211.198. FDA will consider whether to provide additional guidance on SOPs, but outsourcing facilities are required to develop written procedures that enable them to fulfill their review, reporting, and recordkeeping obligations even if FDA does not provide such guidance.

Issue 23: One commenter suggests using the MedWatch Form FDA 3500 voluntary reporting instead of the mandatory Form FDA 3500A reporting form.

FDA Response to Issue 23: FDA disagrees with this comment. Section 503B of the FD&C Act requires that outsourcing facilities report adverse events. Therefore, voluntary reporting mechanisms such as the Form FDA 3500 would not be appropriate for outsourcing facility adverse event reporting.

Issue 24: One commenter asked for clarification about the type of products about which adverse event reports must be submitted, noting that outsourcing facilities often do more than compounding. The commenter asked whether the reporting requirements apply to other activities such as repackaging.

FDA Response to Issue 24: The guidance states that ''for purposes of reporting adverse drug experiences, the term *prescription drug products* includes any compounded drug product subject to the prescription requirements in section 503(b)(1) of the FD&C Act.'' Reporting for other activities such as repackaging will be addressed in separate guidance documents. For example, when finalized, FDA's draft guidance, ''Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities,'' will describe adverse event reporting for drug products repackaged by outsourcing facilities, if they will be expected to report adverse events associated with their repackaged products, as contemplated by the draft guidance.

Burden Estimates:

The total estimated reporting and recordkeeping burdens for the guidance are as follows:

We estimate that approximately 55 outsourcing facilities (''Number of Respondents'' and ''Total Annual Responses'' in table 1) will annually submit adverse event reports to FDA as specified in the guidance, and that preparing and submitting this information will take approximately 1.1 hours per registrant (''Average Burden per Response'' in table 1).

We estimate that approximately 55 outsourcing facilities (''Number of Recordkeepers'' in table 2) will annually maintain records of adverse events as specified in the guidance, and that preparing and maintaining the records will take approximately 16 hours per registrant (''average burden per recordkeeping'' in table 2).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Compounding outsourcing facility	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission of adverse event reports including copy of labeling and other information as described in the guidance	55	1	55	1.1	61

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of recordkeeping	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Records of adverse events, including records of efforts to obtain the data elements for each adverse event report	55	1	55	16	880

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: July 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18911 Filed 7–31–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0007]

Biosimilar User Fee Rates for Fiscal Year 2016

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) 2016. 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 products are made, and a biosimilar biological product fee for each biosimilar biological product approved in a biosimilar biological product application.

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, 2015, and will remain in effect through September 30, 2016.

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 with 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 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. The sponsor will be assessed an annual BPD fee beginning with the first fiscal year after payment of the reactivation fee.

BsUFA also establishes fees for certain applications and supplements, establishments where approved biosimilar biological products are made in final dosage form, and for each biosimilar biological product approved in a biosimilar biological product application (section 744H(a)(2), 744H(a)(3), and 744H(a)(4), respectively, of the FD&C Act). Under certain conditions, FDA may grant a small business a waiver from its first 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 (section 744H(b)(1) of the FD&C Act).

II. Fee Amounts for FY 2016

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/bsufa.* PDUFA fee calculations for FY 2016 are published elsewhere in this issue of the **Federal Register**. The BsUFA fee calculations for FY 2016 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 2016 fee for an application requiring clinical data under PDUFA is $2,374,200. Multiplying the PDUFA application fee, $2,374,200, by 0.1 results in FY 2016 initial and annual BPD fees of $237,420. Multiplying the PDUFA application fee, $2,374,200, by 0.2 results in a FY 2016 reactivation fee of $474,840.

B. Application and Supplement Fees

The FY 2016 fee for a biosimilar biological product application requiring clinical data equals the PDUFA fee for an application requiring clinical data, $2,374,200. The FY 2016 fee for a biosimilar biological product application not requiring clinical data equals half this amount, $1,187,100. However, under section 744H(a)(2)(A) of the FD&C Act, if a sponsor submitting 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 2016 fee for a biosimilar biological product supplement with clinical data is $1,187,100, which is half the fee for a biosimilar biological product application requiring clinical data.

C. Establishment Fee

The FY 2016 biosimilar biological product establishment fee for establishments where approved biosimilar biological products are made is equal to the FY 2016 PDUFA establishment fee of $585,200.

D. Product Fee

The FY 2016 biosimilar biological product fee for each biosimilar biological product approved in a biosimilar biological product application is equal to the FY 2016 PDUFA product fee of $114,450.

III. Fee Schedule for FY 2016

The fee rates for FY 2016 are provided in table 1.

TABLE 1—FEE SCHEDULE FOR FY 2016

Fee category	Fee rates for FY 2016
Initial BPD	$237,420
Annual BPD	237,420
Reactivation	474,840
Applications [1]	
Requiring clinical data	2,374,200
Not requiring clinical data	1,187,100
Supplement requiring clinical data	1,187,100
Establishment	585,200
Product	114,450

[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 an initial BPD fee, 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, 2015. 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, complete the Biosimilar User Fee Cover Sheet, available on FDA's Web site (*http://www.fda.gov/bsufa*) 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 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, 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 2015. Payment instructions will be included in the invoices. Payment will be due on October 1, 2015. If sponsors join the BPD program after the annual BPD invoices have been issued in August 2015, FDA will issue invoices in November 2015 to firms subject to fees for FY 2016 that qualify for the annual BPD fee after the August 2015 billing. FDA will issue invoices in November 2016 for any annual products and establishments subject to fees for FY 2016 that qualify for fee assessments after the August 2015 billing.

Dated: July 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18908 Filed 7–31–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0007]

Outsourcing Facility Fee Rates for Fiscal Year 2016

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2016 rates for the establishment and reinspection fees related to human drug compounding outsourcing facilities (outsourcing facilities) that elect to register under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). The FD&C Act authorizes FDA to assess and collect an annual establishment fee from outsourcing facilities that have elected to register, as well as a reinspection fee for each reinspection of an outsourcing facility. This document establishes the FY 2016 rates for the small business establishment fee ($5,203), the non-small business establishment fee ($16,465), and the reinspection fee ($15,610) for outsourcing facilities; provides information on how the fees for FY 2016 were determined; and describes the payment procedures outsourcing facilities should follow.

FOR FURTHER INFORMATION CONTACT:

For information on pharmacy compounding and pharmacy compounding user fees: Visit FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm.*

For questions relating to this notice: Rachel Richter, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE–14216, Silver Spring, MD 20933–0002, 301–796–7111.

SUPPLEMENTARY INFORMATION:

I. Background

On November 27, 2013, President Obama signed the Drug Quality and Security Act (DQSA), legislation that contains important provisions relating to the oversight of compounding of human drugs. Title I of this law, the Compounding Quality Act, creates a new section 503B in the FD&C Act (21 U.S.C. 353b). Under section 503B of the FD&C Act, a human drug compounder can become an ''outsourcing facility.''

Outsourcing facilities, as defined in section 503B(d)(4) of the FD&C Act, are facilities that meet all of the conditions described in section 503B(a), including registering with FDA as an outsourcing facility and paying an annual establishment fee. If these conditions are satisfied, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from two sections of the FD&C Act: (1) Section 502(f)(1) (21 U.S.C. 352(f)(1)) concerning the labeling of drugs with adequate directions for use and (2) section 505 (21 U.S.C. 355) concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs). Drugs compounded in outsourcing facilities are not exempt from the requirements of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) concerning current good manufacturing practice for drugs.

Section 744K of the FD&C Act (21 U.S.C. 379j–62) authorizes FDA to assess and collect the following fees associated with outsourcing facilities that elect to register under section 503B of the FD&C Act: (1) An annual establishment fee from each outsourcing facility and (2) a reinspection fee from each outsourcing facility subject to a reinspection (see section 744K(a)(1) of the FD&C Act). Under statutorily defined conditions, a qualified applicant may pay a reduced small business establishment fee (see section 744K(c)(4) of the FD&C Act).

FDA announced in the **Federal Register** of November 24, 2014 (79 FR 69856), the availability of a final guidance for industry entitled ''Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act.'' The guidance provides additional information on the annual fees for registered outsourcing facilities and adjustments required by law, reinspection fees, how to submit payment, the effect of failure to pay fees,