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]

BILLING CODE 4164–01–P

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,

and how to qualify as a small business to obtain a reduction of the annual establishment fee. This guidance can be accessed on FDA's Web site at *http://wcms.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM391102.pdf.*

II. Fees for FY 2016 [1]

A. FY 2016 Rates for Small Business Establishment Fee, Non-Small Business Establishment Fee, and Reinspection Fee

1. Establishment Fee for Qualified Small Businesses [2]

The amount of the establishment fee for a qualified small business fee is equal to $15,000 multiplied by the inflation adjustment factor for that fiscal year, divided by three (see section 744K(c)(4)(A) and (c)(1)(A) of the FD&C Act). The inflation adjustment factor for FY 2016 is 1.040646. See section II.B.1 for the methodology used to calculate the FY 2016 inflation adjustment factor. Therefore, the establishment fee for a qualified small business for FY 2016 is one third of $15,610, which, rounded to the nearest dollar, equals $5,203.

2. Establishment Fee for Non-Small Businesses

Under section 744K(c) of the FD&C Act, the amount of the establishment fee for a non-small business fee is equal to $15,000 multiplied by the inflation adjustment factor for that fiscal year, plus the small business adjustment factor for that fiscal year, and plus or minus an adjustment factor to account for over- or under-collections due to the small business adjustment factor in the prior year. The inflation adjustment factor for FY 2016 is 1.040646. The small business adjustment amount for FY 2016 is $855. See section II.B.2 for the methodology used to calculate the small business adjustment factor for FY 2016. Therefore, the establishment fee for a non-small business for FY 2016 is $15,000 multiplied by 1.040646 plus $855, which equals $16,465.3.

3. Reinspection Fee

Section 744K(c)(1)(B) of the FD&C Act provides that the amount of the FY 2016 reinspection fee is equal to $15,000, multiplied by the inflation adjustment factor for that fiscal year. The inflation adjustment factor for FY 2016 is 1.040646. Therefore, the reinspection fee for FY 2016 is $15,000 multiplied by 1.040646, which equals $15,610. There is no reduction in this fee for small businesses.

B. Methodology for Calculating FY 2016 Adjustment Factors

1. Inflation Adjustment Factor

Section 744K(c)(2) of the FD&C Act specifies the annual inflation adjustment for outsourcing facility fees. The inflation adjustment has two components: One based on FDA's payroll costs and one based on FDA's non-pay costs for the first three of the four previous fiscal years. The payroll component of the annual inflation adjustment is calculated by taking the average change in the FDA's per-full time equivalent (FTE) personnel compensation and benefits (PC&B) in the first three of the four previous fiscal years (see section 744K(c)(2)(A)(ii) of the FD&C Act). FDA's total annual spending on PC&B is divided by the total number of FTEs per fiscal year to determine the average PC&B per FTE.

Table 1 summarizes the actual cost and FTE data for the specified fiscal years, and provides the percent change from the previous fiscal year and the average percent change over the first three of the four fiscal years preceding FY 2016. The 3-year average is 2.2328 percent.

TABLE 1—FDA PC&B'S EACH YEAR AND PERCENT CHANGE

Fiscal year	2012	2013	2014	3-Year average
Total PC&B	$1,824,703,000	$1,927,703,000	$2,054,937,000	
Total FTE	13,382	13,974	14,555	
PC&B per FTE	$136,355	$137,949	$141,184	
Percent change from previous year	3.1843%	1.1690%	2.3451%	2.2328%

Section 744K(c)(2)(A)(ii) of the FD&C Act specifies that this 2.2328 percent should be multiplied by the proportion of PC&B to total costs of an average FTE of FDA for the same three fiscal years.

TABLE 2—FDA PC&B'S AS A PERCENT OF FDA TOTAL COSTS OF AN AVERAGE FTE

Fiscal year	2012	2013	2014	3-Year average
Total PC&B	$1,824,703,000	$1,927,703,000	$2,054,937,000	
Total Costs	$3,550,496,000	$4,151,343,000	4,298,476,000	
PC&B Percent	51.3929%	46.4356%	47.8062%	48.5449%

The payroll adjustment is 2.2328 percent multiplied by 48.5449 percent, or 1.0839 percent.

Section 744K(c)(2)(A)(iii) of the FD&C Act specifies that the portion of the inflation adjustment for non-payroll costs for FY 2016 is equal to the average annual percent change in the Consumer Price Index (CPI) for urban consumers (U.S. City Average; Not Seasonally Adjusted; All items; Annual Index) for the first 3 years of the preceding 4 years of available data, multiplied by the proportion of all non-PC&B costs to total costs of an average FTE of the FDA for the same period.

[1] FY 2016 runs from October 1, 2015, through September 30, 2016.

[2] To qualify for a small business reduction of the FY 2016 establishment fee, entities had to submit their exception requests by April 30, 2015. See section 744K(c)(4)(B) of the FD&C Act. Although the time for requesting a small business exception for FY 2016 has now passed, an entity that wishes to request a small business exception for FY 2017 should consult section 744K(c)(4) of the FD&C Act and section III.D of FDA's guidance for industry entitled ''Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act,'' which can be accessed on FDA's Web site at *http://wcms.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM391102.pdf.*

Table 2 provides the summary data for the percent change in the specified CPI for U.S. cities. These data are published by the Bureau of Labor Statistics and can be found on its Web site at *http://data.bls.gov/cgi-bin/surveymost?cu* by checking the box marked ''U.S. All items, 1982–84 = 100 − CUUR0000SA0'' and then clicking on the ''Retrieve Data'' button.

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN U.S. CITY AVERAGE CPI

Year	2012	2013	2014	3-Year average
Annual CPI	229.594	232.957	236.736	.....
Annual Percent Change	2.0694%	1.4648%	1.6222%	1.7188%

Section 744K(c)(2)(A)(iii) of the FD&C Act specifies that this 1.7188 percent should be multiplied by the proportion of all non-PC&B costs to total costs of an average FTE for the same three fiscal years. The proportion of all non-PC&B costs to total costs of an average FTE of FDA for FYs 2012 to 2014 is 51.4551 percent (100 percent − 48.5449 percent = 51.4551 percent). Therefore, the non-pay adjustment is 1.7188 percent times 51.4551 percent, or 0.8844 percent.

The PC&B component (1.0839 percent) is added to the non-PC&B component (0.8844 percent), for a total inflation adjustment of 1.9683 percent (rounded), and then one is added, making the inflation adjustment 1.019683.

Section 744K(c)(2)(B) of the FD&C Act provides for this inflation adjustment to be compounded after FY 2015. This factor for FY 2016 (1.9683 percent) is compounded by adding one to it, and then multiplying it by one plus the inflation adjustment factor for FY 2015 (2.0558 percent), as published in the **Federal Register** of August 1, 2014 (79 FR 44805). The result of this multiplication of the inflation factors for the 1 year since FY 2015 (1.019683 × 1.020558) becomes the inflation adjustment for FY 2016. For FY 2016, the inflation adjustment is 4.0646 percent (rounded). We then add one, making the FY 2016 inflation adjustment factor 1.040646.

2. Small Business Adjustment Factor

Section 744K(c)(3) of the FD&C Act specifies that in addition to the inflation adjustment factor, the establishment fee for non-small businesses is to be further adjusted for a small business adjustment factor. Section 744K(c)(3)(B) of the FD&C Act provides that the small business adjustment factor is the adjustment to the establishment fee for non-small businesses that is necessary to achieve total fees equaling the amount that FDA would have collected if no entity qualified for the small business exception in section 744K(c)(4) of the FD&C Act. Additionally, section 744K(c)(5)(A) states that in establishing the small business adjustment factor for a fiscal year, FDA shall provide for the crediting of fees from the previous year to the next year if FDA overestimated the amount of the small business adjustment factor for such previous fiscal year.

Therefore, to calculate the small business adjustment to the establishment fee for non-small businesses for FY 2016, FDA must estimate: (1) The number of outsourcing facilities that will pay the reduced fee for small businesses for FY 2016 and (2) the total fee revenue it would have collected if no entity had qualified for the small business exception (*i.e.,* if each outsourcing facility that registers for FY 2016 were to pay the inflation-adjusted fee amount of $15,610).

With respect to (1), FDA estimates that eight entities will qualify for small business exceptions and will pay the reduced fee for FY 2016. With respect to (2), to estimate the total number of outsourcing facilities that will register for FY 2016, FDA used data submitted by outsourcing facilities through the voluntary registration process, which began in December 2013. Accordingly, FDA estimates that 55 outsourcing facilities, including 8 small businesses, will register with FDA in FY 2016.

If the projected 55 outsourcing facilities paid the full inflation-adjusted fee of $15,610, this would result in total revenue of $858,550 in FY 2016 ($15,610 × 55). However, because 8 of the outsourcing facilities expected to register for FY 2016 are estimated to qualify for the small business exception and will pay one-third of the full fee ($5,203 × 8), totaling $41,624 instead of paying the full fee ($15,610 × 8), which totals $124,880. This would leave a shortfall of $83,256 ($124,880 − $41,624).

Additionally, section 744K(c)(5)(A) of the FD&C Act states that in establishing the small business adjustment factor for a fiscal year, FDA shall provide for the crediting of fees from the previous year to the next year if FDA overestimated the amount of the small business adjustment factor for such previous fiscal year. For each year, total target collections are calculated as (15,000 × [inflation adjustment factor] × [number of registrants]). This would have been $887,864 for FY 2015 ($15,308 × 58). However, because FDA did not have the exact number of registrants and had to rely on estimates of the number of small businesses and non-small businesses that would register in FY 2015, FDA's FY 2015 small business adjustment factor resulted in excess collections of $43,094 ($930,958 − $887,864) as of June 30, 2015.[3]

Therefore, to calculate the small business adjustment factor for FY 2016, FDA subtracts the $43,094 overage from FY 2015 from the $83,256 projected shortfall for FY 2016 to arrive at the numerator for the small business adjustment amount, which equals $40,162. This number divided by 47 (the number of expected non-small businesses for FY 2016) is the small business adjustment amount for FY 2016, which is $855. Therefore, the establishment fee for a non-small business for FY 2016 is $15,000 multiplied by 1.040646 plus $855, which equals $16,465.

C. Summary of FY 2016 Fee Rates

TABLE 4—OUTSOURCING FACILITY FEES

Qualified Small Business Establishment Fee	$5,203
Non-Small Business Establishment Fee	16,465
Reinspection Fee	15,610

III. Fee Payment Options and Procedures

A. Establishment Fee

Once an entity submits registration information and FDA has determined that the information is complete, the entity will incur the annual establishment fee. FDA will send an invoice to the entity, via email to the

[3] If FDA receives additional excess collections for FY 2015 after June 30, 2015, then FDA will credit this amount when it establishes the small business adjustment factor for FY 2017.

email address indicated in the registration file, or via regular mail if email is not an option. The invoice will contain information regarding the obligation incurred, the amount owed, and payment procedures. A facility will not be deemed registered as an outsourcing facility until it has paid the annual establishment fee under section 744K of the FD&C Act. Accordingly, it is important that facilities seeking to operate as registered outsourcing facilities pay all fees immediately upon receiving an invoice. If an entity does not pay the full invoiced amount within 15 calendar days after FDA issues the invoice, FDA will consider the submission of registration information to have been withdrawn and adjust the invoice to reflect that no fee is due.

Outsourcing facilities that registered in FY 2015 and wish to maintain their status as an outsourcing facility in FY 2016 must register during the annual registration period that lasts from October 1, 2015, to December 31, 2015. Failure to register and complete payment by December 31, 2015, will result in a loss of status as an outsourcing facility on January 1, 2016. Entities should submit their registration information no later than December 10, 2015, to allow enough time for review of the registration information, invoicing, and payment of fees before the end of the registration period.

B. Reinspection Fee

FDA will issue invoices for each reinspection after the conclusion of the reinspection, via email to the email address indicated in the registration file or via regular mail if email is not an option. Invoices must be paid within 30 days.

C. Fee Payment Procedures

1. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay*. Once you search for your invoice, click ''Pay Now'' to be redirected to Pay.gov. Note that electronic payment options are based on the balance due. Payment by credit card is available for balances less than $50,000. If the balance exceeds this amount, only the ACH option is available. Payments must be drawn on U.S. bank accounts as well as U.S. credit cards.

2. If paying with a paper check: Checks must be in U.S. currency from a U.S. bank and made payable to the Food and Drug Administration. Payments can be mailed to: Food and Drug Administration, P.O. Box 956733, St. Louis, MO 63195–6733. If a check is sent by a courier that requests a street address, the courier can deliver the check to: U.S. Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (**Note:** This U.S. Bank address is for courier delivery only; do not send mail to this address.)

3. If paying with a wire transfer: Use the following account information when sending a wire transfer: New York Federal Reserve Bank, U.S. Dept 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. The originating financial institution may charge a wire transfer fee. An outsourcing facility should ask its financial institution about the fee and add it to the payment to ensure that the order is fully paid. The tax identification number of FDA is 53–0196965.

Dated: July 28, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–18916 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–2372]

Promoting Semantic Interoperability of Laboratory Data; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

The Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the National Library of Medicine (NLM) of the National Institutes of Health are announcing the following public workshop entitled ''FDA/CDC/NLM Workshop on Promoting Semantic Interoperability of Laboratory Data.'' The purpose of this workshop is to receive and discuss input from stakeholders regarding proposed approaches to promoting the semantic interoperability of laboratory data between in vitro diagnostic devices and database systems, including laboratory information systems and electronic health records.

Date and Time: The public workshop will be held on September 28, 2015, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*.

Contact Person: Steven Gitterman, Food and Drug Administration, Center for Devices and Radiological Health, Bldg. 66, Rm. 5518, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–6694, FAX: 301–847–2512, email: *steven.gitterman@fda.hhs.gov*.

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public workshop must register online by 4 p.m. September 18, 2015. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the public workshop will be provided beginning at 7 a.m. (EDT).

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5231, Silver Spring, MD 20993–0002, 301–796–5661, email: *susan.monahan@fda.hhs.gov* no later than 4 p.m. on September 14, 2015.

To register for the public workshop, please visit FDA's Medical Devices News & Events—Workshops & Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*. (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title and affiliation, address, email, and telephone number. Those without Internet access should contact Susan Monahan to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register