DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Reduction of Issuer Burden Through Technology Grant

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice of funding opportunity.

SUMMARY: This notice announces the issuance of the March 10, 2021 (and amended on April 29, 2021) single-source funding opportunity titled ''Reduction of Issuer Burden Through Technology Grant'' (hereafter referred to as the ''RIBTT Grant'') available solely to the National Association of Insurance Commissioners (NAIC) to build a connection between the State Electronic Rate and Form Filing (SERFF) system, owned and operated by the NAIC, and the Health Insurance Oversight System (HIOS), which is operated by the Centers for Medicare and Medicaid Services (CMS). This connection will enable health insurance issuers to enter rate justification data into the SERFF system and then have this rate justification data automatically transfer to HIOS. Currently, health insurance issuers have to enter duplicate data into both the SERFF system and HIOS in order to maintain compliance with federal and state law in 49 states and the District of Columbia.

DATES: The project period of the award, in the amount of $250,000 to the NAIC, will be 24 months from the date of award. The tentative award date is July 29, 2021.

FOR FURTHER INFORMATION CONTACT: Jim Taing, (301) 492–4182.

SUPPLEMENTARY INFORMATION:

I. Background

The Reduction of Issuer Burden Through Technology Grant (RIBTT Grant) provides a funding source to build a connection between the SERFF system and the Unified Rate Review (URR) module of HIOS. Forty-nine states and the District of Columbia currently use the SERFF system to collect and review rate data. Building a connection between SERFF and HIOS will reduce burden on health insurance issuers and decrease the potential for data mismatches between the two systems. It will enable health insurance issuers to enter rate justification data into the SERFF system and the rate justification data will automatically transfer to HIOS. Currently, health insurance issuers have to enter duplicate data into both the SERFF system and HIOS in order to maintain compliance with applicable federal and state law. Funding under the RIBTT Grant is available to the NAIC to complete their portion of the technical changes needed in order to build such a connection between the SERFF system and HIOS.

II. Provisions of the Notice

CMS is anticipating approximately a total of $250,000 will be available for the RIBTT Grant, pending availability of funds, to the NAIC to complete their portion of the technical changes needed in order to build such a connection between the SERFF system and HIOS for the transfer of rate filing information. The NAIC may use grant funds for a variety of planning, development, testing, and implementation objectives related to the technical changes needed to build the connection between the SERFF system and HIOS. This includes, but is not limited to, hiring or contracting with information technology professionals or firms to complete the work. Pending an acceptable application and budget, the CMS will recommend awarding a single source grant to the NAIC who is uniquely qualified to complete the work requested. The NAIC is uniquely positioned to perform this work as they are the only applicant under this funding opportunity to meet the objectives of this funding opportunity as they own, operate, and maintain the SERFF system and the SERFF system is what is utilized by health insurance issuers to submit rate filing justification data in 49 states and the District of Columbia. The NAIC has built previous IT connections between their SERFF system and HIOS for the submission of Qualified Health Plan certification data between SERFF and the Plan Management module of HIOS. Funds enable NAIC to establish this new IT connection between the SERFF system and the URR module of HIOS based on the prior system architecture.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: July 19, 2021.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2021–15656 Filed 7–22–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Public Comment Request; State Developmental Disabilities Council—Annual Program Performance Report (PPR) (OMB Control Number 0985–0033)

Correction

In notice document 2021–15025, appearing on page 37337 in the issue of Thursday, July 15, 2021 make the following correction:

On page 37337, in the first column, in the **DATES** section, on the second and third lines, ''August 30, 2021'' should read, ''August 16, 2021''.

[FR Doc. C1–2021–15025 Filed 7–22–21; 8:45 am]

BILLING CODE 0099–10–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0703]

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

AGENCY: Food and Drug Administration, Health and Human Services (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 generic new animal drug user fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Generic Drug User Fee Amendments of 2018 (AGDUFA III), authorizes FDA to collect user fees for certain abbreviated applications for generic new animal drugs, for certain generic new animal drug products, and for certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs. This notice establishes the fee rates for FY 2022.

FOR FURTHER INFORMATION 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* or visit FDA's website at *https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm.* For general questions, you may also email the Center for Veterinary

Medicine (CVM) at *cvmagdufa@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 741 of the FD&C Act (21 U.S.C. 379j–21) establishes three different types of user fees: (1) Fees for certain types of abbreviated applications for generic new animal drugs; (2) annual fees for certain generic new animal drug products; and (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (21 U.S.C. 379j–21(a)). When certain conditions are met, FDA will waive or reduce fees for generic new animal drugs intended solely to provide for a minor use or minor species indication (21 U.S.C. 379j–21(d)).

For FY 2019 through FY 2023, the FD&C Act establishes a yearly base revenue amount and percentages for each of these fee categories (21 U.S.C. 379j–21(b)). Base revenue amounts are subject to adjustment for inflation and workload (21 U.S.C. 379j–21(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 (21 U.S.C. 379j–21(c)(3)(B)). The target revenue amounts for each fee category for FY 2022, are as follows: For application fees, the target revenue amount is $6,199,500; for product fees, the target revenue amount is $9,299,250; and for sponsor fees, the target revenue amount is $9,299,250.

For FY 2022, the generic new animal drug user fee rates are: $548,628 for each abbreviated application for a generic new animal drug other than those subject to the criteria in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)); $274,314 for each abbreviated application for a generic new animal drug subject to the criteria in section 512(d)(4) of the FD&C Act; $17,513 for each generic new animal drug product; $234,297 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; $175,723 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and $117,149 for each generic new animal drug sponsor paying 50 percent of the sponsor fee. FDA will issue invoices for FY 2022 product and sponsor fees by December 31, 2021. These fees will be due by January 31, 2022. The application fee rates are effective for all abbreviated applications for a generic new animal drug 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 related application fees and any other fees owed under the Animal Generic Drug User Fee program (AGDUFA program).

II. Revenue Amount for FY 2022

A. Statutory Fee Revenue Amounts

AGDUFA III, Title II of Public Law 115–234, specifies that the aggregate base fee revenue amount for FY 2022 for all generic new animal drug user fee categories is $18,336,340 (21 U.S.C. 379j–21(b)(1)).

B. Inflation Adjustment to Fee Revenue Amount

AGDUFA III 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 (see 21 U.S.C. 379j–21(c)(2)). 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, 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 PERSONNEL COMPENSATION AND BENEFITS (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 FYs.

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 cost 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''). In order 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 index, less food and energy, in 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 is shown in table 3.

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 − 47.9915 percent = 52.0085 percent). The non-payroll adjustment 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.

AGDUFA III provides for the inflation adjustment to be compounded each fiscal year after FY 2020 (see 21 U.S.C. 379j–21(c)(2)). 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 46647 to 46651), which equals 1.057121 (rounded) (1.020538 × 1.035847) for FY 2022. We then multiply the base revenue amount for FY 2022 ($18,336,340) by 1.057121, yielding an inflation adjusted amount of $19,383,730.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

The fee revenue amounts established in AGDUFA III 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–21(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 four types of applications and submissions specified in the workload adjustment provision (abbreviated applications for generic new animal drugs, manufacturing supplemental abbreviated applications for generic new animal drugs, investigational generic new animal drug study submissions, and investigational generic new 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, reflecting how much of the total FDA generic new animal drug review workload was accounted for by each type of application or submission in the table during the most recent 5 years. Column 5 is the weighted percent change in each category of workload, and was derived by multiplying the weighting factor in each line in column 4 by the percent change from the base years in column 3. At the bottom right of the table the sum of the values in column 5 is calculated, reflecting a total change in workload of 49.0190 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
Abbreviated Application for a Generic New Animal Drug (ANADAs)	24.0	26.6	10.8333	0.1745	1.8904
Manufacturing Supplements ANADAs	169.4	198.2	17.0012	0.2601	4.4212
Generic Investigational Study Submissions	69.2	122.8	77.4566	0.4121	31.9161
Generic Investigational Protocol Submissions	34.4	58.64	70.3488	0.1534	10.7913
FY 2022 AGDUFA III Workload Adjuster	.....	.....	.....	.....	49.0190

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

The statutory revenue amount after the inflation adjustment ($19,383,730) must now be increased by 49.0190 percent to reflect the changes in review workload (workload adjustment), for a workload and inflation-adjusted amount of $28,885,441.

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

Under section 741(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. The workload and inflation-adjusted amount ($28,885,441) is subtracted by the inflation adjusted amount ($19,383,730) to get the workload adjustment amount ($9,501,711). Then the excess fees collected from FY 2020 as of May 31, 2021 ($4,087,114) are subtracted from the workload adjustment amount ($9,501,711) to get a reduced workload adjustment amount of $5,414,597. Next, the reduced workload adjustment amount ($5,414,597) is added to the inflation-adjusted revenue amount ($19,383,730), for a total fee revenue target of $24,798,000 (rounded to the nearest thousand dollars).

E. FY 2022 Fee Revenue Amounts

AGDUFA III specifies that the revenue amount of $24,798,000 for FY 2022 is to be divided as follows: 25 percent, or a total of $6,199,500, is to come from application fees; 37.5 percent, or a total of $9,299,250, is to come from product fees; and 37.5 percent, or a total of $9,299,250, is to come from sponsor fees (21 U.S.C. 379j–21(b)).

III. Abbreviated Application Fee Calculations for FY 2022

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

Each person who submits an abbreviated application for a generic new animal drug shall be subject to an application fee, with limited exceptions (21 U.S.C. 379j–21(a)(1)). The term ''abbreviated application for a generic new animal drug'' means an abbreviated application for the approval of any generic new animal drug submitted under section 512(b)(2) of the FD&C Act (21 U.S.C. 379j–21(k)(1)). The application fees are to be set so that they will generate $6,199,500 in fee revenue for FY 2022.

To set fees for abbreviated applications for generic new animal drugs to realize $6,199,500 FDA must first make some assumptions about the number of fee-paying abbreviated applications it will receive during FY 2022.

The Agency knows the number of applications that have been submitted in previous years. That number fluctuates annually. In estimating the fee revenue to be generated by generic new animal drug applications 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 recently completed fiscal years of the AGDUFA program (FY 2016–FY 2020).

Also, under AGDUFA III, an abbreviated application for an animal generic drug subject to the criteria in section 512(d)(4) of the FD&C Act and submitted on or after October 1, 2013, shall be subject to 50 percent of the fee applicable to all other abbreviated applications for a generic new animal drug (21 U.S.C. 379j–21(a)(1)(C)(ii)).

The average number of original submissions of abbreviated applications for generic new animal drugs over the 5 most recently completed fiscal years is 8.2 applications not subject to the criteria in section 512(d)(4) of the FD&C Act and 6.2 submissions subject to the criteria in section 512(d)(4). Each of the submissions described under section 512(d)(4) of the FD&C Act pays 50 percent of the fee paid by the other applications and will be counted as one half of a fee. Adding all of the applications not subject to the criteria in section 512(d)(4) of the FD&C Act and 50 percent of the number that are subject to such criteria results in a total of 11.30 anticipated full fees.

Based on the previous assumptions, FDA is estimating that it will receive a total of 11.30 fee-paying generic new animal drug applications in FY 2022 (8.2 original applications paying a full fee and 6.2 applications paying a half fee).

B. Application Fee Rates for FY 2022

FDA must set the fee rates for FY 2022 so that the estimated 11.30 abbreviated applications that pay the fee will generate a total of $6,199,500. To generate this amount, the fee for a generic new animal drug application will have to be $548,628 and for those applications that are subject to the criteria set forth in section 512(d)(4) of the FD&C Act, 50 percent of that amount, or $274,314.

IV. Generic New Animal Drug Product Fee Calculations for FY 2022

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

The generic new animal drug product fee must be paid annually by the person named as the applicant in an abbreviated application or supplemental abbreviated application for a generic new animal drug product submitted for listing under section 510 of the FD&C Act (21 U.S.C. 360), and who had an abbreviated application or supplemental abbreviated application for a generic new animal drug product pending at FDA after September 1, 2008 (see 21 U.S.C. 379j–21(a)(2)). The term ''generic new 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 abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug has been approved (21 U.S.C. 379j–21(k)(6)). The product fees are to be set so that they will generate $9,299,250 in fee revenue for FY 2022.

To set generic new animal drug product fees to realize $9,299,250, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2022. FDA gathered data on all generic new animal drug products that have been submitted for listing under section 510 of the FD&C Act and matched this to the list of all persons who had a generic new animal drug application or supplemental abbreviated application pending after September 1, 2008. As of May 2021, FDA estimates a total of 536 products submitted for listing by persons who had an abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug pending after September 1, 2008. Based on this, FDA believes that a total of 536 products will be subject to this fee in FY 2022.

In estimating the fee revenue to be generated by generic new animal drug product fees in FY 2022, FDA is estimating that 1 percent of the products invoiced, or 5 products, will qualify for minor use/minor species fee waiver (see 21 U.S.C. 379j–21(d)). FDA has made this estimate at 1 percent this year, based on historical data over the past 5 completed fiscal years of the AGDUFA program.

Accordingly, the Agency estimates that a total of 531 (536 minus 5) 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 531 products that pay fees will generate a total of $9,299,250. To generate this amount will require the fee for a generic new animal drug product, rounded to the nearest dollar, to be $17,513.

V. Generic New Animal Drug Sponsor Fee Calculations for FY 2022

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

The generic new animal drug sponsor fee must be paid annually by each person who: (1) Is named as the applicant in an abbreviated application for a generic new animal drug, except for an approved application for which all subject products have been removed from listing under section 510 of the FD&C Act, or has submitted an investigational submission for a generic new animal drug that has not been terminated or otherwise rendered inactive and (2) had an abbreviated application for a generic new animal drug, supplemental abbreviated application for a generic new animal drug, or investigational submission for a generic new animal drug pending at FDA after September 1, 2008 (see 21 U.S.C. 379j–21(k)(7) and 379j–21(a)(3), respectively). A generic new animal drug sponsor is subject to only one such fee each fiscal year (see 21 U.S.C. 379j–21(a)(3)(C)). Applicants with more than 6 approved abbreviated applications will pay 100 percent of the sponsor fee; applicants with more than 1 and fewer than 7 approved abbreviated applications will pay 75 percent of the sponsor fee; and applicants with 1 or fewer approved abbreviated applications will pay 50 percent of the sponsor fee (see 21 U.S.C. 379j–21(a)(3)(C)). The sponsor fees are to be set so that they will generate $9,299,250 in fee revenue for FY 2022.

To set generic new animal drug sponsor fees to realize $9,299,250, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2022. FDA estimates that in FY 2022, 12 sponsors will pay 100 percent fees, 18 sponsors will pay 75 percent fees, and 30 sponsors will pay 50 percent fees. That totals the equivalent of 40.5 full sponsor fees (12 $\times$ 100 percent or 12, plus 18 $\times$ 75 percent or 13.5, plus 30 $\times$ 50 percent or 15).

FDA estimates that about 2 percent of all of these sponsors, or 0.81, may qualify for a minor use/minor species fee waiver (see 21 U.S.C. 379j–21(d)). FDA has made the estimate of the percentage of sponsors that will not pay fees at 2 percent this year, based on historical data over the past 5 completed fiscal years of the AGDUFA program.

Accordingly, the Agency estimates that the equivalent of 39.69 full sponsor fees (40.5 − 0.81) are likely to be paid in FY 2022.

B. Sponsor Fee Rates for FY 2022

FDA must set the fee rates for FY 2022 so that the estimated equivalent of 39.69 full sponsor fees will generate a total of $9,299,250. To generate this amount will require the 100 percent fee for a generic new animal drug sponsor, rounded to the nearest dollar, to be $234,297. Accordingly, the fee for those paying 75 percent of the full sponsor fee will be $175,723, and the fee for those paying 50 percent of the full sponsor fee will be $117,149.

VI. Fee Schedule for FY 2022

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

TABLE 5—FY 2022 FEE RATES

Generic new animal drug user fee category	Fee rate for FY 2022
Abbreviated Application Fee for Generic New Animal Drug except those subject to the criteria in section 512(d)(4)	$548,628
Abbreviated Application Fee for Generic New Animal Drug subject to the criteria in section 512(d)(4)	274,314
Generic New Animal Drug Product Fee	17,513
100% Generic New Animal Drug Sponsor Fee.[1]	234,297
75% Generic New Animal Drug Sponsor Fee.[1]	175,723
50% Generic New Animal Drug Sponsor Fee.[1]	117,149

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

VII. Fee Waiver or Reduction; Exemption From Fees

The types of fee waivers and reductions that applied last fiscal year still exist for FY 2022. In AGDUFA III a new exemption from fees was established, as follows:

Fees will not apply to any person who not later than September 30, 2023, submits to CVM a supplemental abbreviated application relating to a generic new animal drug approved under section 512 of the FD&C Act, solely to add the application number to the labeling of the drug in the manner specified in section 502(w)(3) of the FD&C Act (21 U.S.C. 352(w)(3)), if that person otherwise would be subject to user fees under AGDUFA based only on the submission of the supplemental abbreviated application (21 U.S.C. 379j–21(d)(2)).

VIII. Procedures for Paying FY 2022 Generic New Animal Drug User Fees

A. Abbreviated Application Fees and Payment Instructions

The FY 2022 fee established in the new fee schedule must be paid for a generic new animal drug application subject to fees under AGDUFA III that is submitted on or after October 1, 2021. 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 an 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 have found your invoice, select ''Pay Now'' to be redirected to *Pay.gov.* Electronic payment options are based on the balance due. Payment by credit card is available only for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

When paying by check, bank draft, or U.S. postal money order, please write your application's unique Payment Identification Number (PIN), beginning with the letters ''AG'', on the upper right-hand corner of your completed Animal Generic Drug User Fee Cover Sheet. Also write FDA's post office box number (P.O. Box 979033) and PIN on the enclosed check, bank draft, or money order. Mail the payment and a copy of the completed Animal Generic Drug User Fee Cover Sheet to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000. Note: In no case should the payment for the fee be submitted to FDA with the application.

When paying by wire transfer, it is required that the invoice number or PIN is 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 wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account No.: 75060099, Routing No.: 021030004, SWIFT No.: 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 phone number is only for questions about courier delivery.)

It is important that the fee arrives at the bank at least a day or two before the abbreviated application arrives at FDA's CVM. FDA records the official abbreviated 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. Department of the Treasury notifies FDA of payment. U.S. Bank and the United States 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 onto the AGDUFA website at *https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm137049.htm* and scroll down the page until you find the link ''Create AGDUFA User Fee Cover Sheet.'' Select that link and follow the directions. 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 Generic 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 Generic Drug User Fee Cover Sheet. One cover sheet is needed for each abbreviated application for a generic new animal drug. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the cover sheet, you will be able to transmit it electronically to FDA and you will be able to print a copy of your cover sheet showing your unique PIN.

Step Three—Send the payment for your application as described in section VIII.A.

Step Four—Please submit your application and a copy of the completed Animal Generic 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 and Sponsor Fees

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

Dated: July 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0363]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug Advertising

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by August 23, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0686. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St. North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prescription Drug Advertising—21 CFR Part 202

OMB Control Number 0910–0686—Extension

This information collection supports Agency regulations and associated guidance. FDA protects the public health by assuring the safety, effectiveness, and security of a wide range of products. We also help consumers get accurate, science-based information they need to use medicines appropriately and improve their health.