TABLE 2—FY 2015 FEE RATES—Continued

Generic new animal drug user fee category	Fee rate for FY 2015
Abbreviated Application Fee for Generic New Animal Drug subject to the criteria in section 512(d)(4)	94,600
Generic New Animal Drug Product Fee	8,500
100 Percent Generic New Animal Drug Sponsor Fee [1]	80,900
75 Percent Generic New Animal Drug Sponsor Fee [1]	60,675
50 Percent Generic New Animal Drug Sponsor Fee [1]	40,450

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

VII. Procedures for Paying FY 2015 Generic New Animal Drug User Fees

A. Abbreviated Application Fees and Payment Instructions

The FY 2015 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, 2014. Payment must be made in U.S. currency from a U.S. bank by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration, by wire transfer, or by automatic clearing house using *https://www.pay.gov.* (The Pay.gov payment option is available to you after you submit a cover sheet. Click the ''Pay Now'' button). On your check, bank draft, U.S. or postal money order, please write your application's unique Payment Identification Number, beginning with the letters ''AG'', from the upper right-hand corner of your completed Animal Generic Drug User Fee Cover Sheet. Also write the FDA post office box number (P.O. Box 953877) on the enclosed check, bank draft, or money order. Your payment and a copy of the completed Animal Generic Drug User Fee Cover Sheet can be mailed to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000.

If payment is made via wire transfer, send payment to U. S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account No.: 75060099, Routing No.: 021030004, Swift No.: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., Silver Spring, MD 20993–0002. 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, the courier may deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 979033, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. If you have any questions concerning courier delivery contact the U.S. Bank at 314–418–4013. This phone number is only for questions about courier delivery.)

The tax identification number of FDA is 53–0196965. (Note: In no case should the payment for the fee be submitted to FDA with the application.)

It is helpful if the fee arrives at the bank at least a day or two before the abbreviated application arrives at FDA's Center for Veterinary Medicine (CVM). FDA records the official abbreviated application receipt date as the later of the following: The date the application was received by CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U. S. Department of the Treasury notifies FDA of payment. U.S. Bank and the United States Treasury are required to notify FDA within 1 working day, using the Payment Identification Number described previously.

B. Application Cover Sheet Procedures

Step One—Create a user account and password. Log onto the AGDUFA Web site at *http://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm137049.htm* and scroll down the page until you find the link ''Create AGDUFA User Fee Cover Sheet.'' Click on that link and follow the directions. For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two—Create an Animal Generic Drug User Fee Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your user name and password, complete the steps required to create an Animal Generic Drug User Fee Cover Sheet. One cover sheet is needed for each abbreviated animal drug application. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the cover sheet, you will be able to transmit it electronically to FDA and you will be able to print a copy of your cover sheet showing your unique Payment Identification Number.

Step Three—Send the payment for your application as described in Section VII.A of this document.

Step Four—Please submit your application and a copy of the completed Animal Generic Drug User Fee Cover Sheet to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV–199), 7500 Standish Pl., Rockville, MD 20855.

C. Product and Sponsor Fees

By December 31, 2014, FDA will issue invoices and payment instructions for product and sponsor fees for FY 2015 using this fee schedule. Fees will be due by January 31, 2015. FDA will issue invoices in November 2015 for any products and sponsors subject to fees for FY 2015 that qualify for fees after the December 2014 billing.

Dated: July 29, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–18178 Filed 7–31–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0007]

Biosimilar User Fee Rates for Fiscal Year 2015

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) 2015. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Biosimilar User Fee Act of 2012 (BsUFA), authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development, certain applications and supplements for approval of biosimilar biological products, establishments where approved biosimilar biological product products are made, and 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. These fees are effective on October 1, 2014, and will remain in effect through September 30, 2015.

FOR FURTHER INFORMATION CONTACT: Rachel Richter, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE–14216, Silver Spring, MD 20993–0002, 301–796–7111.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 744G, 744H, and 744I of the FD&C Act (21 U.S.C. 379j–51, 379j–52, and 379j–53), as added by BsUFA (Title IV of the Food and Drug Administration Safety and Innovation Act, Pub. L. 112–144), establish fees for biosimilar biological products. Under section 744H(a)(1)(A) of the FD&C Act, 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, or within 5 calendar days after FDA grants the first BPD meeting, whichever occurs first. A sponsor who has paid the initial BPD fee 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 is assessed beginning in the next fiscal year. The annual BPD fee is assessed for the product each fiscal year until the sponsor submits a marketing application for the product that is accepted for filing, or discontinues participation in FDA's BPD program.

Under section 744H(a)(1)(D) of the FD&C Act, if a sponsor has discontinued participation in FDA's BPD program and wants to re-engage with FDA on development of the product, the sponsor must pay a reactivation fee to resume participation in the BPD program. The sponsor must pay the reactivation fee by the earlier of the following dates: No later than 5 calendar days after FDA grants the sponsor's request for a BPD meeting for that product; or upon the date of submission of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application. Annual BPD fees will be due beginning for the fiscal year after the year in which the reactivation fee was paid.

BsUFA also establishes fees for certain types of applications and supplements, establishments where approved biosimilar biological products are made, and biosimilar biological products post-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).

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. 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.

II. Fee Amounts for FY 2015

BsUFA directs FDA to establish the biosimilar biological product fee rates in each fiscal year by reference to the user fees established under PDUFA for that 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 2015 are published elsewhere in this issue of the **Federal Register**. The BsUFA fee calculations for FY 2015 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 application requiring clinical data. The FY 2015 fee for an application requiring clinical data under PDUFA is $2,335,200. Multiplying the PDUFA application fee, $2,335,200, by 0.1 results in FY 2015 initial and annual BPD fees of $233,520. Multiplying the PDUFA application fee, $2,335,200, by 0.2 results in an FY 2015 reactivation fee of $467,040.

B. Application and Supplement Fees

The FY 2015 fee for a biosimilar biological product application requiring clinical data equals the PDUFA fee for an application requiring clinical data, $2,335,200. The FY 2015 fee for a biosimilar biological product application not requiring clinical data equals half this amount, $1,167,600. However, under section 744H(a)(2)(A) of the FD&C Act, if a sponsor that submits a biosimilar biological product application has previously paid an initial BPD fee, annual BPD fee(s), and/or reactivation fee(s) for the product that is the subject of the application, the fee for the application is reduced by the cumulative amount of these previously paid fees. The FY 2015 fee for a biosimilar biological product supplement with clinical data is $1,167,600, which is half the fee for a biosimilar biological product application requiring clinical data.

C. Establishment Fee

The FY 2015 biosimilar biological product establishment fee is equal to the FY 2015 PDUFA establishment fee of $569,200.

D. Product Fee

The FY 2015 biosimilar biological product fee is equal to the FY 2015 PDUFA product fee of $110,370.

III. Fee Schedule for FY 2015

The fee rates for FY 2015 are provided in Table 1.

TABLE 1—FEE SCHEDULE FOR FY 2015

Fee category	Fee rates for FY 2015
Initial BPD	$233,520
Annual BPD	233,520
Reactivation	467,040
Applications [1]:	
Requiring clinical data	2,335,200
Not requiring clinical data	1,167,600
Supplement requiring clinical data	1,167,600
Establishment	569,200
Product	110,370

[1] Under section 744H(a)(2)(A) of the FD&C Act, if a sponsor that submits a biosimilar biological product application has previously paid initial BPD fees, annual BPD fees, and/or reactivation fees for the product that is the subject of the application, the fee for the application is reduced by the cumulative amount of these previously paid fees.

IV. Fee Payment Options and Procedures

A. Initial BPD, Reactivation, Application, and Supplement Fees

The fees established in the new fee schedule are effective October 1, 2014. The initial BPD fee for a product is due when the sponsor submits an IND 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. Sponsors who have discontinued participation in the BPD program must pay the reactivation fee by the earlier of the following dates: No later than 5 calendar days after FDA grants the sponsor's request for a BPD meeting for that product; or upon the date of submission of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application.

The application or supplement fee for a biosimilar biological product is due upon submission of the application or supplement.

To make a payment of the initial BPD, reactivation, supplement, or application fee, you must complete the Biosimilar User Fee Cover Sheet, available on FDA's Web site (*http://www.fda.gov/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/default.htm*) and generate a user fee identification (ID) number. Payment must be made in U.S. currency by electronic check, check, bank draft, U.S. postal money order, or wire transfer.

FDA has partnered with the U.S. Department of the Treasury to use Pay.gov, a Web-based payment application, for online electronic payment. The Pay.gov feature is available on FDA's Web site after completing the Biosimilar User Fee Cover Sheet and generating the user fee ID number.

Please include the user fee ID number on your check, bank draft, or postal money order, and make it payable to the Food and Drug Administration. Your payment can be mailed to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000. If you prefer to send a check by 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, Attention: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only. Contact U.S. Bank at 314–418–4013 if you have any questions concerning courier delivery.) Please make sure that the FDA post office box number (P.O. Box 979108) is written on the check, bank draft, or postal money order.

If paying by wire transfer, please reference your unique user fee ID number when completing your transfer. The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the fee and include it with your payment to ensure that your fee is fully paid. The account information is as follows: New York Federal Reserve Bank, U.S. Department of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 8455 Colesville Rd., Silver Spring, MD, 20993–0002.

The tax identification number of FDA is 53–0196965.

B. Annual BPD, Establishment, and Product Fees

FDA will issue invoices for annual BPD, biosimilar biological product establishment, and biosimilar biological product fees under the new fee schedule in August 2014. Payment instructions will be included in the invoices. Payment will be due on October 1, 2014. If sponsors join the BPD program after the annual BPD invoices have been issued in August 2014, FDA will issue invoices in November 2014 to firms subject to fees for FY 2015 that qualify for the BPD fee after the August 2014 billing. FDA will issue invoices in November 2015 for any annual products and establishments subject to fees for FY 2015 that qualify for fee assessments after the August 2014 billing.

Dated: July 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0007]

Generic Drug User Fee—Abbreviated New Drug Application, Prior Approval Supplement, Drug Master File, Final Dosage Form Facility, and Active Pharmaceutical Ingredient Facility Fee Rates for Fiscal Year 2015

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for abbreviated new drug applications (ANDAs), prior approval supplements to an approved ANDA (PASs), drug master files (DMFs), generic drug active pharmaceutical ingredient (API) facilities, and finished dosage form (FDF) facilities user fees related to the Generic Drug User Fee Program for fiscal year (FY) 2015. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Generic Drug User Fee Amendments of 2012 (GDUFA), authorizes FDA to assess and collect user fees for certain applications and supplements for human generic drug products, on applications in the backlog as of October 1, 2012 (only applicable to FY 2013), on FDF and API facilities, and on type II active pharmaceutical ingredient DMFs to be made available for reference. This document establishes the fee rates for FY 2015.

FOR FURTHER INFORMATION CONTACT: Rachel Richter, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE–14216, Silver Spring, MD 20993–0002, 301–796–7111.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 744A and 744B of the FD&C Act (21 U.S.C. 379j–41 and 379j–42) establish fees associated with human generic drug products. Fees are assessed on: (1) Certain applications in the backlog as of October 1, 2012 (only applicable to FY 2013); (2) certain types of applications and supplements for human generic drug products; (3) certain facilities where APIs and FDFs are produced; and (4) certain DMFs associated with human generic drug products. (See section 744B(a)(1)–(4) of the FD&C Act).

For FY 2015, the generic drug fee rates are: ANDA ($58,730), PAS ($29,370), DMF ($26,720), domestic API facility ($41,926), foreign API facility ($56,926), domestic FDF facility ($247,717), and foreign FDF facility ($262,717). These fees are effective on October 1, 2014, and will remain in effect through September 30, 2015.

II. Fee Revenue Amount for FY 2015

The base revenue amount for FY 2015 is $299 million, as set in the statute prior to the inflation adjustment. GDUFA directs FDA to use the yearly revenue amount as a starting point to set the fee rates for each fee type. For more information about GDUFA, please refer to the FDA Web site (*http://www.fda.gov/gdufa*). The ANDA, PAS, DMF, API facility, and FDF facility fee calculations for FY 2015 are described in this document.

Inflation Adjustment

GDUFA specifies that the $299 million is to be adjusted for inflation increases for FY 2015 using two separate adjustments—one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 744B(c)(1) of the FD&C Act).

The component of the inflation adjustment for PC&B costs shall be one plus the average annual percent change in the cost of all PC&B paid per full-time equivalent position (FTE) at FDA for the first three of the four preceding fiscal years, multiplied by the proportion of PC&B costs to total FDA costs of the review of human generic drug activities for the first three of the preceding four fiscal years (see section 744B(c)(1)(A)–(B) of the FD&C Act). The data on total