



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-N-0708]

#### Biosimilar User Fee Rates for Fiscal Year 2022

**AGENCY:** Food and Drug Administration, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or we) is announcing the rates for biosimilar user fees for fiscal year (FY) 2022. 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, 2021, through September 30, 2022.

**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 reengage 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 2022, the base revenue amount is the FY 2021 inflation-adjusted fee revenue amount of \$42,493,066. The FY 2022 base revenue amount

is to be adjusted for inflation and to reflect changes in the resource capacity needs for the process for the review of biosimilar biological product applications. Additionally, it may be reduced, as appropriate, for long-term financial planning purposes.

This document provides fee rates for FY 2022 for the initial and annual BPD fee (\$57,184), for the reactivation fee (\$114,368), 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, 2021, and will remain in effect through September 30, 2022. For applications that are submitted on or after October 1, 2021, the new fee schedule must be used.

## II. Fee Revenue Amount for FY 2022

The base revenue amount for FY 2022 is \$42,493,066 prior to adjustments for inflation, resource capacity, and operating reserves (see section 744H(c)(1) through (3) of the FD&C Act).

### *A. FY 2022 Statutory Fee Revenue Adjustments for Inflation*

BsUFA II specifies that the \$42,493,066 is to be adjusted for inflation increases for FY 2022 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 fiscal years, 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 fiscal years (see section 744H(c)(1)(B) of the FD&C Act).

Table 1 summarizes the actual cost and FTE data for the specified fiscal years and provides the percent changes from the previous fiscal years and the average percent changes over the first 3 of the 4 fiscal years preceding FY 2022. The 3-year average is 2.7383 percent.

Table 1.--FDA PC&B Each Year and Percent Changes

Fiscal Year	2018	2019	2020	3-Year Average
Total PC&B	\$2,690,678,000	\$2,620,052,000	\$2,875,592,000	

Total FTE	17,023	17,144	17,535	
PC&B per FTE	\$158,061	\$152,826	\$163,992	
Percent Change From Previous Year	4.2206%	-3.3120%	7.3063%	2.7383%

The statute specifies that this 2.7383 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 fiscal years.

Table 2.--PC&B as a Percent of Total Cost of the Process for the Review of Biosimilar Biological Product Applications

Fiscal Year	2018	2019	2020	3-Year Average
Total PC&B	\$35,477,032	\$32,946,252	\$25,445,175	
Total Costs	\$62,604,122	\$65,210,467	\$56,798,694	
PC&B Percent	56.6688%	50.5230%	44.7989%	50.6636%

The payroll adjustment is 2.7383 percent from table 1 multiplied by 50.6636 percent (or 1.3873 percent).

The statute specifies that the portion of the inflation adjustment for nonpayroll 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 fiscal years (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,<sup>1</sup> 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

<sup>1</sup> 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>.

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](https://data.bls.gov/pdq/SurveyOutputServlet?data_tool=dropmap&series_id=CUURS35ASA0,CUUSS35ASA0).

Table 3.--Annual and Three-Year Average Percent Change in CPI for Washington-Arlington-Alexandria Area

Year	2018	2019	2020	3-Year Average
Annual CPI	261.445	264.777	267.157	
Annual Percent Change	2.0389%	1.2745%	0.8989%	1.4041%

The statute specifies that this 1.4041 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 50.6636 percent was obligated for PC&B (as shown in table 2), 49.3364 percent is the portion of costs other than PC&B (100 percent minus 50.6636 percent equals 49.3364 percent). The nonpayroll adjustment is 1.4041 percent times 49.3364 percent, 0.6927 percent.

Next, we add the payroll adjustment (1.3873 percent) to the nonpayroll adjustment (0.6927 percent), for a total inflation adjustment of 2.0800 percent (rounded) for FY 2022.

We then multiply the base revenue amount for FY 2022 (\$42,493,066) by one plus the inflation adjustment (1.0208), yielding an inflation-adjusted amount of \$43,376,922.

#### *B. FY 2022 Statutory Fee Revenue Adjustments for Capacity Planning*

The statute specifies a process to establish and implement a capacity planning adjustment (CPA) to adjust the total revenue amount to reflect changes in the resource capacity needs for the process for the review of biosimilar biological product applications (see section 744H(c)(2) of the FD&C Act). Following a process required in statute, FDA established the capacity planning adjustment methodology and first applied it in the setting of FY 2021 fees. The establishment of this new methodology is described in the *Federal Register* at 85 FR 47220.

The CPA methodology consists of four steps:

1. Forecast workload volumes: predictive models estimate the volume of workload for the upcoming fiscal year.
2. Forecast the resource needs: forecast algorithms are generated utilizing time reporting data. These algorithms estimate the required demand in FTEs<sup>2</sup> for direct review-related effort. This is then compared to current available resources for the direct review-related workload.
3. Assess the resource forecast in the context of additional internal factors: program leadership examines operational, financial, and resourcing data to assess whether the FDA will be able to utilize additional funds during the fiscal year and the funds are required to support additional review capacity. FTE amounts are adjusted, if needed.
4. Convert the FTE need to dollars: utilizing the FDA’s fully loaded FTE cost model, the final feasible FTEs are converted to an equivalent dollar amount.

The following section outlines the major components of the FY 2022 BsUFA CPA.

Table 4 summarizes the forecasted workload volumes for BsUFA in FY 2022 based on predictive models, as well as historical actuals from FY 2020 for comparison.

Table 4.--BsUFA Actual FY 2020 Workload Volumes & Predicted FY 2022 Workload Volumes

Workload Category	FY 2020 Actuals	FY 2022 Predictions
Supplements with Clinical Data	2	4
Labeling Supplements	4	8
Manufacturing Supplements	79	111
Biosimilar Biological Product Applications	7	7
BsUFA Industry Meetings (BIA, BPD Type 1-4)	95	120
Participating BPD Programs	104	131

Utilizing the resource forecast algorithms, the forecasted workload volumes for FY 2022 were then converted into estimated FTE needs for FDA’s BsUFA direct review-related work. The resulting expected FY 2022 FTE need for BsUFA was compared to current onboard capacity for BsUFA direct review-related work to determine the FY 2022 resource delta, as summarized in table 5.

Table 5.--FY 2022 BsUFA Resource Delta

Current Resource Capacity	FY 2022 Resource Forecast	Predicted FY 2022 FTE Delta
54	71	17

<sup>2</sup> Full-time equivalents refers to a paid staff year, rather than a count of individual employees.

The projected 17 FTE delta was then assessed by FDA in the context of additional operational and internal factors to ensure that a fee adjustment is only made for resources which can be utilized in the fiscal year and for which funds are required to support additional review capacity. FDA determined that the expected net FTE gains could be funded through the expected FY 2022 collections amount without a further adjustment from the CPA. In summary, after accounting for these internal factors, FDA determined that in FY 2022 the BsUFA fee amounts did not need adjustment from the CPA to provide funds for the realistic estimated net FTE gains.

Table 6.--FY 2022 BsUFA CPA

Additional FTEs for FY 2022	Cost for Each Additional FTE	FY 2022 BsUFA CPA
0	\$312,185	\$0

Although an adjustment to the fee amounts for resource needs by the CPA will not be made in FY 2022, FDA will evaluate the need for a fee adjustment from the CPA in future fiscal years and will make adjustments as warranted.

*C. FY 2022 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, 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*,<sup>3</sup> 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. Based on estimates published in the FY

<sup>3</sup> See: <https://www.fda.gov/media/100573/download>.

2021 update to the BsUFA II Five-Year Financial Plan, FDA currently shows an operating reserve amount that currently exceeds the committed amount. As such, FDA is applying a downward operating reserve adjustment of \$3,336,686 (rounded to the nearest dollar), an amount equivalent to 4 weeks of operations. With this operating reserve adjustment, the inflation-adjusted amount, \$43,376,922, will be lowered by \$3,336,686, yielding the FY 2022 target revenue amount of \$40,040,000 (rounded to the nearest thousand).

### III. Fee Amounts for FY 2022

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 final year of BsUFA II, FDA considered how best to balance the fee allocation to provide stable funding and reasonable fee amounts.

#### *A. Application Fees*

In establishing the biosimilar biological product application fee amount for FY 2022, FDA utilized an average of the 3 most recently completed fiscal years (i.e., FY 2018-2020) of biosimilar biological product application submissions. Based on the available information, FDA estimates it will receive 7 biosimilar biological product applications requiring clinical data for approval in FY 2022.

FDA will maintain the biosimilar biological product application fee for FY 2022 at the same level as FY 2021, which is \$1,746,745. This is estimated to provide a total of \$12,227,215 representing 31 percent (rounded to the nearest whole number) of the FY 2022 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 section 744H(a)(3)(D) of the FD&C Act).

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 67 program fees will be invoiced for FY 2022, including currently approved products and products with the potential to be approved in pending applications with goal dates in FY 2021. For products invoiced in the FY 2022 regular billing cycle, FDA anticipates that zero program fees will be refunded.

FDA will maintain the biosimilar biological product program fee for FY 2022 at the same level as FY 2021, which is \$304,162. This is estimated to provide a total of \$20,378,854, representing 51 percent (rounded to the nearest whole number) of the FY 2022 target revenue amount.

### *C. Initial and Annual BPD Fees, Reactivation Fees*

To estimate the number of BPD fees to be paid in FY 2022, 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 analyzes available data to estimate the total number of BPD programs for FY 2022. In FY 2022, FDA estimates 39 new BPD programs, no reactivations (a single reactivation is weighted as two BPD fees), and 91 BPD programs (out of 92 invoiced) to pay the annual BPD fee, yielding a total estimated equivalent of 130 BPD fees to be collected in FY 2022.

The remainder of the target revenue of \$7,433,931, or 19 percent (rounded to the nearest whole number), is to be collected from the BPD fees. Dividing this amount by the estimated 130 BPD fees to be paid equals an initial BPD and annual BPD fee amount of \$57,184. The

reactivation fee is set at twice the initial/annual BPD amount at \$114,368 (rounded to the nearest dollar). This represents a reduction of the BPD fees from the FY 2021 levels.

#### IV. Fee Schedule for FY 2022

The fee rates for FY 2022 are displayed in table 7.

Table 7.--Fee Schedule for FY 2022

Fee Category	Fee Rates for FY 2022
Initial BPD	\$57,184
Annual BPD	\$57,184
Reactivation	\$114,368
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 2022, i.e., the period from October 1, 2021, through September 30, 2022. 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) and ID number 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 2022 annual BPD and program fees under the new fee schedule in August 2021. Payment will be due on October 1, 2021. If sponsors join the BPD program after the annual BPD invoices have been issued in August 2021, FDA will issue invoices in December 2021 to firms subject to fees for FY 2022 that qualify for the annual BPD fee after the August 2021 billing. FDA will issue invoices in December 2021 for any annual program fees for FY 2022 that qualify for fee assessments and were not issued in August 2021.

Dated: July 23, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-16084 Filed: 7/27/2021 8:45 am; Publication Date: 7/28/2021]