21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
"De Novo Classification Process (Evaluation of Automatic Class III Designation)".	De Novo classification process	0910–0844
"Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff".	Q-Submissions	0910–0756
801 and 809	Medical Device Labeling Regulations	0910–0485

Dated: July 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3560]

Biosimilar User Fee Rates for Fiscal Year 2020

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) 2020. 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, 2019, through September 30, 2020.

FOR FURTHER INFORMATION CONTACT: Melissa Hurley, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD 20705–4304, 240–402–4585.

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 the sponsor 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 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 2020, the base revenue amount is the FY 2019 inflation adjusted fee revenue amount of $40,947,463. The FY 2020 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 2020 for the initial and annual BPD fee ($117,987), for the reactivation fee ($235,975), 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, 2019, and will remain in effect through September 30, 2020. For applications that are submitted on or after October 1, 2019, the new fee schedule must be used.

II. Fee Revenue Amount for FY 2020

The base revenue amount for FY 2020 is $40,947,463 prior to adjustments for inflation and operating reserves (see section 744H(c)(1) and (3) of the FD&C Act).

A. FY 2020 Statutory Fee Revenue Adjustments for Inflation

BsUFA II specifies that the $40,947,463 is to be adjusted for inflation increases for FY 2020 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 2020. The 3-year average is 3.1175 percent.

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

Fiscal year	2016	2017	2018	3-Year average
Total PC&B	$2,414,728,159	$2,581,551,000	$2,690,678,000	.....
Total FTE	16,381	17,022	17,023	.....
PC&B per FTE	$147,408	$151,660	$158,061	.....
Percent Change From Previous Year	2.2474%	2.8845%	4.2206%	3.1175%

The statute specifies that this 3.1175 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	2016	2017	2018	3-Year average
Total PC&B	$26,775,674	$30,707,050	$35,477,032	.....
Total Costs	$45,569,430	$55,814,043	$62,604,122	.....
PC&B Percent	58.7580%	55.0167%	56.6688%	56.8145%

The payroll adjustment is 3.1175 percent from table 1 multiplied by 56.8145 percent (or 1.7712 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). As a result of a geographical revision made by the Bureau of Labor and Statistics in January 2018,[1] the ''Washington-Baltimore, DC-MD-VA-WV'' index was discontinued and replaced with two separate indices (*i.e.,* ''Washington-Arlington-Alexandria, DC-VA-MD-WV'' and ''Baltimore-Columbia-Towson, MD''). In order to continue applying a CPI which best reflects the geographic region in which FDA is headquartered and which provides the most current data available, the Washington-Arlington-Alexandria index will be used in calculating the relevant adjustment factors for FY 2020 and subsequent years. Table 3 provides the summary data for the percent changes in the specified CPI for the Washington-Arlington-Alexandria 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=CUURS35ASA0,CUUSS35ASA0.*

TABLE 3—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN CPI FOR WASHINGTON-ARLINGTON-ALEXANDRIA AREA

Year	2016	2017	2018	3-Year average
Annual CPI	253.422	256.221	261.445	.....
Annual Percent Change	1.1003%	1.1045%	2.0389%	1.4146%

The statute specifies that this 1.4146 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 56.8145 percent was obligated for PC&B (as shown in table 2), 43.1855 percent is the portion of costs other than PC&B (100 percent minus 56.8145 percent equals 43.1855 percent). The non-payroll adjustment is 1.4146 percent times 43.1855 percent, 0.6109 percent.

Next, we add the payroll adjustment (1.7712 percent) to the non-payroll adjustment (0.6109 percent), for a total inflation adjustment of 2.3821 percent (rounded) for FY 2020.

We then multiply the base revenue amount for FY 2020 ($40,947,463) by one plus the inflation adjustment percentage (1.023821), yielding an inflation-adjusted amount of $41,923,000 (rounded to the nearest thousand).

[1] The Bureau of Labor Statistics' announcement of the geographical revision can be viewed at *https://www.bls.gov/cpi/additional-resources/geographic-revision-2018.htm.*

B. FY 2020 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. FDA has determined that it shall not apply an operating reserve adjustment to lower the FY 2020 target revenue amount as FDA appears on track to reduce the carryover reserve to the committed level.

III. Fee Amounts for FY 2020

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 third 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 2020, FDA considered historical program information as well as input from an annual industry survey. Based on the available information, FDA estimates it will receive 10 biosimilar biological product applications requiring clinical data for approval in FY 2020.

FDA will maintain the biosimilar biological product application fee for FY 2020 at the same level as FY 2019, which is $1,746,745. This is estimated to provide a total of $17,467,450 representing 42 percent (rounded to the nearest whole number) of the FY 2020 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 42 program fees will be invoiced for FY 2020, including currently approved products and products with the potential to be approved in pending applications with goal dates in FY 2019. For products invoiced in the FY 2020 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 2020 at the same level as FY 2019, which is $304,162. This is estimated to provide a total of $12,774,804, representing 30 percent (rounded to the nearest whole number) of the FY 2020 target revenue amount.

C. Initial and Annual BPD Fees, Reactivation Fees

To estimate the number of BPD fees to be paid in FY 2020, FDA must consider the number of new BPD programs, the number of current BPD programs, and the number of BPD programs that will be reactivated. These estimates provide information that, when aggregated, allows FDA to set BPD fees (initial BPD fees, annual BPD fees, reactivation fees).

FDA uses internal data and a survey of BPD sponsors to estimate the total number of BPD programs for FY 2020. In FY 2020, FDA estimates 25 new BPD programs, one reactivation (a single reactivation is weighted as two BPD fees), and 72 BPD programs to be invoiced for the annual BPD fee, for a total equivalent of 99 BPD fees assessed in FY 2020.

The remainder of the target revenue of $11,680,746, or 28 percent (rounded to the nearest whole number), is to be collected from the BPD fees. Dividing this amount by the estimated 99 BPD fees to be paid equals an initial BPD and annual BPD fee amount of $117,987. The reactivation fee is set at twice the initial/annual BPD amount at $235,975. This represents a reduction of the BPD fees from the FY 2019 levels.

IV. Fee Schedule for FY 2020

The fee rates for FY 2020 are displayed in table 4.

TABLE 4—FEE SCHEDULE FOR FY 2020

Fee category	Fee rates for FY 2020
Initial BPD	$117,987
Annual BPD	117,987
Reactivation	235,975
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 2020, *i.e.,* the period from October 1, 2019, through September 30, 2020. 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). 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. 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.

If a check, bank draft, or postal money order is submitted, make it payable to the order of the Food and Drug Administration and include the user fee ID number to ensure that the payment is applied to the correct fee(s). Payments can be mailed 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.

For payments made by wire transfer, include the unique user fee ID number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID number, the payment may not be applied. The originating financial institution may charge a wire transfer fee. Include applicable wire transfer fees with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The following account information should be used to send payments by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33. FDA's tax identification number is 53–0196965.

B. Annual BPD and Program Fees

FDA will issue invoices with payment instructions for FY 2020 annual BPD and program fees under the new fee schedule in August 2019. Payment will be due on October 1, 2019. If sponsors join the BPD program after the annual BPD invoices have been issued in August 2019, FDA will issue invoices in December 2019 to firms subject to fees for FY 2020 that qualify for the annual BPD fee after the August 2019 billing. FDA will issue invoices in December 2019 for any annual program fees for FY 2020 that qualify for fee assessments and were not issued in August 2019.

Dated: July 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3523]

Animal Generic Drug User Fee Rates and Payment Procedures for Fiscal Year 2020

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the fee rates and payment procedures for fiscal year (FY) 2020 generic new animal drug user fees. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Animal Generic Drug User Fee Amendments of 2018 (AGDUFA III), authorizes FDA to collect user fees for certain abbreviated applications for generic new animal drugs, for certain generic new animal drug products, and for certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs. This notice establishes the fee rates for FY 2020.

FOR FURTHER INFORMATION CONTACT: Visit FDA's website at *https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/default.htm,* or contact Lisa Kable, Center for Veterinary Medicine (HFV–10), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–6888, *Lisa.Kable@fda.hhs.gov.* For general questions, you may also email the Center for Veterinary Medicine (CVM) at *cvmagdufa@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 741 of the FD&C Act (21 U.S.C. 379j–21) establishes three different types of user fees: (1) Fees for certain types of abbreviated applications for generic new animal drugs; (2) annual fees for certain generic new animal drug products; and (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (21 U.S.C. 379j–21(a)). When certain conditions are met, FDA will waive or reduce fees for generic new animal drugs intended solely to provide for a minor use or minor species indication (21 U.S.C. 379j–21(d)).

For FY 2019 through FY 2023, the FD&C Act establishes a yearly base revenue amount and percentages for each of these fee categories (21 U.S.C. 379j–21(b)). Base revenue amounts are subject to adjustment for inflation and workload. Workload increases will be adjusted for excess collections after FY 2020, if applicable (21 U.S.C. 379j–21(c)). The target revenue amounts for each fee category for FY 2020, are as follows: For application fees, the target revenue amount is $5,037,750; for product fees, the target revenue amount is $7,556,625; and for sponsor fees, the target revenue amount is $7,556,625.

For FY 2020, the generic new animal drug user fee rates are: $493,897 for each abbreviated application for a generic new animal drug other than those subject to the criteria in section 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)); $246,949 for each abbreviated application for a generic new animal drug subject to the criteria in section 512(d)(4); $16,645 for each generic new animal drug product; $172,329 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; $129,247 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and $86,165 for each generic new animal drug sponsor paying 50 percent of the sponsor fee. FDA will issue invoices for FY 2020 product and sponsor fees by December 31, 2019. These fees will be due by January 31, 2020. The application fee rates are effective for all abbreviated applications for a generic new animal drug submitted on or after October 1, 2019, and will remain in effect through September 30, 2020. Applications will not be accepted for