In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: April 1, 2009.

Janean Chambers,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0148]

Generic New Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2009

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) 2009 generic new animal drug user fees. The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Animal Generic Drug User Fee Act of 2008 (AGDUFA), authorizes FDA to collect user fees for certain abbreviated applications for a generic new animal drug, on certain generic new animal drug products, and on 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 2009.

For FY 2009, the generic new animal drug user fee rates are: $41,400 for each abbreviated application for a generic new animal drug; $3,005 for each generic new animal drug product; $56,350 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; $42,265 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and $28,175 for a generic new animal drug sponsor paying 50 percent of the sponsor fee. AGDUFA required FDA to issue invoices for FY 2009 product and sponsor fees by December 31, 2008, or within 30 days of enactment of an appropriation for these fees, whichever is later. The appropriations were enacted on March 11, 2009. These fees will be due and payable within 30 days of the issuance of the invoices. The application fee rates are effective for all abbreviated applications for generic new animal drugs submitted on or after July 1, 2008, and will remain in effect through September 30, 2009.

FOR FURTHER INFORMATION CONTACT: Visit the FDA Web site at *http://www.fda.gov/oc/adufa/agdufamain.html* or contact Bryan Walsh, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7529 Standish Pl., Rockville, MD 20855, 240–276–9730. For general questions, you may also e-mail the Center for Veterinary Medicine (CVM) at: *cvmagdufa@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 741 of the act (21 U.S.C. 379j–21) establishes three different kinds 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 2009 through FY 2013, the act establishes aggregate yearly base revenue amounts for each of these fee categories. Base revenue amounts established for years after FY 2009 are subject to adjustment 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.

II. Revenue Amount for FY 2009

A. Statutory Fee Revenue Amounts

AGDUFA (Title II of Public Law 110–316, signed by the President on August 14, 2008) specifies that the aggregate revenue amount for FY 2009 for abbreviated application fees is $1,449,000 and the other two generic new animal drug user fee categories, annual product fees and annual sponsor fees, are $1,691,000 each, before any adjustment for workload is made (see 21 U.S.C. 379j–21(b)).

B. Inflation Adjustment to Fee Revenue Amount

The amounts established in AGDUFA for each year for FY 2009 through FY 2013 include an inflation adjustment, so no further inflation adjustment is required.

C. Workload Adjustment Fee Revenue Amount

For each FY beginning after FY 2009, AGDUFA provides that statutory fee revenue amounts shall be further adjusted to reflect changes in review workload (21 U.S.C. 379j–21(c)(1)). No workload adjustment is to be made in fee revenue amounts for FY 2009.

III. Abbreviated Application Fee Calculations for FY 2009

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 generic new animal drugs that are subject to fees under AGDUFA and that are submitted on or after July 1, 2008. The application fees are to be set so that they will generate $1,449,000 in fee revenue for FY 2009. This is the amount set out in the statute and no adjustments to it are required for FY 2009.

To set fees for abbreviated applications for generic new animal drugs to realize $1,449,000, FDA must first make some assumptions about the number of fee-paying abbreviated applications it will receive over the 15 months from July 1, 2008, through September 30, 2009.

The agency knows the number of such applications that have been submitted in previous years. That number

fluctuates significantly from year to year. FDA is assuming that the number of abbreviated applications that will pay fees in FY 2009 will equal the average number of submissions over the 4 most recent years. 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 about 5 years of experience with other user fee programs. Further, because the imposition of a fee may reduce somewhat the number of abbreviated applications submitted, FDA will use a 12-month average estimate in estimating the number of abbreviated applications that will be subject to and pay fees in the 15-month period from July 1, 2008, through September 30, 2009.

Over the past 4 years, the average number of abbreviated applications for generic new animal drugs that would have been subject to the fee was 38.75, including the number for the most recent year, which is estimated at 40. FDA will also assume that 10 percent of these applications, or 3.875, may be subject to fee waivers or reduction based on indications solely for minor use or minor species.

Thus, for FY 2009, FDA estimates receipt of 34.55 (38.75 minus 3.875) fee-paying abbreviated applications.

B. Fee Rates for FY 2009

FDA must set the fee rates for FY 2009 so that the estimated 35 abbreviated applications that pay the fee will generate a total of $1,449,000. To generate this amount, the fee for an animal drug application, rounded to the nearest hundred dollars, will have to be $41,400.

IV. Generic Product Fee Calculations for FY 2009

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 for a generic new animal drug or a supplemental abbreviated application for a generic new animal drug product submitted for listing under section 510 of the act (21 U.S.C. 360), and who had an abbreviated application or a 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 $1,691,000 in fee revenue for FY 2009. This is the amount set out in the statute and no further adjustments are required for FY 2009.

To set generic new animal drug product fees to realize $1,691,000, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2009. FDA developed data on all generic new animal drug products that have been submitted for listing under section 510 of the act, and matched this to the list of all persons who FDA estimated would have an abbreviated application for a generic new animal drug or supplemental abbreviated application pending after September 1, 2008. FDA estimates there is a total of 626 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 626 products will be subject to this fee in FY 2009.

In estimating the fee revenue to be generated by generic new animal drug product fees in FY 2009, FDA is assuming that 10 percent of the products invoiced, or 63, will not pay fees in FY 2009 due to fee waivers and reductions. Based on experience with other user fee programs and the first 5 years of the Animal Drug User Fee Act program (ADUFA), FDA believes that this is a reasonable basis for estimating the number of fee-paying products in FY 2009.

Accordingly, the agency estimates that a total of 563 (626 minus 63) products will be subject to product fees in FY 2009.

B. Product Fee Rates for FY 2009

FDA must set the fee rates for FY 2009 so that the estimated 563 products that pay fees will generate a total of $1,691,000. To generate this amount will require the fee for a generic new animal drug product, rounded to the nearest $5, to be $3,005.

V. Generic New Animal Drug Sponsor Fee Calculations for FY 2009

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, that has not been withdrawn by the applicant and for which approval has not been withdrawn by the secretary, 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)(B)). Applicants with more than 6 approved abbreviated applications will pay 100 percent of the sponsor fee, applicants with 2 to 6 approved abbreviated applications will pay 75 percent of the sponsor fee, and applicants with 1 or fewer approved abbreviated applications will pay 50 percent of the sponsor fee (see 21 U.S.C. 379j–21(a)(3)(B)). The sponsor fees are to be set so that they will generate $1,691,000 in fee revenue for FY 2009. This is the amount set out in the statute and no adjustments are required for FY 2009.

To set generic new animal drug sponsor fees to realize $1,691,000, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2009. Based on the number of firms that would have met this definition in each of the past 5 years, FDA estimates that in FY 2009 11 sponsors will pay 100 percent (full) fees, 11 sponsors will pay 75 percent fees, and 28 sponsors will pay 50 percent fees. That totals the equivalent of 33.25 full sponsor fees (11 times 100 percent or 11, plus 11 times 75 percent or 8.25, plus 28 times 50 percent or 14).

FDA estimates that about 10 percent of all of these sponsors, or 3.25, may qualify for a minor use/minor species waiver or reduction.

Accordingly, the agency estimates that the equivalent of 30 full sponsor fees (33.25 minus 3.25) are likely to be paid in FY 2009.

B. Sponsor Fee Rates for FY 2009

FDA must set the fee rates for FY 2009 so that the estimated equivalent of 30

full sponsor fees will generate a total of $1,691,000. To generate this amount will require the 100 percent fee for a generic new animal drug sponsor, rounded to the nearest $50, to be $56,350. Accordingly, the fee for those paying 75 percent of the full sponsor fee, rounded to the nearest $5, will be $42,265, and the fee for those paying 50 percent of the full sponsor fee will be $28,175.

VI. Fee Schedule for FY 2009

The fee rates for FY 2009 are summarized in table 1 of this document.

TABLE 1.—FY 2009 FEE RATES

Generic New Animal Drug User Fee Category	Fee Rate for FY 2009
Abbreviated Application for Generic New Animal Drug Fee	$41,400
Generic New Animal Drug Product Fee	$3,005
100 Percent Generic New Animal Drug Sponsor Fee*	$56,350
75 Percent Generic New Animal Drug Sponsor Fee*	$42,265
50 Percent Generic New Animal Drug Sponsor Fee*	$28,175

* An animal drug sponsor is subject to only one such fee each fiscal year.

VII. Procedures for Paying the FY 2009 Abbreviated New Animal Drug Application Fees

A. Abbreviated Application Fees and Payment Instructions

The appropriate application fee established in the new fee schedule must be paid for an abbreviated new animal drug application subject to fees under AGDUFA that was submitted on or after July 1, 2008. For those sponsors who have submitted an abbreviated new animal drug application between July 1, 2008, and the publication date of this **Federal Register** notice, a cover sheet is not necessary, as the Food and Drug Administration will complete a cover sheet for you and invoice you accordingly. 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 by automatic clearing house (ACH) using Pay.gov. On your check, bank draft, or U.S. 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 by wire transfer, send payment to U.S. Department of Treasury, TREAS, NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account Number: 75060099, Routing Number: 021030004, Swift Number: FRNYUS33.

If you prefer to send a check by a courier such as FEDEX or UPS, the courier may deliver the check and printed copy of the cover sheet to: US 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 US Bank at 314–418–4821. This phone number is only for questions about courier delivery.)

The tax identification number of the Food and Drug Administration is 530196965. (Note: In no case should the check 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 US Bank notifies FDA that your check in the full amount of the payment due has been received or when the U.S. Department of Treasury notifies FDA of payment. US Bank is 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/oc/adufa/agdufamain.html* and, under the ''Forms'' heading, click on the link ''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 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

Thirty days after the March 11, 2009, enactment of appropriations for generic animal drug user fees, FDA will issue invoices and payment instructions for product and sponsor fees for FY 2009 using this fee schedule. Fees will be due and payable 30 days after the date the invoice is issued. FDA will issue invoices in November 2009 for any qualifying products and sponsors subject to fees received after this initial FY 2009 billing.

Dated: April 1, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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