DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0007]

Biosimilar User Fee Rates for Fiscal Year 2014

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) 2014. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Biosimilar User Fee Act of 2012 (BsUFA), 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. These fees are effective on October 1, 2013, and will remain in effect through September 30, 2014.

FOR FURTHER INFORMATION CONTACT: David Miller, Office of Financial Management (HFA–100), Food and Drug Administration, 1350 Piccard Dr., PI50, Rm. 210J, Rockville, MD 20850, 301–796–7103.

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 for the product, or within 5 calendar days after FDA grants the first BPD meeting for the product, whichever occurs first. A sponsor who 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 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 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).

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 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.

II. Fee Amounts for FY 2014

BsUFA directs FDA to use the yearly fee amounts established for PDUFA to calculate the biosimilar biological product 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 2014 are published elsewhere in this issue of the **Federal Register.** The BsUFA fee calculations for FY 2014 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 2014 fee for an application requiring clinical data under PDUFA is $2,169,100. Multiplying the PDUFA application fee, $2,169,100, by .1 results in FY 2014 initial and annual BPD fees of $216,910. Multiplying the PDUFA application fee, $2,169,100, by .2 results in an FY 2014 reactivation fee of $433,820.

B. Application and Supplement Fees

The FY 2014 fee for a biosimilar biological product application requiring clinical data equals the PDUFA fee for an application requiring clinical data, $2,169,100, and the FY 2014 fee for a biosimilar biological product application not requiring clinical data equals half this amount, $1,084,550. 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 2014 fee for a biosimilar biological product supplement with clinical data is $1,084,550, which is half the fee for a biosimilar biological product application requiring clinical data.

C. Establishment Fee

The FY 2014 biosimilar biological product establishment fee is set equal to the FY 2014 PDUFA establishment fee of $554,600.

D. Product Fee

The FY 2014 biosimilar biological product fee is set equal to the FY 2014 PDUFA product fee of $104,060.

III. Fee Schedule for FY 2014

The fee rates for FY 2014 are set out in Table 1.

TABLE 1—FEE SCHEDULE FOR FY 2014

Fee category	Fee rates for FY 2014
Initial BPD	$216,910
Annual BPD	216,910
Reactivation	433,820
Applications [1]	
Requiring clinical data	2,169,100
Not requiring clinical data	1,084,550
Supplement requiring clinical data	1,084,550
Establishment	554,600
Product	104,060

[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, 2013. 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 who 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 FDA's Web site (*http://www.fda.gov/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/default.htm*) starting October 1, 2013, 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 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 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, 1350 Piccard Dr., Rockville, MD, 20850.

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 2013. Payment instructions will be included in the invoices. Payment will be due on October 1, 2013. FDA will issue invoices in November 2014 for any annual BPD, products and establishments subject to fees for FY 2014 that qualify for fee assessments after the August 2013 billing.

Dated: July 29, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0010]

Cooperative Agreement to Support the Food and Agriculture Organization

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to receive and consider a single source application for award of a cooperative agreement in fiscal year 2013 to the Food and Agriculture Organization (FAO) of the United Nations to support global strategies that address food safety and public health.

The goal of this collaborative project between FDA and FAO is to contribute to the knowledge base and development of food safety systems globally due to the increasingly diverse and complex food supply. The project is also designed to enhance and broaden FDA's ability to address global food safety and public health issues associated with food as well as provide opportunities to leverage additional resources of other countries. The collaborative project will also support the FDA's implementation of the FDA Food Safety Modernization Act (FSMA), including FDA's International Food Safety Capacity Building Plan, which emphasizes the concept of preventing food safety-related problems before they occur and the importance of establishing strong relationships and mutual support among all stakeholders, including multilateral organizations, to improve worldwide food safety. In addition, the collaborative project will support food safety, nutrition, and public health programs that align with FDA's mission.

DATES: Important dates are as follows:

1. The application due date is September 1, 2013.

2. The anticipated start date is September 2013.

3. The expiration date is September 2, 2013.

ADDRESSES: Submit electronic applications to: *http://www.grants.gov.* For more information, see section III of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: *Scientific/Programmatic Contact:* Julie Moss, Center for Food Safety and Applied Nutrition (HFS–550), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2031, *Julie.moss@fda.hhs.gov. Grants Management Contact:* Gladys