TABLE 1—FY 2014 FEE RATES—Continued

Animal drug user fee category	Fee rate for FY 2014
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	198,300
Animal Drug Product Fee	9,075
Animal Drug Establishment Fee [1]	105,800
Animal Drug Sponsor Fee [2]	101,150

[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 2014 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 that is submitted after September 30, 2013. Payment must be made in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration, by wire transfer, or electronically 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, 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 953877) 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 953877, St. Louis, MO 63195–3877.

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. 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 such as Federal Express or United Parcel Service, the courier may deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 953877, 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 of this document.

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, 2013, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2014 using this fee schedule. Payment will be due by January 31, 2014. FDA will issue invoices in November 2014 for any products, establishments, and sponsors subject to fees for FY 2014 that qualify for fees after the December 2013 billing.

Dated: July 29, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–18619 Filed 8–1–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0007]

Animal Generic Drug User Fee Rates and Payment Procedures for Fiscal Year 2014

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) 2014 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, which was signed by the President on June 13, 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 2014.

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, 7529 Standish Pl., Rockville, MD 20855, 240–276–9718. 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. Fees for applications, products, and sponsors are to be established each year by FDA so that the revenue for each fee category will approximate the level established in the statute, after the level has been adjusted for workload.

For FY 2014 the generic new animal drug user fee rates are: $177,900 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)); $88,950 for each abbreviated application for a generic new animal drug subject to the criteria in section 512(d)(4); $8,035 for each generic new animal drug product; $72,800 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; $54,600 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and $36,400 for each generic new animal drug sponsor paying 50 percent of the sponsor fee. FDA will issue invoices for FY 2014 product and sponsor fees by December 31, 2013. These fees will be due by January 31, 2014. The application fee rates are effective for all abbreviated applications for a generic new animal drug submitted on or after October 1, 2013, and will remain in effect through September 30, 2014. 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 2014

A. Statutory Fee Revenue Amounts

AGDUFA II, Title II of Public Law 113–14, specifies that the aggregate revenue amount for FY 2014 for abbreviated application fees is $1,832,000 and each of the other two generic new animal drug user fee categories, annual product fees and annual sponsor fees, is $2,748,000 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. However the statutory fee revenue amount for FY 2014 is not to be further adjusted for workload. (See 21 U.S.C. 379j–21(c)(2).)

III. Abbreviated Application Fee Calculations for FY 2014

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 $1,832,000 in fee revenue for FY 2014. This is the amount set out in the statute (21 U.S.C. 379j–21(b)(1)).

To set fees for abbreviated applications for generic new animal drugs to realize $1,832,000, FDA must first make some assumptions about the number of fee-paying abbreviated applications it will receive during FY 2014.

The Agency knows the number of applications that have been submitted in previous years. That number fluctuates significantly from year to year. FDA is making estimates and applying different assumptions for two types of 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 2014 will equal the average number of submissions over the 4 most recent completed years (2009–2012). This may not fully account for possible year to year fluctuations in numbers of fee-paying applications, but FDA believes that this is a reasonable approach after 5 years of experience with this program.

The average number of original submissions of abbreviated applications for generic new animal drugs over the 4 most recently completed years is 9.3 applications not subject to the criteria in section 512(d)(4) of the FD&C Act and 2 submissions subject to the criteria in section 512(d)(4). Each of the submissions described under section 512(d)(4) of the FD&C Act pays 50 percent of the fee paid by the other applications, and will be counted as one half of a fee. Adding all of the applications not subject to the criteria in section 512(d)(4) of the FD&C Act and 50 percent of the number which are subject to such criteria results in a total of 10.3 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 decreased over the years of AGDUFA I, 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, of course, it will still be expected to pay the appropriate fee.

Based on the previous assumptions, FDA is estimating that it will receive a total of 10.3 fee-paying generic new animal drug applications in FY 2014 (9.3 original applications paying a full fee and 2 applications subject to the criteria described in section 512(d)(4) of the FD&C Act that combined will pay 1 full fee).

B. Fee Rates for FY 2014

FDA must set the fee rates for FY 2014 so that the estimated 10.3 abbreviated applications that pay the fee will generate a total of $1,832,000. To generate this amount, the fee for a generic new animal drug application, rounded to the nearest hundred dollars, will have to be $177,900, 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 $88,950.

IV. Generic New Animal Drug Product Fee Calculations for FY 2014

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 new animal drug application or supplemental abbreviated application for generic new animal drugs 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 abbreviated application for a generic new animal drug or supplemental abbreviated application for a generic new animal drug 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 $2,748,000 in fee revenue for FY 2014. This is the amount set out in the statute and no further adjustments are required for FY 2014.

To set generic new animal drug product fees to realize $2,748,000, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2014. 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. FDA estimates a total of 360 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 360 products will be subject to this fee in FY 2014.

In estimating the fee revenue to be generated by generic new animal drug product fees in FY 2014, FDA is assuming that 5 percent of the products invoiced, or 18, will not pay fees in FY 2014 due to fee waivers and reductions. FDA has reduced the estimate of the percentage of products that will not pay fees from 10 percent to 5 percent this year, based on historical data over the past 5 years.

Accordingly, the Agency estimates that a total of 342 (360 minus 18) products will be subject to product fees in FY 2014.

B. Product Fee Rates for FY 2014

FDA must set the fee rates for FY 2014 so that the estimated 342 products that pay fees will generate a total of $2,748,000. To generate this amount will require the fee for a generic new animal drug product, rounded to the nearest 5 dollars, to be $8,035.

V. Generic New Animal Drug Sponsor Fee Calculations for FY 2014

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 two to six 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 $2,748,000 in fee revenue for FY 2014. This is the amount set out in the statute and no adjustments are required for FY 2014.

To set generic new animal drug sponsor fees to realize $2,748,000, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2014. FDA now has 4 complete years of experience with 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 44 completed years of AGDUFA (FY 2009 through FY 2012), FDA estimates that in FY 2014, 12 sponsors will pay 100 percent fees, 13 sponsors will pay 75 percent fees, and 36 sponsors will pay 50 percent fees. That totals the equivalent of 39.75 full sponsor fees (12 times 100 percent or 12, plus 13 times 75 percent or 9.75, plus 36 times 50 percent or 18.0).

FDA estimates that about 5 percent of all of these sponsors, or 1.99, may qualify for a minor use/minor species fee waiver (see 21 U.S.C. 379j–21(d)). FDA has reduced the estimate of the percentage of sponsors that will not pay fees from 10 percent to 5 percent this year, based on historical data over the past 5 years.

Accordingly, the Agency estimates that the equivalent of 37.76 full sponsor fees (39.75 minus 1.99) are likely to be paid in FY 2014.

B. Sponsor Fee Rates for FY 2014

FDA must set the fee rates for FY 2014 so that the estimated equivalent of 37.76 full sponsor fees will generate a total of $2,748,000. To generate this amount will require the 100 percent fee for a generic new animal drug sponsor, rounded to the nearest $50, to be $72,800. Accordingly, the fee for those paying 75 percent of the full sponsor fee will be $54,600, and the fee for those

paying 50 percent of the full sponsor fee will be $36,400.

VI. Fee Schedule for FY 2014

The fee rates for FY 2014 are summarized in table 1 of this document.

TABLE 1—FY 2014 FEE RATES

Generic new animal drug user fee category	Fee rate for FY 2014
Abbreviated Application Fee for Generic New Animal Drug except those subject to the criteria in section 512(d)(4)	$177,900
Abbreviated Application Fee for Generic New Animal Drug subject to the criteria in section 512(d)(4)	88,950
Generic New Animal Drug Product Fee	8,035
100 Percent Generic New Animal Drug Sponsor Fee[1]	72,800
75 Percent Generic New Animal Drug Sponsor Fee[1]	54,600
50 Percent Generic New Animal Drug Sponsor Fee[1]	$36,400

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

VII. Procedures for Paying FY 2014 Generic New Animal Drug User Fees

A. Abbreviated Application Fees and Payment Instructions

The FY 2014 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, 2013. 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 953877, St. Louis, MO 63195–3877.

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. 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 such as Federal Express or United Parcel Service, the courier may deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 953877, 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. FDA records the official abbreviated application receipt date as the later of the following: The date the application was received by FDA's Center for Veterinary Medicine, 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, 2013, FDA will issue invoices and payment instructions for product and sponsor fees for FY 2014 using this fee schedule. Fees will be due by January 31, 2014. FDA will issue invoices in November 2014 for any products and sponsors subject to fees for FY 2014 that qualify for fees after the December 2013 billing.

Dated: July 29, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–18620 Filed 8–1–13; 8:45 am]

BILLING CODE 4160–01–P