

- With respect to each of the 3 most recent 12-month periods for which data are available as of the date the hospital submits its request, has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located.

- Does not discriminate against beneficiaries of federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

Individuals and entities wishing to submit comments on the hospital's request should review the **DATES** and **ADDRESSES** sections and state whether or not they are in the community in which the hospital is located.

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

V. Response to Public Comments

We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Dated: July 14, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016-17928 Filed 7-27-16; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0007]

Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2017

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates and payment procedures for fiscal

year (FY) 2017 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Animal Drug User Fee Amendments of 2013 (ADUFA III), 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 2017.

FOR FURTHER INFORMATION CONTACT: Visit FDA's Web site at <http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm> or contact Lisa Kable, Center for Veterinary Medicine (HFV-10), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6888. 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 2014 through FY 2018, 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 established for years after FY 2014 are subject to adjustment for inflation and workload (21 U.S.C. 379j-12(c)). 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 2017, the animal drug user fee rates are: \$350,700 for an animal drug

application; \$175,350 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)); \$8,195 for an annual product fee; \$111,900 for an annual establishment fee; and \$103,100 for an annual sponsor fee. FDA will issue invoices for FY 2017 product, establishment, and sponsor fees by December 31, 2016, and payment will be due by January 31, 2017. The application fee rates are effective for applications submitted on or after October 1, 2016, and will remain in effect through September 30, 2017. 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 program (ADUFA program).

II. Revenue Amount for FY 2017

A. Statutory Fee Revenue Amounts

ADUFA III, Title I of Public Law 113-14, specifies that the aggregate fee revenue amount for FY 2017 for all animal drug user fee categories is \$21,600,000 (21 U.S.C. 379j-12(b)(1)(B)).

B. Inflation Adjustment to Fee Revenue Amount

The fee revenue amount established in ADUFA III for FY 2015 and subsequent fiscal years are subject to an inflation adjustment (21 U.S.C. 379j-12(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 personnel compensation and benefits (PC&B) paid per full-time equivalent position (FTE) at FDA for the first three of the four preceding fiscal years, multiplied by the proportion of PC&B costs to total FDA costs for the first three of the four preceding fiscal years (see 21 U.S.C. 379j-12(c)(2)(A) and (B)). 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 three of the four fiscal years preceding FY 2017. The 3-year average is 1.8759 percent.

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

Fiscal year	2013	2014	2015	3-year average
Total PC&B	\$1,927,703,000	\$2,054,937,000	\$2,232,304,000
Total FTE	13,974	14,555	15,484
PC&B per FTE	137,949	141,184	144,168
Percent Change from Previous Year	1.1690%	2.3451%	2.1136%	1.8759%

The statute specifies that this 1.8759 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	2013	2014	2015	3-year average
Total PC&B	\$1,927,703,000	\$2,054,937,000	\$2,232,304,000
Total Costs	4,151,343,000	4,298,476,000	4,510,565,000
PC&B Percent	46.4356%	47.8062%	49.4906%	47.9108%

The payroll adjustment is 1.8759 percent multiplied by 47.9108 percent (or 0.8988 percent).

The statute specifies that the portion of the inflation adjustment for non-payroll costs for FY 2017 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 proportion of all

costs other than PC&B costs to total FDA costs (see 21 U.S.C. 379j–12(c)(2)(C)). Table 3 provides the summary data for the percent change in the specified CPI for the Baltimore-Washington area. The data from the Bureau of Labor Statistics is shown in table 3.

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

Year	2013	2014	2015	3-year average
Annual CPI	146.953	149.581	152.242
Annual Percent Change	1.7588%	1.7883%	1.7790%	1.7754%

To calculate the inflation adjustment for non-pay costs, we multiply the 1.7754 percent by the proportion of all costs other than PC&B to total FDA costs. Since 47.9108 percent was obligated for PC&B as shown in table 2, 52.0892 percent is the portion of costs other than PC&B (100 percent minus 47.9108 percent equals 52.0892 percent). The non-payroll adjustment is 1.7754 percent times 52.0892 percent, or 0.9248 percent.

Next, we add the payroll component (0.8988 percent) to the non-pay component (0.9248 percent), for a total inflation adjustment of 1.8236 percent for FY 2017.

ADUFA III provides for the inflation adjustment to be compounded each fiscal year after FY 2014 (see 21 U.S.C. 379j–12(c)(2)). The factor for FY 2017 (1.8236 percent) is compounded by adding 1 and then multiplying by 1 plus the inflation adjustment factor for FY 2016 (2.1121 percent), as published in the **Federal Register** of August 3, 2015 (80 FR 45993 to 45998), which equals

1.060746 (rounded) (1.018236 times 1.041749) for FY 2017. We then multiply the base revenue amount for FY 2017 (\$21,600,000) by 1.060746, yielding an inflation adjusted amount of \$22,912,114.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

A workload adjustment will be calculated to the inflation adjusted fee revenue amount established in ADUFA III for FY 2015 and subsequent fiscal years (21 U.S.C. 379j–12(c)(3)).

FDA calculated the average 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,

2013 (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 June 30, 2016.

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 five 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 table 4 the sum of the values in column 5 is added, reflecting a total change in workload of 3.3206 percent for FY 2017. This is the workload adjuster for FY 2017.

TABLE 4—WORKLOAD ADJUSTER CALCULATION
[Numbers may not add due to rounding]

Application type	Column 1	Column 2	Column 3	Column 4	Column 5
	5-year average (base years)	Latest 5-year average	Percent change	Weighting factor	Weighted percent change
New Animal Drug Applications (NADAs)	9.8000	13.4000	36.7347	0.0250	0.9168
Supplemental NADAs with Safety or Efficacy Data	9.6000	12.4000	29.1667	0.0342	0.9971
Manufacturing Supplements	361.0000	324.6000	–10.0831	0.1565	–1.5783
Investigational Study Submissions	216.4000	204.6000	–5.4529	0.6002	–3.2727
Investigational Protocol Submissions	133.6000	179.0000	33.9820	0.1841	6.2577
FY 2017 Workload Adjuster	3.3206

FDA experienced an increase in the number of new animal drug applications (NADAs) and supplemental NADAs with safety or effectiveness data. Over the last several years FDA has seen an increase in the number of animal drug products brought by animal drug sponsors for review in the drug evaluation process. These new animal drug products come from both existing animal drug sponsors as well as sponsors new to the animal drug market. The increase in new animal drug products have contributed to an increase in the number of protocol submissions and NADAs submitted for many novel drug classes and novel indications for both food-producing animals and companion animals. FDA can expect that the increases in reviewed protocols will lead in the near future to an increase in the number of Investigational Study Submissions and NADAs or supplemental NADAs as sponsors work their products through the regulatory review process. Additionally, FDA has seen an increase in the number of animal drug sponsors pursuing multiple changes to their existing NADAs (e.g., new indications, new species, changes in dosage). For this reason we are seeing an increase in the number of supplemental NADAs with safety or effectiveness data. As a result, the statutory revenue amount after the inflation adjustment (\$22,912,114) must now be increased by 3.3206 percent to reflect the changes in review workload (workload adjustment), for a total fee revenue target of \$23,673,000 (rounded to the nearest thousand dollars).

D. FY 2017 Fee Revenue Amounts

ADUFA III specifies that the revenue amount of \$23,673,000 for FY 2017 is to be divided as follows: 20 percent, or a total of \$4,734,000 (rounded to the nearest thousand dollars), is to come from application fees; 27 percent, or a total of \$6,392,000 (rounded to the nearest thousand dollars), is to come

from product fees; 26 percent, or a total of \$6,155,000 (rounded to the nearest thousand dollars), is to come from establishment fees; and 27 percent, or a total of \$6,392,000 (rounded to the nearest thousand dollars), is to come from sponsor fees (21 U.S.C. 379j–12(b)).

III. Application Fee Calculations for FY 2017

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) (21 U.S.C. 379j–11(1)). A “supplemental animal drug application” is defined as a request to the Secretary to approve a change in an animal drug application which has been approved, or a request to the Secretary to approve a change to an application approved under section 512(c)(2) 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 \$4,734,000 in fee revenue for FY 2017. 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 \$4,734,000 FDA must first make some assumptions about the number of fee-paying applications and supplements the Agency will receive in FY 2017.

The Agency knows the number of applications that have been submitted

in previous years. That number fluctuates from year to year. In estimating the fee revenue to be generated by animal drug application fees in FY 2017, FDA is assuming that the number of applications that will pay fees in FY 2017 will equal the average number of submissions over the five most recent completed years of the ADUFA program (FY 2011 to FY 2015). FDA believes that this is a reasonable approach after 12 completed years of experience with this program.

Over the five most recent completed years, the average number of animal drug applications that would have been subject to the full fee was 7.2. Over this same period, the average number of supplemental applications 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 12.6.

B. Application Fee Rates for FY 2017

FDA must set the fee rates for FY 2017 so that the estimated 7.2 applications that pay the full fee and the estimated 12.6 supplemental applications and applications subject to the criteria set forth in section 512(d)(4) of the FD&C Act that pay half of the full fee will generate a total of \$4,734,000. To generate this amount, the fee for an animal drug application, rounded to the nearest \$100, will have to be \$350,700, 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 \$175,350.

IV. Product Fee Calculations for FY 2017

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

The animal drug product fee (also referred to as the 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 \$6,392,000 in fee revenue for FY 2017.

To set animal drug product fees to realize \$6,392,000, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2017. 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 2016, FDA estimates that there are a total of 804 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 804 products will be subject to this fee in FY 2017.

In estimating the fee revenue to be generated by animal drug product fees in FY 2017, FDA is assuming that 3 percent of the products invoiced, or 24, will not pay fees in FY 2017 due to fee waivers and reductions. FDA has kept this estimate at 3 percent this year, based on historical data over the past 5 completed years of the ADUFA program. Based on experience over the first 12 completed years of the ADUFA program, FDA believes that this is a reasonable basis for estimating the number of fee-paying products in FY 2017.

Accordingly, the Agency estimates that a total of 780 (804 minus 24) products will be subject to product fees in FY 2017.

B. Product Fee Rates for FY 2017

FDA must set the fee rates for FY 2017 so that the estimated 780 products that pay fees will generate a total of \$6,392,000. To generate this amount will require the fee for an animal drug

product, rounded to the nearest \$5, to be \$8,195.

V. Establishment Fee Calculations for FY 2017

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

The animal drug establishment fee (also referred to as the 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 which is 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 \$6,155,000 in fee revenue for FY 2017.

To set animal drug establishment fees to realize \$6,155,000, FDA must make some assumptions about the number of establishments for which these fees will be paid in FY 2017. 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 2016, FDA estimates that there are a total of 62 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 62 establishments will be subject to this fee in FY 2017.

In estimating the fee revenue to be generated by animal drug establishment fees in FY 2017, FDA is assuming that 11 percent of the establishments invoiced, or seven, will not pay fees in FY 2017 due to fee waivers and reductions. FDA has reduced this estimate from 12 percent to 11 percent this year, based on historical data over the past 5 completed years. Based on experience over the past 12 completed

years of the ADUFA program, FDA believes that this is a reasonable basis for estimating the number of fee-paying establishments in FY 2017.

Accordingly, the Agency estimates that a total of 55 establishments (62 minus 7) will be subject to establishment fees in FY 2017.

B. Establishment Fee Rates for FY 2017

FDA must set the fee rates for FY 2017 so that the estimated 55 establishments that pay fees will generate a total of \$6,155,000. To generate this amount will require the fee for an animal drug establishment, rounded to the nearest \$50, to be \$111,900.

VI. Sponsor Fee Calculations for FY 2017

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

The animal drug sponsor fee (also referred to as the 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 \$6,392,000 in fee revenue for FY 2017.

To set animal drug sponsor fees to realize \$6,392,000, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2017. Based on the number of firms that would have met this definition in each of the past 12 completed years of the ADUFA program, FDA estimates that a total of 189 sponsors will meet this definition in FY 2017.

Careful review indicates that 35 percent of these sponsors will qualify for minor use/minor species waiver or reduction (21 U.S.C. 379j–12(d)(1)(D)). Based on the Agency's experience to date with sponsor fees, FDA's current best estimate is that an additional 32 percent will qualify for other waivers or reductions, for a total of 67 percent of the sponsors invoiced, or 127, who will not pay fees in FY 2017 due to fee waivers and reductions. FDA has increased this estimate from 65 percent

to 67 percent this year, based on historical data over the past 5 completed years of the ADUFA program. FDA believes that this is a reasonable basis for estimating the number of fee-paying sponsors in FY 2017.

Accordingly, the Agency estimates that a total of 62 sponsors (189 minus

127) will be subject to and pay sponsor fees in FY 2017.

B. Sponsor Fee Rates for FY 2017

FDA must set the fee rates for FY 2017 so that the estimated 62 sponsors that pay fees will generate a total of \$6,392,000. To generate this amount

will require the fee for an animal drug sponsor, rounded to the nearest \$50, to be \$103,100.

VII. Fee Schedule for FY 2017

The fee rates for FY 2017 are summarized in Table 5.

TABLE 5—FY 2017 FEE RATES

Animal drug user fee category	Fee rate for FY 2017 (\$)
Animal Drug Application Fees:	
Animal Drug Application	350,700
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	175,350
Animal Drug Product Fee	8,195
Animal Drug Establishment Fee ¹	111,900
Animal Drug Sponsor Fee ²	103,100

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. Procedures for Paying the FY 2017 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 III that is submitted on or after October 1, 2016. Payment must be made in U.S. currency by check, bank draft, U.S. postal money order payable to the order of the Food and Drug Administration, wire transfer, or electronically using *Pay.gov*. 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. Once you search for your invoice, click “Pay Now” to be redirected to *Pay.gov*. Note that electronic payment options are based on the balance due. Payment by credit card is available for balances less than \$25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be drawn on U.S. bank accounts as well as U.S. credit cards.

On your check, bank draft, or U.S. postal money order, please write your application’s unique Payment Identification Number (PIN), beginning with the letters AD, from 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) on the enclosed check, bank draft, or money order. Your payment and a copy of the completed Animal Drug User Fee Cover Sheet can be mailed to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000.

If payment is made by wire transfer, send payment to: U.S. Department of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, FDA Deposit Account Number: 75060099, U.S. Department of Treasury routing/transit number: 021030004, SWIFT Number: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., 14th Floor, Silver Spring, MD 20993–0002. You are responsible for any administrative costs associated with the processing of a wire transfer. Contact your bank or financial institution about the fee and add it to your payment to ensure that your fee is fully paid.

If you prefer to send a check by a courier, the courier may 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 the U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery.)

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.)

It is helpful if 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.

B. Application Cover Sheet Procedures

Step One—Create a user account and password. Log on to the ADUFA Web site at <http://www.fda.gov/ForIndustry/UserFees/AnimalDrugUserFeeActADUFA/default.htm> and, under Tools and Resources, click “The Animal Drug User Fee Cover Sheet” and then click “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 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 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 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, 2016, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2017 using this fee schedule. Payment will be due by January 31, 2017. FDA will issue invoices in November 2017 for any products, establishments, and sponsors subject to fees for FY 2017 that qualify for fees after the December 2016 billing.

Dated: July 22, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-17848 Filed 7-27-16; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0007]

Animal Generic Drug User Fee Rates and Payment Procedures for Fiscal Year 2017

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) 2017 generic new animal drug user fees. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Animal Generic Drug User Fee Amendments of 2013 (AGDUFA II), 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 2017.

FOR FURTHER INFORMATION CONTACT: Visit FDA's Web site at <http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm>, or contact

Lisa Kable, Center for Veterinary Medicine (HFV-10), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6888. 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 2014 through FY 2018, the FD&C Act establishes aggregate yearly base revenue amounts for each of these fee categories (21 U.S.C. 379j-21(b)). Base revenue amounts established for fiscal years after FY 2014 are subject to adjustment for workload (21 U.S.C. 379j-21(c)). The target revenue amounts for each fee category for FY 2017, after the adjustment for workload, are as follows: For application fees the target revenue amount is \$2,835,000; for product fees the target revenue amount is \$4,253,000; and for sponsor fees the target revenue amount is \$4,253,000.

For FY 2017, the generic new animal drug user fee rates are: \$232,400 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)); \$116,200 for each abbreviated application for a generic new animal drug subject to the criteria in section 512(d)(4); \$10,200 for each generic new animal drug product; \$96,350 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; \$72,263 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and \$48,175 for each generic new animal drug sponsor paying 50 percent of the sponsor fee. FDA will issue invoices for FY 2017 product and sponsor fees by December 31, 2016. These fees will be due by January 31, 2017. The application fee rates are effective for all abbreviated applications for a generic new animal drug submitted on or after

October 1, 2016, and will remain in effect through September 30, 2017. 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 2017

A. Statutory Fee Revenue Amounts

AGDUFA II, Title II of Public Law 113-14, specifies that the aggregate revenue amount for FY 2017 for abbreviated application fees is \$1,984,000 and each of the other two generic new animal drug user fee categories, annual product fees and annual sponsor fees, is \$2,976,000 each (see 21 U.S.C. 379j-21(b)).

B. Inflation Adjustment to Fee Revenue Amount

The amounts established in AGDUFA II for each year for FY 2014 through FY 2018 include an inflation adjustment; therefore, no further inflation adjustment is required.

C. Workload Adjustment Fee Revenue Amount

For each FY beginning after FY 2014, AGDUFA II provides that statutory fee revenue amounts shall be further adjusted to reflect changes in review workload. (See 21 U.S.C. 379j-21(c)(2).)

FDA calculated the average 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, 2013 (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 on June 30, 2016.

The results of these calculations are presented in the first two columns in table 1. 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