

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 application requiring clinical data. The FY 2013 fee for an application requiring clinical data under PDUFA is \$1,958,800. Multiplying the PDUFA application fee, \$1,958,800, by 0.1 results in FY 2013 initial and annual BPD fees of \$ 195,880. Multiplying the PDUFA application fee, \$1,958,800, by 0.2 results in an FY 2013 reactivation fee of \$391,760.

B. Application and Supplement Fees

The FY 2013 fee for a biosimilar biological product application requiring clinical data equals the PDUFA fee for an application requiring clinical data, \$1,958,800, and the FY 2013 fee for a biosimilar biological product application not requiring clinical data equals half this amount, \$979,400. 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 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. The FY 2013 fee for a biosimilar biological product supplement with clinical data is \$979,400, which is half the fee for a biosimilar biological product application requiring clinical data.

C. Establishment Fee

The FY 2013 biosimilar biological product establishment fee is set equal to the FY 2013 PDUFA establishment fee of \$526,500.

D. Product Fee

The FY 2013 biosimilar biological product fee is set equal to the FY 2013 PDUFA product fee of \$98,380.

III. Fee Schedule for FY 2013

The fee rates for FY 2013 are set out in table 1 of this document.

Table 1.--Fee Schedule for FY 2013

Fee Category	Fee Rates for FY 2013
Initial BPD	\$195,880
Annual BPD	\$195,880
Reactivation	\$391,760
Applications ¹	
Requiring Clinical Data	\$1,958,800 *
Not Requiring Clinical Data	\$979,400 *
Supplement Requiring Clinical Data	\$979,400
Establishment	\$526,500
Product	\$98,380

¹Under 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, 2012. For a sponsor that submitted an IND for a biosimilar biological product prior to the date of enactment of BsUFA, FDA expects to receive the initial BPD fee by December 1, 2012 (unless the IND is withdrawn before the fee due date), or within 5 calendar days after FDA grants the first BPD meeting for the product, whichever occurs first. Otherwise, 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. For sponsors that have discontinued participation in the BPD Program, a reactivation fee will be due 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.

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 the FDA Web site starting October 1, 2012, 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 utilize Pay.gov, a Web-based payment application, for online electronic payment. The www.Pay.gov feature is available

on the FDA 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 payable to the order of 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 checks are to be sent by a courier that requests a street address, the courier can deliver the checks 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.) Please make sure that 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 between \$15.00 and \$35.00. 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, Account Number: 75060099, Routing Number: 021030004, Swift Number: FRNYUS33, Beneficiary: FDA, 1350 Piccard Dr., Rockville, MD, 20850.

The tax identification number of the Food and Drug Administration 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. Payment instructions will be included in the invoices. No annual BPD invoices will be issued for FY 2013. FDA will issue invoices in November 2013 for any products and establishments subject to fees for FY 2013.

Dated: July 24, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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