thresholds for certain data items to reduce reporting burden. The comment period expired June 29, 2018.

Detailed Discussion of Public Comments

The Federal Reserve received one comment from a banking association. The commenter noted several inconsistencies on the FR Y–9C report form and one inconsistency on the instructions when compared to the Call Report pertaining to Schedule HC–Q Memoranda items 4.b and 4.d, column A and Schedule HC–S Column G instructions and requested clarification on the proper reporting. The draft report form was inadvertently updated to reflect the removal of items 4.b and 4.d and a line item reference on the instructions for Schedule HC–S Column G was also inadvertently struck through. The Board has revised these items so that both the report form and instructions align with the Call Report. Additionally, the commenter noted an inconsistency between the caption on the report form and the caption on the instructions pertaining to *Equity investments without readily determinable fair values* on Schedule HC–F line item 4 on the FR Y–9C report. The Board has updated the instructions so that the report form and instructions align.

The revisions will be implemented as proposed, with the modifications described above, effective for the June 30, 2018, report date.

Board of Governors of the Federal Reserve System, July 25, 2018.

Michele Taylor Fennell,

Assistant Secretary of the Board.

[FR Doc. 2018–16265 Filed 7–30–18; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Patient Safety Organizations: Voluntary Relinquishment From Diagnostic Quality Assurance

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of delisting.

SUMMARY: The Patient Safety Rule authorizes AHRQ, on behalf of the Secretary of HHS, to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' by the Secretary if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. AHRQ has accepted a notification of voluntary relinquishment from Diagnostic Quality Assurance of its status as a PSO, and has delisted the PSO accordingly. Diagnostic Quality Assurance, PSO number P0170, submitted this request for voluntary relinquishment after receiving a Notice of Preliminary Finding of Deficiency.

DATES: The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. The delisting was effective at 12:00 Midnight ET (2400) on July 1, 2018.

ADDRESSES: Both directories can be accessed electronically at the following HHS website: *http://www.pso.ahrq.gov/listed.*

FOR FURTHER INFORMATION CONTACT: Eileen Hogan, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, Room 06N94B, Rockville, MD 20857; Telephone (toll free): (866) 403–3697; Telephone (local): (301) 427–1111; TTY (toll free): (866) 438–7231; TTY (local): (301) 427–1130; Email: *pso@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b–21 to b–26, (Patient Safety Act) and the related Patient Safety and Quality Improvement Final Rule, 42 CFR part 3 (Patient Safety Rule), published in the **Federal Register** on November 21, 2008, 73 FR 70732–70814, establish a framework by which hospitals, doctors, and other health care providers may voluntarily report information to Patient Safety Organizations (PSOs), on a privileged and confidential basis, for the aggregation and analysis of patient safety events.

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs.

AHRQ has accepted a notification from Diagnostic Quality Assurance, a component entity of Quality Star, LLC, to voluntarily relinquish its status as a PSO. Accordingly, Diagnostic Quality Assurance was delisted effective at 12:00 Midnight ET (2400) on July 1, 2018. AHRQ notes that that Diagnostic Quality Assurance submitted this request for voluntary relinquishment following receipt of the Notice of Preliminary Finding of Deficiency sent on April 10, 2018.

More information on PSOs can be obtained through AHRQ's PSO website at *http://www.pso.ahrq.gov.*

Francis D. Chesley, Jr.,

Acting Deputy Director.

[FR Doc. 2018–16327 Filed 7–30–18; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0007]

Biosimilar User Fee Rates for Fiscal Year 2019

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) 2019. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Biosimilar User Fee Amendments of 2017 (BsUFA II), authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological product development; review of certain applications for approval of biosimilar biological products; and each biosimilar biological product approved in a biosimilar biological product application.

BsUFA II directs FDA to establish, before the beginning of each fiscal year, the amount of initial and annual biosimilar biological product development (BPD) fees, the reactivation fee, and the biosimilar biological product application and

program fees for such year. These fees apply to the period from October 1, 2018, through September 30, 2019.

FOR FURTHER INFORMATION CONTACT: David Haas, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE–14202I, Silver Spring, MD 20993–0002, 240–402–9845.

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 amended by BsUFA II (title IV of the FDA Reauthorization Act of 2017, Pub. L. 115–52), authorize the collection of 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 by the sponsor of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application for that product. The sponsor will be assessed an annual BPD fee beginning with the first fiscal year after payment of the reactivation fee.

BsUFA II also authorizes fees for certain biosimilar biological product applications and for each biosimilar biological product identified in an approved biosimilar biological product application (section 744H(a)(2) and (3) of the FD&C Act). Under certain conditions, FDA will grant a small business a waiver from its first biosimilar biological product application fee (section 744H(d)(1) of the FD&C Act).

For FY 2018 through FY 2022, the base revenue amounts for the total revenues from all BsUFA fees are established by BsUFA II. For FY 2019, the base revenue amount is the FY 2018 inflation adjusted fee revenue amount of $40,214,000. The FY 2019 base revenue amount is to be adjusted for inflation and may be reduced, as appropriate, for long-term financial planning purposes.

This document provides fee rates for FY 2019 for the initial and annual BPD fee ($185,409), for the reactivation fee ($370,818), for an application requiring clinical data ($1,746,745), for an application not requiring clinical data ($873,373), and for the program fee ($304,162). These fees are effective on October 1, 2018, and will remain in effect through September 30, 2019. For applications that are submitted on or after October 1, 2018, the new fee schedule must be used.

II. Fee Revenue Amount for FY 2019

The base revenue amount for FY 2019 is $40,214,000 prior to adjustments for inflation and operating reserves (see section 744H(c)(1) and (3) of the FD&C Act).

A. FY 2019 Statutory Fee Revenue Adjustments for Inflation

BsUFA II specifies that the $40,214,000 is to be adjusted for inflation increases for FY 2019 using two separate adjustments—one for personnel compensation and benefits (PC&B) and one for non-PC&B costs (see section 744H(c)(1) of the FD&C Act).

The component of the inflation adjustment for payroll costs shall be one plus the average annual percent change in the cost of all PC&B paid per full-time equivalent (FTE) positions at FDA for the first 3 of the preceding 4 FYs, multiplied by the proportion of PC&B costs to total FDA costs of the process for the review of biosimilar biological product applications for the first 3 of the preceding 4 FYs (see section 744H(c)(1)(B) of the FD&C Act).

Table 1 summarizes the actual cost and FTE data for the specified FYs and provides the percent changes from the previous FYs and the average percent changes over the first 3 of the 4 FYs preceding FY 2019. The 3-year average is 2.4152 percent.

TABLE 1—FDA PC&B EACH YEAR AND PERCENT CHANGES

Fiscal year	2015	2016	2017	3-year average
Total PC&B	$2,232,304,000	$2,414,728,159	$2,581,551,000	.....
Total FTE	15,484	16,381	17,022	.....
PC&B per FTE	144,168	147,408	151,660	.....
Percent Change From Previous Year	2.1136	2.2474	2.8845	2.4152

The statute specifies that this 2.4152 percent be multiplied by the proportion of PC&B costs to the total FDA costs of the process for the review of biosimilar biological product applications. Table 2 shows the PC&B and the total obligations for the process for the review of biosimilar biological product applications for the first 3 of the preceding 4 FYs.

TABLE 2—PC&B AS A PERCENT OF TOTAL COST OF THE PROCESS FOR THE REVIEW OF BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS

Fiscal year	2015	2016	2017	3-year average
Total PC&B	$23,265,434	$26,775,674	$30,707,050	.....
Total Costs	34,817,217	45,569,430	55,814,043	.....

TABLE 2—PC&B AS A PERCENT OF TOTAL COST OF THE PROCESS FOR THE REVIEW OF BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS—Continued

Fiscal year	2015	2016	2017	3-year average
PC&B Percent	66.8216	58.7580	55.0167	60.1988

The payroll adjustment is 2.4152 percent from table 1 multiplied by 60.1988 percent (or 1.4539 percent).

The statute specifies that the portion of the inflation adjustment for non-payroll costs is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Baltimore, DC–MD–VA–WV; 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 costs other than PC&B costs to total costs of the process for the review of biosimilar biological product applications for the first 3 years of the preceding 4 FYs (see section 744H(c)(1)(B) of the FD&C Act). Table 3 provides the summary data for the percent changes in the specified CPI for the Washington-Baltimore area. The data are published by the Bureau of Labor Statistics and can be found on its website at: *https://data.bls.gov/pdq/SurveyOutputServlet?data_tool=dropmap&series_id=CUURA311SA0, CUUSA311SA0.*

TABLE 3—ANNUAL AND THREE-YEAR AVERAGE PERCENT CHANGE IN CPI FOR WASHINGTON-BALTIMORE AREA

Year	2015	2016	2017	3-year average
Annual CPI	155.353	157.180	159.202	.....
Annual Percent Change	0.3268	1.1760	1.2864	0.9297

The statute specifies that this 0.9297 percent be multiplied by the proportion of all costs other than PC&B to total costs of the process for the review of biosimilar biological product applications obligated. Since 60.1988 percent was obligated for PC&B (as shown in table 2), 39.8012 percent is the portion of costs other than PC&B (100 percent minus 60.1988 percent equals 39.8012 percent). The non-payroll adjustment is 0.9297 percent times 39.8012 percent, 0.3700 percent.

Next, we add the payroll adjustment (1.4539 percent) to the non-payroll adjustment (0.3700 percent), for a total inflation adjustment of 1.8239 percent (rounded) for FY 2019.

We then multiply the base revenue amount for FY 2019 ($40,214,000) by one plus the inflation adjustment percentage (1.018239), yielding an inflation-adjusted amount of $40,947,463.

B. FY 2019 Statutory Fee Revenue Adjustments for Operating Reserve

BsUFA II provides for an operating reserve adjustment to allow FDA to adjust the fee revenue and fees for any given fiscal year during BsUFA II, after FY 2018, to maintain an appropriate operating reserve of carryover user fees. Beginning in FY 2019, FDA may reduce the fee revenue and fees for long-term financial planning purposes. Once the capacity planning adjustment is effective (see section 744H(c)(2) of the FD&C Act), which FDA expects to occur in FY 2021, FDA also may, if necessary, increase the fee revenue and fees to maintain not more than 21 weeks of operating reserve of carryover user fees.

As described in the BsUFA II commitment letter, *Biosimilar Biological Product Reauthorization Goals and Procedures Fiscal Years 2018 Through 2022,* FDA is committed to reducing the BsUFA carryover reserve to an amount no greater than 21 weeks of operating reserve of carryover user fees by the end of FY 2022. In support of this commitment, FDA has determined that it shall apply an operating reserve adjustment to lower the FY 2019 target revenue amount by $2,100,000. This would establish an adjusted FY 2019 BsUFA fee revenue amount of $38,847,000 (rounded to the nearest thousand dollars).

III. Fee Amounts for FY 2019

Under section 744H(b)(3)(A) of the FD&C Act, FDA must determine the percentage of the total revenue amount for a fiscal year to be derived from: (1) Initial and annual BPD fees and reactivation fees; (2) biosimilar biological product application fees; and (3) biosimilar biological product program fees. In establishing the fee amounts for the second year of BsUFA II, FDA considered how best to balance the fee allocation to provide stable funding and reasonable fee amounts. In future years, FDA will consider the most appropriate means of allocating the fee amounts to collect the adjusted target revenue amount, subject to the relevant statutory provisions.

A. Application Fees

In establishing the biosimilar biological product application fee amount for FY 2019, FDA considered historical program information as well as input from an annual industry survey. Based on the available information, FDA estimates it will receive nine biosimilar biological product applications requiring clinical data for approval in FY 2019.

FDA will maintain the biosimilar biological product application fee for FY 2019 at the same level as FY 2018, which is $1,746,745. This is estimated to provide a total of $15,720,705 representing 40 percent (rounded to the nearest whole number) of the FY 2019 target revenue amount.

B. Biosimilar Biological Product Program Fee

Under BsUFA II, FDA assesses biosimilar biological product program fees (''program fees''). An applicant in a biosimilar biological product application shall not be assessed more than five program fees for a fiscal year for biosimilar biological products identified in a single biosimilar biological product application (see FD&C Act section 744H(a)(3)(D)). Applicants are assessed a program fee for a fiscal year only for biosimilar biological products identified in a biosimilar biological product application approved as of October 1 of such fiscal year.

Based on available information, FDA estimates that 23 program fees will be

invoiced for FY 2019, including currently approved products and products with the potential to be approved in pending applications with goal dates in FY 2018. For products invoiced in the FY 2019 regular billing cycle, FDA anticipates that zero program fees will be refunded. This is based on observations dating to 2015, when the first biosimilar product was approved.

FDA will maintain the biosimilar biological product program fee for FY 2019 at the same level as FY 2018, which is $304,162. This is estimated to provide a total of $6,995,726, representing 18 percent (rounded to the nearest whole number) of the FY 2019 target revenue amount.

C. Initial and Annual BPD Fees, Reactivation Fees

To estimate the number of participants in the BPD program in FY 2019, FDA must consider the number of new participants in the BPD program (initial BPD), the number of current participants (annual BPD), and the number of participants who will re-enter the BPD program (reactivation).

FDA uses internal data and a survey of BPD sponsors to estimate the total number of participants in the BPD program. In FY 2019, FDA estimates 24 participants entering the BPD program, zero reactivations, and 63 participants to be invoiced for the annual BPD fee for a total of 87 participants in the BPD program in FY 2019.

The remainder of the target revenue of $16,130,569, or 42 percent (rounded to the nearest whole number), is to be collected from the BPD fees. Dividing this amount by the estimated 87 BPD fees to be paid equals a BPD fee amount of $185,409. The reactivation fee is set at twice the initial/annual BPD amount at $370,818. This represents a reduction of the BPD fee from the FY 2018 levels.

IV. Fee Schedule for FY 2019

The fee rates for FY 2019 are displayed in table 4.

TABLE 4—FEE SCHEDULE FOR FY 2019

Fee category	Fee rates for FY 2019
Initial BPD	$185,409
Annual BPD	185,409
Reactivation	370,818
Applications:	
Requiring clinical data	1,746,745
Not requiring clinical data	873,373
Program	304,162

V. Fee Payment Options and Procedures

A. Initial BPD, Reactivation, and Application Fees

The fees established in the new fee schedule apply to FY 2019, *i.e.,* the period from October 1, 2018, through September 30, 2019. 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 for a product and seek to resume participation in such 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 by the sponsor of an IND describing an investigation that FDA determines is intended to support a biosimilar biological product application for that product.

The application fee for a biosimilar biological product is due upon submission of the application (see section 744H(a)(2)(C) of the FD&C Act).

To make a payment of the initial BPD, reactivation, or application fee, complete the Biosimilar User Fee Cover Sheet, available on FDA's website (*https://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. 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* (*Note:* only full payments are accepted. No partial payments can be made online). Once you search for your invoice, click ''Pay Now'' to be redirected to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S bank accounts as well as U.S. credit cards.

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 the FDA website after the user fee ID number is generated.

Please include the user fee ID number on your check, bank draft, or postal money order. Mail your payment to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000. If a check, bank draft, or money order is to be sent by a courier that requests a street address, the courier should deliver your payment 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. If you have any questions concerning courier delivery, contact U.S. Bank at 314–418–4013. This telephone number is only for questions about 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 the 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 for wire transfers is as follows: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53–0196965.

B. Annual BPD and Program Fees

FDA will issue invoices with payment instructions for FY 2019 annual BPD and program fees under the new fee schedule in August 2018. Payment will be due on October 1, 2018. If sponsors join the BPD program after the annual BPD invoices have been issued in August 2018, FDA will issue invoices in December 2018 to firms subject to fees for FY 2019 that qualify for the annual BPD fee after the August 2018 billing. FDA will issue invoices in December 2018 for any annual program fees for FY 2019 that qualify for fee assessments and were not issued in August 2018.

Dated: July 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–16312 Filed 7–30–18; 8:45 am]

BILLING CODE 4164–01–P