953877, 1005 Convention Plaza, St. Louis, Missouri 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 application arrives at FDA's Center for Veterinary Medicine (CVM). FDA records the official application receipt date as the later of the following: the date the application was received by CVM, or the date US Bank notifies FDA that your check in the full amount of the payment due has been received, or when the United States Treasury notifies FDA of receipt of an electronic payment. US 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 ADUFA Web site at *http://www.fda.gov/oc/adufa* 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 they use this site. Online instructions will walk you through this process.

Step Two—Create an Animal 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 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 Payment Identification Number.

Step Three—Send the payment for your application as described in section IX.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, 2008, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2009 using this fee schedule. Payment will be due and payable on or before January 31, 2009. FDA will issue invoices in November 2009 for any products, establishments, and sponsors subject to fees for FY 2009 but that qualified for fees after the December 2008 billing.

Dated: September 8, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–21450 Filed 9–12–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0479]

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

AGENCY: Food and Drug Administration

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. FDA will 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. 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. However, FDA may not collect application fees until enactment of an appropriation for these fees. Within 30 days of enactment of an appropriation for these fees, FDA will issue invoices for applications received on or after July 1, 2008, and will publish a **Federal Register** notice stating that for the remainder of fiscal year 2009 FDA will not accept any further abbreviated applications for generic new animal drugs for review until FDA has received full payment of application fees and any other generic new animal drug user fees owed. That **Federal Register** notice will also provide instructions for payment of abbreviated applications for generic new animal drug fees.

FOR FURTHER INFORMATION CONTACT: Visit the FDA Web site at *http://www.fda.gov/oc/agdufa* or contact Roxanne Schweitzer, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7529 Standish Place, Rockville, MD 20855, 240–276–9705. For general questions, you may also e-mail the Center for Veterinary Medicine 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 five dollars, 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 of Health and Human Services, 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 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)(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 fifty dollars, to be $56,350. Accordingly, the fee for those paying 75 percent of the full sponsor fee, rounded to the nearest five dollars, 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 FY 2009 Generic New Animal Drug User Fees

FDA may not collect user fees for abbreviated applications, for generic new animal drug products, and for generic new animal drug sponsors until an appropriation of fees is provided by Congress (see 21 U.S.C. 379j–21(g)(1)). For this reason FDA may not begin to collect these fees at this time.

Fees for generic new animal drug products and sponsors will be invoiced at the rates published in this notice on the later of December 31, 2008, or 30 days after appropriation of generic new animal drug user fees by Congress.

Invoices for fees for abbreviated applications for generic new animal drugs submitted on or after July 1, 2008, will be issued 30 days after appropriation of generic new animal drug user fees by Congress. After that time, FDA will not consider an abbreviated application for a generic abbreviated new animal drug complete unless the application fee for that application has been paid in advance. Within 30 days after appropriation of generic new animal drug user fees by Congress, FDA will publish another notice in the **Federal Register** providing payment instructions so that these fees may be paid in advance of the submission of such abbreviated applications from that time forward.

Dated: September 3, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–21453 Filed 9–12–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Application of Platform Technologies for the Development of Therapeutics for Biodefense-A.

Date: October 16–17, 2008.

Time: 8:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

Contact Person: Alec Ritchie, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID/DHHS, 6700 B Rockledge Drive, MSC 7616,