

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 regarding additional fees.

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 the Food and Drug Administration is 530196965. (**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, 2012, FDA will issue invoices and payment instructions for product, establishment, and sponsor fees for FY 2013 using this Fee Schedule. Payment will be due and payable within 30 days of issuance of the invoice. FDA will issue invoices in November 2013 for any products, establishments, and sponsors subject to fees for FY 2013 that qualify for fees after the December 2012 billing.

Dated: July 26, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0807]

Animal Generic Drug User Fee Rates and Payment Procedures for Fiscal Year 2013

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) 2013 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 Act of 2008 (AGDUFA), 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 2013.

FOR FURTHER INFORMATION CONTACT: Visit the FDA 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 2009 through FY 2013, the FD&C Act establishes aggregate yearly base revenue amounts for each of these fee categories. Base revenue amounts established for years after FY 2009 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 2013, the generic new animal drug user fee rates are: \$148,300 for each abbreviated application for a generic new animal drug; \$6,515 for each generic new animal drug product; \$63,000 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; \$47,250 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and \$31,500 for each generic new animal drug sponsor paying 50 percent of the sponsor fee. FDA will issue invoices for FY 2013 product and sponsor fees by December 31, 2012. 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 a generic new animal drug submitted on or after October 1, 2012, and will remain in effect through September 30, 2013. 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 2013

A. Statutory Fee Revenue Amounts

AGDUFA (Title II of Pub. L. 110–316 signed by the President on August 14, 2008) specifies that the aggregate revenue amount for FY 2013 for abbreviated application fees is \$1,809,000 and each of the other two generic new animal drug user fee categories, annual product fees and annual sponsor fees, is \$2,111,000 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; therefore, no 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)).

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,

2008 (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, 2012.

The results of these calculations are presented in the first two columns of table 1 of this document. 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 of table 1 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 negative 17 percent for FY 2013. This is the workload adjuster for FY 2013.

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)	44.2	24.6	-44	0.4608	-20
Manufacturing Supplements ANADAs	114.6	123.6	8	0.2490	2
Generic Investigational Study Submissions	17.4	21.8	25	0.1921	5
Generic Investigational Protocol Submissions	21.6	13.2	-39	0.0980	-4
FY 2013 AGDUFA Workload Adjuster					-17

AGDUFA specifies that the workload adjuster may not result in fees for a fiscal year that are less than the statutory revenue amount (21 U.S.C. 379j–21(c)(1)(B)) for that fiscal year. Because applying the workload adjuster for FY 2013 would result in fees less than the statutory amount, the workload adjustment will not be applied in FY 2013. As a result, the statutory revenue amount for each category of fees for FY 2013 (\$1,809,000 for application fees and \$2,111,000 for both product and sponsor fees) becomes the revenue target for the fees in FY 2013, for a total fee revenue target in FY 2013 of

\$6,031,000 for fees from all three categories.

D. Offset for Excess Collections Through FY 2012

Under the provisions of the FD&C Act, if the cumulative amount of the fees collected for fiscal years 2009 through 2011, and the amount of fees estimated to be collected under this section for FY 2012, exceeds the cumulative amount appropriated for fees for fiscal years 2009 through 2012, the excess will be subtracted from the amount of fees that FDA would otherwise be authorized to collect for

FY 2013 pursuant to the FD&C Act (21 U.S.C. 379j–21(g)(4)).

Table 2 shows the amounts appropriated for each year from FY 2009 through FY 2012, and the amounts FDA has collected for FY 2009, FY 2010, and FY 2011 as of March 31, 2012, and the amount that FDA estimated it would collect in FY 2012 when it published the notice of FY 2012 fees in the **Federal Register** on August 1, 2011 (76 FR45814). The bottom line of Table 2 shows the estimated cumulative amount by which fees collected fell below amounts appropriated for FY 2009 through FY 2012.

TABLE 2—OFFSETS TO BE TAKEN IN FY 2013—FOR FY 2009–2011, FEES COLLECTED THROUGH 3/31/2012; FOR FY 2012, ESTIMATE AS OF 8/1/2011

Fiscal year	Fees appropriated	Fees collected	Difference
2009	\$4,831,000	\$5,099,084	\$268,084
2010	5,106,000	4,392,209	(713,791)
2011	5,397,000	4,942,876	(454,124)

TABLE 2—OFFSETS TO BE TAKEN IN FY 2013—FOR FY 2009–2011, FEES COLLECTED THROUGH 3/31/2012; FOR FY 2012, ESTIMATE AS OF 8/1/2011—Continued

Fiscal year	Fees appropriated	Fees collected	Difference
2012 estimate	5,706,000	5,706,000	0
Cumulative Difference Less than Appropriations			(899,831)
Balance to be Offset in a Subsequent Fiscal Year			0

As can be seen from the above table, no offset is required for the period FY 2009 through FY 2012 since collections have fallen below the amounts appropriated in aggregate.

E. Final Year Adjustment

Under the provisions of the FD&C Act, as amended, the Secretary may, in addition to the workload adjustment and offset, further increase the fees and fee revenues if such an adjustment is necessary to provide for up to 3 months

of operating reserves of carryover user fees for the process for the review of abbreviated applications for generic new animal drugs for the first 3 months of FY 2014. The rationale for the amount of this increase shall be contained in the annual notice establishing fee revenues and fees for FY 2013 (See the FD&C Act, section 741(c)(2)[21U.S.C. 379j–21(c)(2)]). Table 3 below estimates the amount of carryover reserve FDA currently estimates to have available at the end of FY 2013. It begins with the

balance available at the end of FY 2011, rounded to the nearest thousand dollars, and adds the net prior year collections for the 6 months ending March 31, 2012. In addition, FDA is keeping aside a reserve of \$200,000 for potential refunds, and a net of \$955,000 for the last 2 years of AGDUFA. The amount of carryover balance FDA expects to be available for obligation at the end of FY 2013 is \$3,694,000, as shown in the last line of Table 3.

TABLE 3—ESTIMATED CARRYOVER BALANCE AT THE END OF FY 2013, AFTER ADJUSTMENTS

Total Carryover Balance End of FY 2011	\$2,727,000
Net Prior Year Fees Collected After 9/30/2011 (3/31/2012)	212,000
Reserve for Refunds for FY 2012 and FY 2013	(200,000)
Estimated Change to Carryover Balance at the End of FY 2012	1,327,000
Estimated Change to Carryover Balance at the End of FY 2013	(372,000)
Estimated 2013 End of FY Carryover Balance	3,694,000

In FY 2013, FDA expects to spend a total of \$6,031,000, the amount authorized for collection from AGDUFA fees in that year, as shown in table 4 below. To maintain FY 2013 operations in FY 2014, FDA is applying an anticipated inflation rate of 2.01 percent to the amount of fee revenues FDA expects to obligate in FY 2013. This 2.01 percent is the statutory inflation adjustment to be applied to PDUFA and several other user fee programs in FY 2013, and the only statutory inflation adjustment for FDA available at this time; its derivation is published elsewhere in this issue of the **Federal Register** where the FY 2013 fees for the PDUFA user fee program is published. FDA expects to obligate a total of \$6,152,000 in FY 2014—or a total of about \$1,538,000 during the first 3 months of FY 2014, rounded to the nearest thousand dollars. The available carryover balance at the beginning of FY 2013 is estimated at \$3,694,000, rounded to the nearest thousand dollars. Since the estimated carryover balance is greater than the amount FDA will need to operate for the first 3 months of FY 2014, no final year adjustment is needed.

TABLE 4—ESTIMATED FEE REVENUE NEEDED TO SUSTAIN FY 2013 OPERATIONS FOR THE FIRST 3 MONTHS OF FY 2014

Estimated Total Spending from Fees in FY 2013	\$6,031,000
Estimated FY 2014 Inflation Costs at 2.01%	121,000
Estimated FY 2014 Funds to Sustain FY 2013 Operations	6,152,000
Estimated Fees Needed for 3 Months in FY 2014	1,538,000
Estimated End-of-FY 2013 Carryover Balance	3,694,000
Final Year Adjustment Needed	0

Since there is no offset nor final year adjustment to be applied in FY 2013, the AGDUFA revenue targets for FY 2013 remain as set in the statute: \$1,809,000 for application fees and \$2,111,000 each for both product and sponsor fees. The final revenue target for the fees in FY 2013 is \$6,031,000 for fees from all three categories.

III. Abbreviated Application Fee Calculations for FY 2013

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 \$1,809,000 in fee revenue for FY 2013. This is the amount set out in the statute.

To set fees for abbreviated applications for generic new animal drugs to realize \$1,809,000, FDA must first make some assumptions about the number of fee-paying abbreviated applications it will receive during FY 2013.

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 the 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 after July 1 because the initial submission was not approved by the FDA (i.e. the 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 after July 1, 2008, are subject to user fees. In this notice, FDA refers to these resubmitted applications as “reactivated” applications.

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 2013 will equal 15 percent less than the average number of submissions over the 5 most recent completed years (2007–2011). This 15 percent reduction is made because of the anticipated impact of fees on the number on submissions. The average number of original submissions of abbreviated applications for generic new animal drugs over the 5 most recently completed years is 13.2. Applying a 15 percent reduction to the 13.2 average, the estimate for original submissions of abbreviated applications for generic new animal drugs for FY 2013 is 11.2.

Regarding reactivated submissions of abbreviated applications for generic new animal drugs, FDA is applying a 90 percent reduction. This is based on the fact that there were a limited number of original submissions of abbreviated applications for generic new animal drugs received by FDA before July 1, 2008, which were not assessed fees. For these original submissions that were not approved before July 1, 2008, resubmission to the FDA would trigger an application fee (21 U.S.C. 379j–21(a)(1)(A)). Once these initial original submissions of abbreviated applications for generic new animal drugs received by the FDA before July 1, 2008, have either been withdrawn or resubmitted, “reactivation submissions” will cease completely. This reduction is consistent with estimates made when this user fee program was in the development process. The average number of receipts for reactivated submission of abbreviated applications for generic new animal drugs over the 5 most recently completed fiscal years is 10.2. Applying a 90 percent reduction to the 10.2 average, the estimate for reactivated submissions of abbreviated applications for generic new animal drugs for FY 2013 is 1. These reductions 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 years of experience with other user fee programs.

Based on the previous assumptions, FDA is estimating that it will receive a total of 12.2 fee paying generic new animal drug applications in FY 2013 (11.2 original applications and 1 reactivation).

B. Fee Rates for FY 2013

FDA must set the fee rates for FY 2013 so that the estimated 12.2 abbreviated applications that pay the fee will generate a total of \$1,809,000. To generate this amount, the fee for a generic new animal drug application, rounded to the nearest hundred dollars, will have to be \$148,300.

IV. Generic New Animal Drug Product Fee Calculations for FY 2013

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 \$2,111,000 in fee revenue for FY 2013. This is the amount set out in the statute and no further adjustments are required for FY 2013.

To set generic new animal drug product fees to realize \$2,111,000, FDA must make some assumptions about the number of products for which these fees will be paid in FY 2013. 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 2013.

In estimating the fee revenue to be generated by generic new animal drug product fees in FY 2013, FDA is assuming that 10 percent of the products invoiced, or 36, will not pay fees in FY 2013 due to fee waivers and reductions. Based on experience with other user fee programs and the first 4 years of AGDUFA, FDA believes that this is a reasonable basis for estimating the number of fee-paying products in FY 2013.

Accordingly, the Agency estimates that a total of 324 (360 minus 36) products will be subject to product fees in FY 2013.

B. Product Fee Rates for FY 2013

FDA must set the fee rates for FY 2013 so that the estimated 324 products that pay fees will generate a total of \$2,111,000. To generate this amount will require the fee for a generic new animal drug product, rounded to the nearest 5 dollars, to be \$6,515.

V. Generic New Animal Drug Sponsor Fee Calculations for FY 2013

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 new generic 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)(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 \$2,111,000 in fee revenue for FY 2013. This is the amount set out in the statute and no adjustments are required for FY 2013.

To set generic new animal drug sponsor fees to realize \$2,111,000, FDA must make some assumptions about the number of sponsors who will pay these fees in FY 2013. FDA now has 3 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 3 completed years of AGDUFA (FY 2009–FY 2011) FDA estimates that in FY 2013, 11 sponsors will pay 100 percent fees, 13 sponsors will pay 75 percent fees, and 33 sponsors will pay 50 percent fees. That totals the equivalent of 37.25 full sponsor fees (11 times 100 percent or 11, plus 13 times 75 percent or 9.75, plus 33 times 50 percent or 16.5).

FDA estimates that about 10 percent of all of these sponsors, or 3.73, may qualify for a minor use/minor species waiver.

Accordingly, the Agency estimates that the equivalent of 33.52 full sponsor fees (37.25 minus 3.73) are likely to be paid in FY 2013.

B. Sponsor Fee Rates for FY 2013

FDA must set the fee rates for FY 2013 so that the estimated equivalent of 33.52 full sponsor fees will generate a total of \$2,111,000. To generate this amount will require the 100 percent fee for a generic new animal drug sponsor, rounded to the nearest \$50, to be \$63,000. Accordingly, the fee for those paying 75 percent of the full sponsor fee will be \$47,250, and the fee for those paying 50 percent of the full sponsor fee will be \$31,500.

VI. Fee Schedule for FY 2013

The fee rates for FY 2013 are summarized in table 5 of this document.

TABLE 5—FY 2013 FEE RATES

Generic new animal drug user fee category	Fee rate for FY 2013
Abbreviated Application Fee for Generic New Animal Drug Application	\$148,300

TABLE 5—FY 2013 FEE RATES—Continued

Generic new animal drug user fee category	Fee rate for FY 2013
Generic New Animal Drug Product Fee	6,515
¹ 100 Percent Generic New Animal Drug Sponsor Fee	63,000
¹ 75 Percent Generic New Animal Drug Sponsor Fee	47,250
¹ 50 Percent Generic New Animal Drug Sponsor Fee	31,500

(¹) An animal drug sponsor is subject to only one fee each fiscal year.

VII. Procedures for Paying FY 2013 Generic New Animal Drug User Fees

A. Abbreviated Application Fees and Payment Instructions

The FY 2013 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, 2012. 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 www.Pay.gov. (The www.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 Number: 75060099, Routing 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 regarding the amount of the fees that need to be paid in addition to the wire transfer amount.

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 the Food and Drug Administration is 530196965. (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 one 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, 2012, FDA will issue invoices and payment instructions for product and sponsor fees for FY 2013 using this fee schedule. Fees will be due and payable 30 days after the issuance of the invoices. FDA will issue invoices in November 2013 for any products and sponsors subject to fees for FY 2013 that qualify for fees after the December 2012 billing.

Dated: July 26, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0007]

Biosimilar User Fee Rates for Fiscal Year 2013

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for biosimilar user fees for fiscal year (FY) 2013. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Biosimilar User Fee Act of 2012 (BsUFA) (Title IV of the Food and Drug Administration Safety and Innovation Act, Public Law 112-144, which was signed by the President on July 9, 2012), authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development, for certain applications and supplements for approval of biosimilar biological products, on establishments where approved biosimilar biological product products are made, and on biosimilar biological products after approval. BsUFA directs FDA to establish, before the beginning of each fiscal year, the initial and annual biosimilar biological product development (BPD) fees, the reactivation fee, and the biosimilar biological product application, establishment, and product fees.

Under BsUFA, the initial and annual BPD fee rates for a fiscal year are equal

to 10 percent of the fee rate established under the Prescription Drug User Fee Act (PDUFA) for an application requiring clinical data for that fiscal year (FY). The reactivation fee is equal to 20 percent of the fee rate established under PDUFA for an application requiring clinical data for that fiscal year. Finally, the application, establishment, and product fee rates under BsUFA are equal to the application, establishment, and product fee rates under PDUFA, respectively. This document, which establishes FY 2013 rates for BsUFA fees, uses the PDUFA application, establishment, and product fee amounts for FY 2013 published elsewhere in this issue of the **Federal Register**.

The FY 2013 rates for BsUFA fees are as follows: Initial and annual biosimilar BPD fees (\$195,880), reactivation fee (\$391,760), fee for a biosimilar biological product application requiring clinical data (\$1,958,800), fee for a biosimilar biological product application not requiring clinical data (\$979,400), fee for a biosimilar biological product supplement requiring clinical data (\$979,400), biosimilar biological product establishment fee (\$526,500), and biosimilar biological product fee (\$98,380). These fees are effective on October 1, 2012, and will remain in effect through September 30, 2013.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

Sections 744G, 744H, and 744I of the FD&C Act, as added by BsUFA, establish fees for biosimilar biological products. Under section 744H(a)(1)(A), the initial BPD fee for a product is due when the sponsor submits an investigational new drug (IND) application that FDA determines is intended to support a biosimilar biological product application for the product, or within 5 calendar days after FDA grants the first BPD meeting for the product, whichever occurs first. For a sponsor that submitted an IND for a biosimilar biological product prior to the date of enactment of BsUFA, FDA expects the initial BPD fee to be paid by December 1, 2012, or within 5 calendar days after FDA grants the first BPD meeting for the product, whichever occurs first. A sponsor that has paid the initial BPD fee for a product is

considered to be participating in FDA's BPD Program for that product.

Under section 744H(a)(1)(B) of the FD&C Act, once a sponsor has paid the initial BPD fee for a product, the annual BPD fee for the product is assessed beginning in the next fiscal year. The annual BPD fee is assessed for the product until the sponsor submits a marketing application for the product that is accepted for filing, or discontinues participation in FDA's BPD Program for the product.

Under section 744H(a)(1)(D) of the FD&C Act, if a sponsor has discontinued participation in FDA's BPD Program for a product, and wants to again engage with FDA on development of the product as a biosimilar biological product, the sponsor must pay a reactivation fee to resume participation in the BPD Program for that product. The reactivation fee is assessed when the sponsor submits an IND for an investigation that FDA determines is intended to support a biosimilar biological product application, or within 5 calendar days after FDA grants the sponsor's request for a BPD meeting for a product, whichever occurs first. Annual BPD fees will resume beginning in the fiscal year after the year in which the reactivation fee was paid.

BsUFA also establishes fees for certain types of applications and supplements for approval of biosimilar biological products, establishments where approved biosimilar biological products are made, and on biosimilar biological products after approval (section 744H(a)(2), 744H(a)(3), and 744H(a)(4) respectively of the FD&C Act). When certain conditions are met, FDA may grant small businesses a waiver from the biosimilar biological product application fee (section 744H(c)(1) of the FD&C Act).

II. Fee Amounts for FY 2013

BsUFA directs FDA to use the yearly fee amounts for PDUFA to calculate the biosimilar fee rates in each fiscal year. For more information about BsUFA, please refer to the FDA Web site at <http://www.fda.gov/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/default.htm>. PDUFA fee calculations for FY 2013 are published elsewhere in this issue of the **Federal Register**. The BsUFA fee calculations for FY 2013 are described in this document.

A. Initial and Annual BPD Fees; Reactivation Fees

Under BsUFA, the initial and annual BPD fees equal 10 percent of the PDUFA fee for an application requiring clinical data, and the reactivation fee equals 20 percent of the PDUFA fee for an