



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0007]

Animal 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 rates and payment procedures for fiscal year (FY) 2014 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, which was signed by the President on June 13, 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 2014.

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, 7529 Standish Pl., Rockville, MD 20855, 240-276-9718. 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 is derived from each type of user fee will be as follows: Revenue from application fees will be 20 percent of total fee revenue; revenue from product fees will 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 2014, the animal drug user fee rates are: \$396,600 for an animal drug application; \$198,300 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)); \$9,075 for an annual product fee; \$105,800 for an annual establishment fee; and \$101,150 for an annual sponsor fee. FDA will issue invoices for FY 2014 product, establishment, and sponsor fees by December 31, 2013, and

payment will be due by January 31, 2014. The application fee rates are effective for applications 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 application fees and any other animal drug user fees owed under ADUFA.

II. Revenue Amount for FY 2014

A. Statutory Fee Revenue Amounts

ADUFA III (Title I of Public Law 113-14) specifies that the aggregate revenue amount for FY 2014 for all animal drug user fee categories is \$23,600,000. (21 U.S.C. 379j-12(b)(1)(A).)

B. Inflation Adjustment to Fee Revenue Amount

The amount established in ADUFA III for FY 2014 includes an inflation adjustment; therefore, no further inflation adjustment is required for FY 2014. For FY 2015 and subsequent years an inflation adjustment will be made (21 U.S.C. 379j-12(c)(2)).

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

The amount established in ADUFA III for FY 2014 is not to be further adjusted for workload. For FY 2015 and subsequent years a workload adjustment will be calculated (21 U.S.C. 379j-12(c)(3)).

D. FY 2014 Fee Revenue Amounts

ADUFA III specifies a total revenue amount of \$23,600,000 for FY 2014. Of this amount: 20 percent, or a total of \$4,720,000, is to come from application fees; 27 percent, or a total of \$6,372,000, is to come from product fees; 26 percent, or a total of \$6,136,000, is to come from establishment fees; and 27 percent, or a total of \$6,372,000, is to come from sponsor fees (21 U.S.C. 379j-12(b)).

III. Application Fee Calculations for FY 2014

The terms "animal drug application" and "supplemental animal drug application" are defined in section 739 of the FD&C Act (21 U.S.C. 379j-11(1) and (2)).

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

The application fee must be paid for any animal drug application or supplemental animal drug application that is subject to fees under ADUFA and that is submitted on or after September 1, 2003. The application fees are to be set so that they will generate \$4,720,000 in fee revenue for FY 2014. This is the amount derived in section II.D of this document. 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 \$4,720,000 FDA must first make some assumptions about the number of fee-paying applications and supplements the Agency will receive in FY 2014.

The Agency knows the number of applications that have been submitted in previous years. That number fluctuates significantly from year to year. In estimating the fee revenue to be generated by animal drug application fees in FY 2014, FDA is assuming that the number of applications that will pay fees in FY 2014 will equal the average number of submissions over the 5 most recent completed years (FY 2008-FY 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 10 years of experience with this program.

Over the 5 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 9.4.

B. Fee Rates for FY 2014

FDA must set the fee rates for FY 2014 so that the estimated 7.2 applications that pay the full fee and the estimated 9.4 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 \$4,720,000. To generate this amount, the fee for an animal drug application, rounded to the nearest \$100, will have to be \$396,600, 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 \$198,300.

IV. Product Fee Calculations for FY 2014

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. (See 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

\$6,372,000 in fee revenue for FY 2014. This is the amount derived in section II.D of this document.

To set animal drug product fees to realize \$6,372,000, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2014. 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 2013, FDA estimates that there are a total of 747 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 747 products will be subject to this fee in FY 2014.

In estimating the fee revenue to be generated by animal drug product fees in FY 2014, FDA is assuming that 6 percent of the products invoiced, or 45, 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 6 percent this year, based on historical data over the past 5 years. Based on experience with other user fee programs and the first 10 years of ADUFA, FDA believes that this is a reasonable basis for estimating the number of fee-paying products in FY 2014.

Accordingly, the Agency estimates that a total of 702 (747 minus 45) 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 702 products that pay fees will generate a total of \$6,372,000. To generate this amount will require the fee for an animal drug product, rounded to the nearest \$5, to be \$9,075.

V. Establishment Fee Calculations for FY 2014

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. (See 21 U.S.C. 379j-12(a)(3).) The term "animal drug establishment" is defined in 21 U.S.C. 379j-11(4). The establishment fees are to be set so that they will generate \$6,136,000 in fee revenue for FY 2014. This is the amount derived in section II.D of this document.

To set animal drug establishment fees to realize \$6,136,000, FDA must make some assumptions about the number of establishments for which these fees will be paid in FY 2014. 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 2013, FDA estimates that there are a total of 66 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 66 establishments will be subject to this fee in FY 2014.

In estimating the fee revenue to be generated by animal drug establishment fees in FY 2014, FDA is assuming that 12 percent of the establishments invoiced, or 8, will not pay fees in

FY 2014 due to fee waivers and reductions. FDA has increased the estimate of the percentage of establishments that will not pay fees from 10 percent to 12 percent this year, based on historical data over the past 5 years. Based on experience with the first 10 years of ADUFA, FDA believes that this is a reasonable basis for estimating the number of fee-paying establishments in FY 2014.

Accordingly, the Agency estimates that a total of 58 establishments (66 minus 8) will be subject to establishment fees in FY 2014.

B. Establishment Fee Rates for FY 2014

FDA must set the fee rates for FY 2014 so that the estimated 58 establishments that pay fees will generate a total of \$6,136,000. To generate this amount will require the fee for an animal drug establishment, rounded to the nearest \$50, to be \$105,800.

VI. Sponsor Fee Calculations for FY 2014

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 \$6,372,000 in fee revenue for FY 2014. This is the amount derived in section II.D of this document.

To set animal drug sponsor fees to realize \$6,372,000, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2014. Based on the number of firms that would have met this definition in each of the past 10 years, FDA estimates that a total of 181 sponsors will meet this definition in FY 2014.

Careful review indicates that about one third or 33 percent of all 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 65 percent of the sponsors invoiced, or 118, who will not pay fees in FY 2014 due to fee waivers and reductions. FDA has increased the estimate of the percentage of sponsors that will not pay fees from 60 percent to 65 percent this year, based on historical data over the past 5 years. FDA believes that this is a reasonable basis for estimating the number of fee-paying sponsors in FY 2014.

Accordingly, the Agency estimates that a total of 63 sponsors (181 minus 118) will be subject to and pay sponsor fees in FY 2014.

B. Sponsor Fee Rates for FY 2014

FDA must set the fee rates for FY 2014 so that the estimated 63 sponsors that pay fees will generate a total of \$6,372,000. To generate this amount will require the fee for an animal drug sponsor, rounded to the nearest \$50, to be \$101,150.

VII. 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

| Animal Drug User Fee Category | Fee Rate for FY 2014 |
|--|----------------------|
| Animal Drug Application Fees: | |
| Animal Drug Application | \$396,600 |
| 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 User Fee Category | Fee Rate for FY 2014 |
|--|----------------------|
| Animal Drug Product Fee | \$9,075 |
| Animal Drug Establishment Fee ¹ | \$105,800 |
| Animal Drug Sponsor Fee ² | \$101,150 |

¹An animal drug establishment is subject to only one such fee each fiscal year.

²An 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.

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