that this 1.2644 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	2017	2018	2019	3-Year average
Total PC&B	$2,581,551,000	$2,690,678,000	$2,620,052,000	
Total Costs	$5,104,580,000	$5,370,935,000	$5,663,389,000	
PC&B Percent	50.5732%	50.0970%	46.2630%	48.9777%

The portion of the inflation adjustment relating to payroll costs is 1.2644 percent multiplied by 48.9777 percent, or 0.6193 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''). In order to continue applying a CPI which best reflects the geographic region in which FDA is headquartered and which 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	2017	2018	2019	3-Year average
Annual CPI	266.897	272.414	275.841	.....
Annual Percent Change	0.5894%	2.0671%	1.2580%	1.3048%

To calculate the inflation adjustment for non-payroll costs, we multiply 1.3048 percent by the proportion of all costs other than PC&B to total FDA costs. Since 48.9777 percent was obligated for PC&B as shown in table 2, 51.0223 percent is the portion of costs other than PC&B (100 percent − 48.9777 percent = 51.0223 percent). The portion of the inflation adjustment relating to non-payroll costs is 1.3048 percent times 51.0223 percent, or 0.6657 percent.

Next, we add the payroll component (0.6193 percent) to the non-payroll component (0.6657 percent), for an inflation adjustment of 1.2850 percent for FY 2021.

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 2021 (1.2850 percent) is compounded by adding 1 and then multiplying by 1 plus the inflation adjustment factor for FY 2020 (2.2705 percent), as published in the **Federal Register** on August 2, 2019 (84 FR 37896 to 37901), which equals 1.035847 (rounded) (1.012850 × 1.022705) for FY 2021. We then multiply the base revenue amount for FY 2021 ($29,931,240) by 1.035847, yielding an inflation adjusted amount of $31,004,185.

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, 2020.

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, 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 added, reflecting a total change in workload of 2.2092 percent for FY 2021. This is the workload adjuster for FY 2021.

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 Applications (NADAs)	16.4	16.8	2.4390%	0.0414	0.1011%
Supplemental NADAs with Safety or Efficacy Data	11.6	8.6	−25.8621%	0.0192	−0.4963%
Manufacturing Supplements	353.2	366.4	3.7373%	0.1662	0.6210%
Investigational Study Submissions	183.2	175.0	−4.4760%	0.5615	−2.5131%
Investigational Protocol Submissions	236.4	286.6	21.2352%	0.2117	4.4964%
FY 2021 ADUFA IV Workload Adjuster	.....	.....	.....	.....	2.2092%

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)). The statutory revenue amount after the inflation adjustment ($31,004,185) must now be increased by 2.2092 percent to reflect the changes in review workload (workload adjustment), for a workload and inflation-adjusted amount of $31,689,129.

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. In FY 2019, the total revenue amount was $30,331,000 and the total collections as of May 31, 2020, were $28,680,823. Because the total amount of fees collected did not exceed the total revenue amount, there were no excess collections for FY 2019 that can be applied to reduce the workload-based increase for FY 2021.

E. Recovery of Collection Shortfalls

Under section 740(g)(5)(A) of the FD&C Act, for FY 2021, the amount of fees otherwise authorized to be collected shall be increased by the amount, if any, by which the amount collected and appropriated for FY 2019

falls below the amount of fees authorized for FY 2019.

In FY 2019, the total revenue amount was $30,331,000 and the total amount of fees collected as of May 31, 2020, was $28,680,823. Because the amount of fees collected is less than the total revenue amount, there was a collection shortfall in FY 2019 in the amount of $1,650,177 ($30,331,000 − $28,680,823). In accordance with section 740(g)(5)(A) of the FD&C Act, the amount of the collection shortfall in FY 2019 ($1,650,177) is to be recovered by adjusting the fee revenue amount for FY 2021. To make this adjustment, the collection shortfall amount ($1,650,177) is added to the workload and inflation-adjusted fee revenue amount ($31,689,129), resulting in a fee revenue amount of $33,339,000 (rounded to the nearest thousand dollars).

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 did not have excess collections in FY 2019, there will be no reduction of the shortfall-based fee increase for FY 2021.

G. FY 2021 Fee Revenue Amounts

ADUFA IV specifies that the revenue amount of $33,339,000 (rounded to the nearest thousand dollars) for FY 2021 is to be divided as follows: 20 percent, or a total of $6,667,800, is to come from application fees; 27 percent, or a total of $9,001,530, is to come from product fees; 26 percent, or a total of $8,668,140, is to come from establishment fees; and 27 percent, or a total of $9,001,530, is to come from sponsor fees (21 U.S.C. 379j–12(b)).

III. Application Fee Calculations for FY 2021

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 $6,667,800 in fee revenue for FY 2021. 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 $6,667,800, FDA must first make some assumptions about the number of fee-paying applications and supplements the Agency will receive in FY 2021.

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 2021, FDA is assuming that the number of applications for which fees will be paid in FY 2021 will equal the average number of submissions over the 5 most recent completed fiscal years of the ADUFA program (FY 2015 to FY 2019).

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 6.8. 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 9.6.

B. Application Fee Rates for FY 2021

FDA must set the fee rates for FY 2021 so that the estimated 6.8 applications for which the full fee will be paid and the estimated 9.6 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 $6,667,800. To generate this amount, the fee for an animal drug application, rounded to the nearest dollar, will have to be $574,810, 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 $287,405.

IV. Product Fee Calculations for FY 2021

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 $9,001,530 in fee revenue for FY 2021.

To set animal drug product fees to realize $9,001,530, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2021. 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 supplement pending after September 1, 2003. As of June 2020, FDA estimates that there are a total of 751 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 751 products will be subject to this fee in FY 2021.

In estimating the fee revenue to be generated by animal drug product fees in FY 2021, FDA is assuming that 2 percent of the products invoiced, or 15, will not pay fees in FY 2021 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 736 (751 minus 15) products will be subject to product fees in FY 2021.

B. Product Fee Rates for FY 2021

FDA must set the fee rates for FY 2021 so that the estimated 736 products that pay fees will generate a total of $9,001,530. To generate this amount will require the fee for an animal drug product, rounded to the nearest dollar, to be $12,230.

V. Establishment Fee Calculations for FY 2021

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 $8,668,140 in fee revenue for FY 2021.

To set animal drug establishment fees to realize $8,668,140, FDA must make some assumptions about the number of establishments for which these fees will be paid in FY 2021. FDA developed data on all animal drug establishments and matched this to the list of all persons who had an animal drug application or supplement pending after September 1, 2003. As of June 2020, FDA estimates that there are a total of 57 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 57 establishments will be subject to this fee in FY 2021.

In estimating the fee revenue to be generated by animal drug establishment fees in FY 2021, FDA is assuming that 8 percent of the establishments invoiced, or 5, will not pay fees in FY 2021 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 52 establishments (57 minus 5) will be subject to establishment fees in FY 2021.

B. Establishment Fee Rates for FY 2021

FDA must set the fee rates for FY 2021 so that the fees paid for the estimated 52 establishments will generate a total of $8,668,140. To generate this amount will require the fee for an animal drug establishment, rounded to the nearest dollar, to be $166,695.

VI. Sponsor Fee Calculations for FY 2021

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 $9,001,530 in fee revenue for FY 2021.

To set animal drug sponsor fees to realize $9,001,530, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2021. FDA estimates that a total of 192 sponsors will meet this definition in FY 2021.

In estimating the fee revenue to be generated by animal drug sponsor fees in FY 2021, FDA is assuming that 67 percent of the sponsors invoiced, or 129, will not pay sponsor fees in FY 2021 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 63 sponsors (192 129) will be subject to and pay sponsor fees in FY 2021.

B. Sponsor Fee Rates for FY 2021

FDA must set the fee rates for FY 2021 so that the estimated 63 sponsors that pay fees will generate a total of $9,001,530. To generate this amount will require the fee for an animal drug sponsor, rounded to the nearest dollar, to be $142,881.

VII. Fee Schedule for FY 2021

The fee rates for FY 2021 are summarized in table 5.

TABLE 5—FY 2021 FEE RATES

Animal drug user fee category	Fee rate for FY 2021
Animal Drug Application Fees:	
Animal Drug Application	$574,810
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	287,405
Animal Drug Product Fee	12,230
Animal Drug Establishment Fee[1]	166,695
Animal Drug Sponsor Fee[2]	142,881

[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. FDA 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 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 2021 will be $21,607,020; 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 2021.

B. Exemptions From Fees

The types of fee waivers and reductions that applied during ADUFA III still exist for FY 2021. 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 2021 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, 2020. 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 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.

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

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 needs to be included; without the invoice number, 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 FDA's CVM. FDA records the official application receipt date as the later of the following: the date the application was received by FDA's 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, 2020, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2021 using this fee schedule. Payment will be due by January 31, 2021. FDA will issue invoices in November 2021 for any products, establishments, and sponsors subject to fees for FY 2021 that qualify for fees after the December 2020 billing.

Dated: July 29, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–16839 Filed 7–30–20; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–D–1106, FDA–2020–D–1136, FDA–2020–D–1137, FDA–2020–D–1138, FDA–2020–D–1139, and FDA–2020–D–1140]

Guidance Documents Related to Coronavirus Disease 2019; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of FDA guidance documents related to the Coronavirus Disease 2019 (COVID–19) public health emergency (PHE). This notice of availability (NOA) is pursuant to the process that FDA announced, in the **Federal Register** of March 25, 2020, for making available to the public COVID–19-related guidances. The guidances identified in this notice address issues related to the COVID–19 PHE and have been issued in accordance with the process announced in the March 25, 2020, notice. The guidance documents have been implemented without prior comment, but they remain subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidances is published in the **Federal Register** on August 3, 2020. The guidance documents have been implemented without prior comment, but they remain subject to comment in accordance with the Agency's good guidance practices.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that 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