wire transfer. 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). FDA has partnered with the U.S. Department of the Treasury to use *Pay.gov*, a web-based payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website after the user fee ID number is generated. Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay* (*Note:* Only full payments are accepted. No partial payments can be made online). Once you search for your invoice, click ''Pay Now'' to be redirected to *Pay.gov.* Electronic payment options are based on the balance due. Payment by credit card is available 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.

If a check, bank draft, or postal money order is submitted, make it payable to the order of the Food and Drug Administration and include the user fee ID number to ensure that the payment is applied to the correct fee(s). Payments can be mailed to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000. If a check, bank draft, or money order is to be sent by a courier that requests a street address, the courier should deliver your payment to: U.S. Bank, Attention: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (*Note:* This U.S. Bank 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.) Please make sure that the FDA post office box number (P.O. Box 979108) is written on the check, bank draft, or postal money order.

For payments made by wire transfer, include the unique user fee ID number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID number, the payment may not be applied. The originating financial institution may charge a wire transfer fee. Include applicable wire transfer fees with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The following account information should be used to send payments by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33. FDA's tax identification number is 53–0196965.

*B. Annual BPD and Program Fees*

FDA will issue invoices with payment instructions for FY 2020 annual BPD and program fees under the new fee schedule in August 2019. Payment will be due on October 1, 2019. If sponsors join the BPD program after the annual BPD invoices have been issued in August 2019, FDA will issue invoices in December 2019 to firms subject to fees for FY 2020 that qualify for the annual BPD fee after the August 2019 billing. FDA will issue invoices in December 2019 for any annual program fees for FY 2020 that qualify for fee assessments and were not issued in August 2019.

Dated: July 29, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–16495 Filed 8–1–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–N–3523]**

### Animal Generic Drug User Fee Rates and Payment Procedures for Fiscal Year 2020

**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) 2020 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 2020.

**FOR FURTHER INFORMATION CONTACT:** Visit FDA's website at *https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/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 *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. Workload increases will be adjusted for excess collections after FY 2020, if applicable (21 U.S.C. 379j–21(c)). The target revenue amounts for each fee category for FY 2020, are as follows: For application fees, the target revenue amount is $5,037,750; for product fees, the target revenue amount is $7,556,625; and for sponsor fees, the target revenue amount is $7,556,625.

For FY 2020, the generic new animal drug user fee rates are: $493,897 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)); $246,949 for each abbreviated application for a generic new animal drug subject to the criteria in section 512(d)(4); $16,645 for each generic new animal drug product; $172,329 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; $129,247 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and $86,165 for each generic new animal drug sponsor paying 50 percent of the sponsor fee. FDA will issue invoices for FY 2020 product and sponsor fees by December 31, 2019. These fees will be due by January 31, 2020. The application fee rates are effective for all abbreviated applications for a generic new animal drug submitted on or after October 1, 2019, and will remain in effect through September 30, 2020. 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 2020

### *A. Statutory Fee Revenue Amounts*

AGDUFA III, Title II of Pub. L. 115–234, specifies that the aggregate revenue amount for FY 2020 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, 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 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 2020. The 3-year average is 3.1175 percent.

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

| Fiscal Year | 2016 | 2017 | 2018 | 3-Year average |
|---|---|---|---|---|
| Total PC&B | $2,414,728,159 | $2,581,551,000 | $2,690,678,000 | |
| Total FTE | 16,381 | 17,002 | 17,023 | |
| PC&B per FTE | $147,408 | $151,660 | $158,061 | |
| Percent Change from Previous Year | 2.2474% | 2.8845% | 4.2206% | 3.1175% |

The statute specifies that this 3.1175 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 | 2016 | 2017 | 2018 | 3-Year average |
|---|---|---|---|---|
| Total PC&B | $2,414,728,159 | $2,581,551,000 | $2,690,678,000 | |
| Total Costs | $4,666,236,000 | $5,104,580,000 | $5,370,935,000 | |
| PC&B Percent | 51.7490% | 50.5732% | 50.0970% | 50.8064% |

The portion of the inflation adjustment relating to payroll cost is 3.1175 percent multiplied by 50.8064 percent (or 1.5839 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 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 proportion of all costs other than PC&B costs to total FDA costs. 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, the Washington-Arlington-Alexandria less food and energy index will be used 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 | 2016 | 2017 | 2018 | 3-Year average |
|---|---|---|---|---|
| Annual CPI | 265.333 | 266.897 | 272.414 | |
| Annual Percent Change | 1.5306% | 0.5894% | 2.0671% | 1.3957% |

To calculate the inflation adjustment for non-payroll costs, we multiply the 1.3957 percent by the proportion of all costs other than PC&B to total FDA costs. Since 50.8064 percent was obligated for PC&B as shown in table 2, 49.1936 percent is the portion of costs other than PC&B (100 percent 2012; 50.8064 percent = 49.1936 percent). The non-payroll adjustment is 1.3957 percent times 49.1936 percent, or 0.6866 percent.

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

Next, we add the payroll component (1.5839 percent) to the non-payroll component (0.6866 percent), for a total inflation adjustment of 2.2705 percent, and then add one, making 1.022705. We then multiply the base revenue amount for FY 2020 ($18,336,340) by 1.022705, yielding an inflation adjusted amount of $18,752,667 for FY 2020.

*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, 2019.

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 7.4558 percent for FY 2020. This is the workload adjuster for FY 2020.

TABLE 4—WORKLOAD ADJUSTER CALCULATION

| Application Type | Column 1<br>5-Year average (base years) | Column 2<br>Latest 5-year average | Column 3<br>Percent change | Column 4<br>Weighting factor | Column 5<br>Weighted percent change |
|---|---|---|---|---|---|
| Abbreviated Application for a Generic New Animal Drug (ANADAs) | 24.0 | 22.0 | −8.3333 | 0.2577 | −2.1478 |
| Manufacturing Supplements ANADAs | 169.4 | 176.6 | 4.2503 | 0.2857 | 1.2142 |
| Generic Investigational Study Submissions | 69.2 | 84.4 | 21.9653 | 0.3209 | 7.0478 |
| Generic Investigational Protocol Submissions | 34.4 | 37.8 | 9.8837 | 0.1357 | 1.3417 |
| FY 2020 AGDUFA III Workload Adjuster | | | | | 7.4558 |

The statutory revenue amount after the inflation adjustment ($18,752,667) must now be increased by 7.4558 percent to reflect the changes in review workload (workload adjustment), for a total fee revenue target of $20,151,000 (rounded to the nearest thousand dollars).

*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. This provision does not take effect until FY 2021.

*E. FY 2020 Fee Revenue Amounts*

AGDUFA III specifies that the revenue amount of $20,151,000 for FY 2020 is to be divided as follows: 25 percent, or a total of $5,037,750, is to come from application fees; 37.5 percent, or a total of $7,556,625, is to come from product fees; and 37.5 percent, or a total of $7,556,625, is to come from sponsor fees (21 U.S.C. 379j–21(b)).

## III. Abbreviated Application Fee Calculations for FY 2020

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

Each person that 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) (21 U.S.C. 379j–21(k)(1)). The application fees are to be set so that they will generate $5,037,750 in fee revenue for FY 2020.

To set fees for abbreviated applications for generic new animal drugs to realize $5,037,750, FDA must first make some assumptions about the number of fee-paying abbreviated applications it will receive during FY 2020.

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 2020, FDA is assuming that the number of applications for which fees will be paid in FY 2020 will equal the average number of submissions over the 5 most recently completed fiscal years of the AGDUFA program (FY 2014–FY 2018).

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 9.0 applications not subject to the criteria in section 512(d)(4) of the FD&C Act and 2.4 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 10.2 anticipated full fees.

Based on the previous assumptions, FDA is estimating that it will receive a total of 10.2 fee-paying generic new animal drug applications in FY 2020 (9.0 original applications paying a full fee and 2.4 applications paying a half fee).

*B. Application Fee Rates for FY 2020*

FDA must set the fee rates for FY 2020 so that the estimated 10.2 abbreviated applications that pay the fee will generate a total of $5,037,750. To generate this amount, the fee for a generic new animal drug application will have to be $493,897 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 $246,949.

## IV. Generic New Animal Drug Product Fee Calculations for FY 2020

*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 $7,556,625 in fee revenue for FY 2020.

To set generic new animal drug product fees to realize $7,556,625, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2020. 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 June 2019, FDA estimates a total of 459 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 459 products will be subject to this fee in FY 2020.

In estimating the fee revenue to be generated by generic new animal drug product fees in FY 2020, 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 one 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 454 (459 minus 5) products will be subject to product fees in FY 2020.

*B. Product Fee Rates for FY 2020*

FDA must set the fee rates for FY 2020 so that the estimated 454 products that pay fees will generate a total of $7,556,625. To generate this amount will require the fee for a generic new animal drug product, rounded to the nearest dollar, to be $16,645.

## V. Generic New Animal Drug Sponsor Fee Calculations for FY 2020

*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 six approved abbreviated applications will pay 100 percent of the sponsor fee; applicants with more than one and fewer than seven approved abbreviated applications will pay 75 percent of the sponsor fee; and applicants with one 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 $7,556,625 in fee revenue for FY 2020.

To set generic new animal drug sponsor fees to realize $7,556,625, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2020. Based on the number of firms that meet this definition and the average number of firms paying fees at each level over the 5 most recently completed fiscal years of the AGDUFA program (FY 2014 through FY 2018), FDA estimates that in FY 2020, 11 sponsors will pay 100 percent fees, 19 sponsors will pay 75 percent fees, and 39 sponsors will pay 50 percent fees. That totals the equivalent of 44.75 full sponsor fees (11 × 100 percent or 11, plus 19 × 75 percent or 14.25, plus 39 × 50 percent or 19.5).

FDA estimates that about two percent of all of these sponsors, or 0.90, 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 two 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 43.85 full sponsor fees (44.75 minus 0.90) are likely to be paid in FY 2020.

*B. Sponsor Fee Rates for FY 2020*

FDA must set the fee rates for FY 2020 so that the estimated equivalent of 43.85 full sponsor fees will generate a total of $7,556,625. To generate this amount will require the 100 percent fee for a generic new animal drug sponsor, rounded to the nearest dollar, to be $172,329. Accordingly, the fee for those paying 75 percent of the full sponsor fee will be $129,247, and the fee for those paying 50 percent of the full sponsor fee will be $86,165.

## VI. Fee Schedule for FY 2020

The fee rates for FY 2020 are summarized in table 5.

TABLE 5—FY 2020 FEE RATES

| Generic new animal drug user fee category | Fee rate for FY 2020 |
|---|---|
| Abbreviated Application Fee for Generic New Animal Drug except those subject to the criteria in section 512(d)(4) | $493,897 |
| Abbreviated Application Fee for Generic New Animal Drug subject to the criteria in section 512(d)(4) | 246,949 |
| Generic New Animal Drug Product Fee | 16,645 |
| 100 Percent Generic New Animal Drug Sponsor Fee [1] | 172,329 |
| 75 Percent Generic New Animal Drug Sponsor Fee [1] | 129,247 |
| 50 Percent Generic New Animal Drug Sponsor Fee [1] | 86,165 |

[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 2020. However, a new exemption from fees was established by AGDUFA III, 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 2020 Generic New Animal Drug User Fees

### *A. Abbreviated Application Fees and Payment Instructions*

The FY 2020 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, 2019. 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, beginning with the letters ''AG'', on the upper right-hand corner of your completed Animal Generic Drug User Fee Cover Sheet. Also write the FDA post office box number (P.O. Box 979033) 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.

When paying by wire transfer, it is required that the invoice number is included; without the invoice number the payment may not be applied. If the payment amount is not applied, 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 Payment Identification Number described previously.

The tax identification number of FDA is 53–0196965. (Note: In no case should the payment for the fee be submitted to FDA with the application.)

### *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 Payment Identification Number.

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, 2019, FDA will issue invoices and payment instructions for product and sponsor fees for FY 2020 using this fee schedule. Fees will be due by January 31, 2020. FDA will issue invoices in November 2020 for any products and sponsors subject to fees for FY 2020 that qualify for fees after the December 2019 billing.

Dated: July 29, 2019.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

[FR Doc. 2019–16433 Filed 8–1–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2019–N–3523]**

### Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2020

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA, Agency, or we) is announcing the fee rates and payment procedures for fiscal year (FY) 2020 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 2020.

**FOR FURTHER INFORMATION CONTACT:** Visit FDA's website at *http://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 FY 2019 through FY 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, and for excess collections to reduce workload-based increases or collection shortfalls after FY 2020 (21 U.S.C. 379j–12(c) and (g)). 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: Revenue from application fees shall be 20 percent of total fee revenue; revenue from product fees shall be 27 percent of total fee revenue; revenue from establishment fees shall be 26 percent of total fee revenue; and revenue from sponsor fees shall be 27 percent of total fee revenue (21 U.S.C. 379j–12(b)(2)).

For FY 2020, the animal drug user fee rates are: $440,446 for an animal drug application; $220,223 for a supplemental animal drug application for which safety or effectiveness data are required and for an animal drug application subject to the criteria set forth in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)); $11,353 for an annual product fee; $159,177 for an annual establishment fee; and $144,999 for an annual sponsor fee. FDA will issue invoices for FY 2020 product, establishment, and sponsor fees by December 31, 2019, and payment will be due by January 31, 2020. The application fee rates are effective for applications submitted on or after October 1, 2019, and will remain in effect through September 30, 2020. 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 2020

*A. Statutory Fee Revenue Amounts*

ADUFA IV, Title I of Public Law 115–234, specifies that the aggregate fee revenue amount for FY 2020 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*

The fee revenue amounts established in ADUFA IV for FY 2020 and subsequent fiscal years are subject to an inflation adjustment (21 U.S.C. 379j–12(c)(2)).

ADUFA IV specifies that the annual fee revenue amount is to be adjusted 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 (FTE) position at FDA for the first 3 of the 4 preceding fiscal years, 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 2020. The 3-year average is 3.1175 percent.

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

| Fiscal year | 2016 | 2017 | 2018 | 3-Year average |
|---|---|---|---|---|
| Total PC&B | $2,414,728,159 | $2,581,551,000 | $2,690,678,000 | |
| Total FTE | 16,381 | 17,022 | 17,023 | |