on file in the public docket (docket number found in brackets in the heading of this document) and will post it at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*. The deadline for submitting comments to this document for presentation at the public workshop is September 18, 2015, although comments related to this document can be made until September 28, 2015.

The Agencies will use the input from this workshop and public comments to determine appropriate next steps to advance sematic interoperability of laboratory data.

Dated: July 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0007]

Animal Generic Drug User Fee Rates and Payment Procedures for Fiscal Year 2016

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) 2016 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 2016.

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. Base revenue amounts established for fiscal years after FY 2014 may be adjusted for workload. The target revenue amounts for each fee category for FY 2016, after the adjustment for workload, are as follows: For application fees the target revenue amount is $2,426,000; for product fees the target revenue amount is $3,639,000; and for sponsor fees the target revenue amount is $3,639,000.

For FY 2016, the generic new animal drug user fee rates are: $233,300 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)); $116,650 for each abbreviated application for a generic new animal drug subject to the criteria in section 512(d)(4); $8,705 for each generic new animal drug product; $83,800 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; $62,850 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and $41,900 for each generic new animal drug sponsor paying 50 percent of the sponsor fee. FDA will issue invoices for FY 2016 product and sponsor fees by December 31, 2015. These fees will be due by January 31, 2016. The application fee rates are effective for all abbreviated applications for a generic new animal drug submitted on or after October 1, 2015, and will remain in effect through September 30, 2016. 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.

II. Revenue Amount for FY 2016

A. Statutory Fee Revenue Amounts

AGDUFA II, Title II of Public Law 113–14, specifies that the aggregate revenue amount for FY 2016 for abbreviated application fees is $1,857,000 and each of the other two generic new animal drug user fee categories, annual product fees and annual sponsor fees, is $2,786,000 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 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, 2015.

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 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 1, the sum of the values in column 5 is calculated, reflecting a total change in workload of 30.6305 percent for FY 2016. This is the workload adjuster for FY 2016.

TABLE 1—WORKLOAD ADJUSTER CALCULATION

Application type	Column 1 5-year average (base years)	Column 2 latest 5-year average	Column 3 percent change	Column 4 weighting factor	Column 5 weighted percent change
Abbreviated New Animal Drug Applications (ANADAs)	25.0	29.2	17	0.3741	6.2855
Manufacturing Supplements ANADAs	128.0	143.2	12	0.2780	3.3015
Generic Investigational Study Submissions	23.0	39.2	70	0.2217	15.6183
Generic Investigational Protocol Submissions	17.2	24.6	43	0.1261	5.4252
FY 2016 AGDUFA Workload Adjuster					30.6305

Over the last year FDA has continued to see more sponsors getting involved in the generic animal drug approval process including pioneer sponsors. This has contributed to small sustained increases in the number of ANADAs, manufacturing supplements, and protocols submitted. Additionally, more sponsors continue to pursue drug approvals that do not qualify for a waiver of the requirement to conduct an in vivo bioequivalence study. For this reason we are seeing a large sustained increase in the number of generic investigational new animal drug study submissions.

As a result, the statutory revenue amount for each category of fees for FY 2016 ($1,857,000 for application fees and $2,786,000 for both product and sponsor fees) must now be increased by 30.6305 percent, for a total fee revenue target in FY 2016 of $9,705,000 (rounded to the nearest thousand dollars) for fees from all three categories. The target for application fee revenue is $1,857,000 times 30.6305 percent, for a total of $2,426,000, rounded to the nearest thousand. The target for product fee revenue is $2,786,000 times 30.6305 percent, for a total of $3,639,000, rounded to the nearest thousand dollars, and the target for sponsor fee revenue is the same as for product fees ($3,639,000, rounded to the nearest thousand dollars).

III. Abbreviated Application Fee Calculations for FY 2016

The term ''abbreviated application for a generic new animal drug'' is defined in 21 U.S.C. 379j–21(k)(1).

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

The application fee must be paid for abbreviated applications for a generic new animal drug that is subject to fees under AGDUFA and that is submitted on or after July 1, 2008. The application fees are to be set so that they will generate $2,426,000 in fee revenue for FY 2016. This is the amount set out in the statute (21 U.S.C. 379j–21(b)(1)) after applying the workload adjuster.

To set fees for abbreviated applications for generic new animal drugs to realize $2,426,000, FDA must first make some assumptions about the number of fee-paying abbreviated applications it will receive during FY 2016.

The Agency knows the number of applications that have been submitted in previous years. That number fluctuates from year to year. FDA is making estimates and applying different assumptions for two types of full fee submissions: Original submissions of abbreviated applications for generic new animal drugs and ''reactivated'' submissions of abbreviated applications for generic new animal drugs. Any original submissions of abbreviated applications for generic new animal drugs that were received by FDA before July 1, 2008, were not assessed fees (21 U.S.C. 379j–21(a)(1)(A)). Some of these non-fee-paying submissions were later resubmitted on or after July 1 because the initial submission was not approved by FDA (*i.e.,* FDA marked the submission as incomplete and requested additional non-administrative information) or because the original submission was withdrawn by the sponsor. Abbreviated applications for generic new animal drugs resubmitted on or after July 1, 2008, are subject to user fees. In this notice, FDA refers to these resubmitted applications as ''reactivated'' applications.

Also, under AGDUFA II, 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.

Regarding original submissions of abbreviated applications for generic new animal drugs, FDA is assuming that the number of applications that will pay fees in FY 2016 will equal the average number of submissions over the 5 most recent completed years of AGDUFA (FY 2010–FY 2014). FDA believes that this is a reasonable approach after 6 complete years of experience with this program.

The average number of original submissions of abbreviated applications for generic new animal drugs over the 5 most recently completed years is 8.6 applications not subject to the criteria in section 512(d)(4) of the FD&C Act and 3.6 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 which are subject to such criteria results in a total of 10.4 anticipated full fees.

Under AGDUFA I, FDA estimated the number of reactivations of abbreviated applications for generic new animal drugs which had been originally submitted prior to July 1, 2008. That number has decreased over the years to the point that FDA no longer expects to receive any reactivations of applications initially submitted prior to July 1, 2008, and will include no provision for them in its fee estimates. Should such a submission be made, the submitter will be expected to pay the appropriate fee.

Based on the previous assumptions, FDA is estimating that it will receive a total of 10.4 fee-paying generic new animal drug applications in FY 2016 (8.6 original applications paying a full fee and 3.6 applications paying a half fee).

B. Application Fee Rates for FY 2016

FDA must set the fee rates for FY 2016 so that the estimated 10.4 abbreviated applications that pay the fee will generate a total of $2,426,000. To generate this amount, the fee for a generic new animal drug application, rounded to the nearest hundred dollars, will have to be $233,300, 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 $116,650.

IV. Generic New Animal Drug Product Fee Calculations for FY 2016

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

The generic new animal drug product fee (also referred to as the 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 $3,639,000 in fee revenue for FY 2016, after workload adjustment ($2,786,000 times 1.306305, rounded to the nearest thousand dollars).

To set generic new animal drug product fees to realize $3,639,000, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2016. 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 FDA estimated would have an abbreviated new animal drug application or supplemental abbreviated application pending after September 1, 2008. As of June 2015, FDA estimates a total of 418 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 418 products will be subject to this fee in FY 2016.

In estimating the fee revenue to be generated by generic new animal drug product fees in FY 2016, FDA is assuming that no products invoiced will qualify for minor use/minor species fee waiver (see 21 U.S.C. 379j–21(d)). FDA has changed the estimate of the percentage of products that will not pay fees to zero percent this year, based on historical data over the past 5 completed years of the AGDUFA program.

Accordingly, the Agency estimates that a total of 418 products will be subject to product fees in FY 2016.

B. Product Fee Rates for FY 2016

FDA must set the fee rates for FY 2016 so that the estimated 418 products that pay fees will generate a total of $3,639,000. To generate this amount will require the fee for a generic new animal drug product, rounded to the nearest $5, to be $8,705.

V. Generic New Animal Drug Sponsor Fee Calculations for FY 2016

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

The generic new 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 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)). 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 $3,639,000 in fee revenue for FY 2016, after workload adjustment ($2,786,000 times 1.306305, rounded to the nearest thousand dollars).

To set generic new animal drug sponsor fees to realize $3,639,000, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2016. FDA now has 6 complete years of experience collecting these sponsor fees. 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 recent completed years of AGDUFA (FY 2010 through FY 2014), FDA estimates that in FY 2016, 12 sponsors will pay 100 percent fees, 17 sponsors will pay 75 percent fees, and 41 sponsors will pay 50 percent fees. That totals the equivalent of 45.25 full sponsor fees (12 times 100 percent or 12, plus 17 times 75 percent or 12.75, plus 41 times 50 percent or 20.5).

FDA estimates that about 4 percent of all of these sponsors, or 1.81, may qualify for a minor use/minor species fee waiver (see 21 U.S.C. 379j–21(d)). FDA has changed the estimate of the percentage of sponsors that will not pay fees to 4 percent this year, based on historical data over the past 5 completed years of the AGDUFA program.

Accordingly, the Agency estimates that the equivalent of 43.44 full sponsor fees (45.25 minus 1.81) are likely to be paid in FY 2016.

B. Sponsor Fee Rates for FY 2016

FDA must set the fee rates for FY 2016 so that the estimated equivalent of 43.44 full sponsor fees will generate a total of $3,639,000. To generate this amount will require the 100 percent fee for a generic new animal drug sponsor, rounded to the nearest $50, to be $83,800. Accordingly, the fee for those paying 75 percent of the full sponsor fee will be $62,850, and the fee for those paying 50 percent of the full sponsor fee will be $41,900.

VI. Fee Schedule for FY 2016

The fee rates for FY 2016 are summarized in table 2 of this document.

TABLE 2—FY 2016 FEE RATES

Generic new animal drug user fee category	Fee rate for FY 2016
Abbreviated Application Fee for Generic New Animal Drug except those subject to the criteria in section 512(d)(4)	$233,300

TABLE 2—FY 2016 FEE RATES—Continued

Generic new animal drug user fee category	Fee rate for FY 2016
Abbreviated Application Fee for Generic New Animal Drug subject to the criteria in section 512(d)(4)	116,650
Generic New Animal Drug Product Fee	8,705
100 Percent Generic New Animal Drug Sponsor Fee [1]	83,800
75 Percent Generic New Animal Drug Sponsor Fee [1]	62,850
50 Percent Generic New Animal Drug Sponsor Fee [1]	41,900

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

VII. Procedures for Paying FY 2016 Generic New Animal Drug User Fees

A. Abbreviated Application Fees and Payment Instructions

The FY 2016 fee established in the new fee schedule must be paid for an abbreviated new animal drug application subject to fees under AGDUFA that is submitted on or after October 1, 2015. Payment must be made in U.S. currency from a U.S. bank by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration, by wire transfer, or by automatic clearing house using Pay.gov. (The Pay.gov payment option is available to you after you submit a cover sheet. Click the ''Pay Now'' button). On your check, bank draft, U.S. or postal money order, please write your application's unique Payment Identification Number, beginning with the letters ''AG'', from 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 953877) on the enclosed check, bank draft, or money order. Your payment and a copy of the completed Animal Generic 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 via wire transfer, send payment to 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, Beneficiary: FDA, 8455 Colesville Rd., 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 phone 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 abbreviated application arrives at FDA's Center for Veterinary Medicine (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.

B. Application Cover Sheet Procedures

Step One—Create a user account and password. Log onto the AGDUFA Web site at *http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm137049.htm* and scroll down the page until you find the link ''Create AGDUFA User Fee Cover Sheet.'' Click on 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 animal drug application. 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 VII.A of this document.

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, 2015, FDA will issue invoices and payment instructions for product and sponsor fees for FY 2016 using this fee schedule. Fees will be due by January 31, 2016. FDA will issue invoices in November 2016 for any products and sponsors subject to fees for FY 2016 that qualify for fees after the December 2015 billing.

Dated: July 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0007]

Generic Drug User Fee—Abbreviated New Drug Application, Prior Approval Supplement, Drug Master File, Final Dosage Form Facility, and Active Pharmaceutical Ingredient Facility Fee Rates for Fiscal Year 2016

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for abbreviated new drug applications (ANDAs), prior approval supplements to an approved ANDA (PASs), drug master files (DMFs),