TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity/21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
812.36(f); treatment IDE reports	1	1	1	20	20
812.150; non-significant risk study reports	1	1	1	6	6
Total			5,513		53,897

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

Our estimate of the average reporting burden is based on our continued experience with the information collection. We have adjusted the currently approved burden to reflect an increase we attribute to Agency rulemaking that has become effective (OMB control number 0910–AG48) since our last evaluation. Regulations in part 812 were amended to provide for reporting associated with the acceptance of data from clinical investigations conducted outside the United States.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
812.2(c)(3); records regarding leftover specimens not individually identifiable used in certain studies	700	1	700	4	2,800
812.28(d); records for clinical investigations conducted outside United States	1,500	1	1,500	1	1,500
812.140; retention of records	1,249	3.09	3,865	1.9937	7,706
Total					12,006

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

In the guidance document ''Informed Consent For In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable'' (April 2006), available for download at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-informed-consent-vitro-diagnostic-device-studies-using-leftover-human-specimens-are-not,* FDA communicates its enforcement policy with regard to the informed consent regulations (as required by section 520(g) of the FD&C Act and 21 CFR part 50) for in vitro diagnostic device studies that are conducted using leftover specimens and that meet the criteria for exemption from IDE regulation at 21 CFR 812.2(c)(3). We include burden that may be attributable to FDA recommendations that sponsors of studies document certain information, in table 2, row 1. We have otherwise adjusted our estimate upward of the average recordkeeping burden attributable to provisions in part 812 to reflect those requirements associated with clinical investigations conducted outside the United States, and in recognition of the required retention period for records.

Dated: September 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21852 Filed 10–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2352]

Biosimilar User Fee Rates for Fiscal Year 2023

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the rates for biosimilar user fees for fiscal year (FY) 2023. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Biosimilar User Fee Amendments of 2022 (BsUFA III), 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 III 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, 2022, through September 30, 2023.

FOR FURTHER INFORMATION CONTACT: Robert Marcarelli, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD, 301–796–7223, and the User Fees Support Staff at *OO-OFBAP-OFM-UFSS-Government@fda.hhs.gov.*

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 III, 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 7 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, the sponsor discontinues participation in FDA's BPD program for the product, or the sponsor has been administratively removed from the 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 or has been administratively removed from the BPD program for a product and wants to reengage with FDA on development of the product, the sponsor must pay all annual BPD fees previously assessed for such product and still owed, and a reactivation fee to resume participation in the program. The sponsor must pay the reactivation fee by the earlier of the following dates: (1) no later than 7 calendar days after FDA grants the sponsor's request for a BPD meeting for that product or (2) 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 III 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 2023 through FY 2027, the base revenue amounts for the total revenues from all BsUFA fees are established by BsUFA III. For FY 2023, the base revenue amount is the FY 2022 total revenue amount minus the operating reserve adjustment, which equates to the amount of $43,376,922. The FY 2023 base revenue amount is to be adjusted by the inflation adjustment, strategic hiring and retention adjustment, capacity planning adjustment (CPA), operating reserve adjustment, and the additional dollar amount. Each of these adjustments will be discussed in the sections below.

This document provides fee rates for FY 2023 for the initial and annual BPD fee ($47,325), for the reactivation fee ($94,650), 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, 2022, and will remain in effect through September 30, 2023. For applications that are submitted on or after October 1, 2023, the new fee schedule must be used.

II. Fee Revenue Amount for FY 2023

The base revenue amount for FY 2023 is $43,376,922 prior to adjustments for inflation, strategic hiring and retention, capacity planning, operating reserves, and the additional dollar amount (see section 744H(b)–(c) of the FD&C Act).

A. FY 2023 Statutory Fee Revenue Adjustments for Inflation

BsUFA III specifies that the $43,376,922 is to be adjusted for inflation increases for FY 2023 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 2023. The 3-year average is 1.3918 percent.

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

	FY 2019	FY 2020	FY 2021	3-Year Average
Total PC&B	$2,620,052,000	$2,875,592,000	$3,039,513,000	
Total FTE	$17,144	$17,535	$18,501	
PC&B per FTE	$152,826	$163,992	$164,289	
Percent Change From Previous Year	-3.3120%	7.3063%	0.1811%	1.3918%

The statute specifies that this 1.3918 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

	FY 2019	FY 2020	FY 2021	3-Year Average
Total PC&B	$32,946,252	$25,445,175	$30,932,267	
Total Costs	$65,210,467	$56,798,694	$55,928,075	
PC&B Percent	50.5230%	44.7989%	55.3072%	50.2097%

The payroll adjustment is 1.3918 percent from table 1 multiplied by 50.2097 percent (or 0.6988 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-Arlington-Alexandria, DC-VA-MD-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). Table 3 provides the summary data for the percent changes in the specified CPI for the Washington-Arlington-Alexandria area.[1]

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

	2019	2020	2021	3-Year Average
Annual CPI	264.78	267.16	277.73	
Annual Percent Change	1.2745%	0.8989%	3.9568%	2.0434%

The statute specifies that this 2.0434 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 50.2097 percent was obligated for PC&B (as shown in table 2), 49.7903 percent is the portion of costs other than PC&B (100 percent minus 50.2097 percent equals 49.7903 percent). The non-payroll adjustment is 2.0434 percent times 49.7903 percent, 1.0174 percent.

Next, we add the payroll adjustment (0.6988 percent) to the nonpayroll adjustment (1.0174 percent), for a total inflation adjustment of 1.7162 percent (rounded) for FY 2023.

We then multiply the base revenue amount for FY 2023 ($43,376,922) by the inflation adjustment percentage (1.7162 percent), yielding an inflation adjustment of $744,435. Adding this amount yields an inflation-adjusted amount of $44,121,357.

B. Strategic Hiring and Retention Adjustment

The statute specifies that for each fiscal year, after the annual base revenue is adjusted for inflation, FDA shall further increase the fee revenue and fees by the strategic hiring and retention adjustment, which is $150,000 for FY 2023 (see section 744H(c)(2) of the FD&C Act).

C. FY 2023 Statutory Fee Revenue Adjustments for Capacity Planning

The statute specifies that the fee revenue and fees shall be further adjusted to reflect changes in the resource capacity needs for the process for the review of biosimilar biological product applications (see section 744H(c)(3) 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 methodology is described in the **Federal Register** at 85 FR 47220. This methodology includes a continuous, iterative improvement approach, under which the Agency intends to refine its data and estimates for the core review activities to improve their accuracy over time.

Beginning in FY 2023, updates were made to refine the time reporting categories included within the CPA. As such, time reporting data and baseline capacity have been revised to match the refinements; in the coming fiscal years, additional updates are anticipated to be made to account for additional activities that are also directly related to the direct review of biosimilar biological product applications and supplements, including additional formal meeting types and the direct review of postmarketing commitments and requirements, the direct review of risk evaluation and mitigation strategies, and the direct review of annual reports for approved biosimilar biological products.

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[2] 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 FDA will be able to utilize additional funds during the fiscal year and those funds are required to support additional review capacity. FTE amounts are adjusted, if needed.

4. Convert the FTE need to dollars: utilizing 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 2023 BsUFA III CPA. Table 4 summarizes the forecasted workload volumes for BsUFA III in FY 2023 based on predictive models, as well as historical actuals from FY 2021 for comparison.

[1] 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.*

[2] Full-time equivalents refer to a paid staff year, rather than a count of individual employees.

Table 4.--BsUFA III Actual FY 2021 Workload Volumes & Predicted FY 2023 Workload Volumes

Workload Category	FY 2021 Actuals	FY 2023 Predictions
Supplements with Clinical Data	8	8
Labeling Supplements	14	10
Manufacturing Supplements	95	127
Biosimilar Biological Product Applications	9	8
BsUFA Industry Meetings (BIA, BPD Type 1-4)	113	127
Participating BPD Programs	117	122

Utilizing the resource forecast algorithms, the forecasted workload volumes for FY 2023 were then converted into estimated FTE needs for FDA's BsUFA III direct review-related work. The resulting expected FY 2023 FTE need for BsUFA III was compared to current onboard capacity for BsUFA III direct review-related work to determine the FY 2023 resource delta, as summarized in table 5.

Table 5.--FY 2023 BsUFA III Resource Delta

Current Resource Capacity	FY 2023 Resource Forecast	Predicted FY 2023 FTE Delta
50	67	17

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 recognizes that FY 2023 presents significant hiring commitments for the Agency, including the hiring goals set forth for FY 2023 per the BsUFA III Commitment Letter, as well as hiring commitments for other user fee programs. In addition, current labor market conditions may present continuing hiring and retention challenges. In light of these commitments and challenges, FDA determined that there is no need for an adjustment from the CPA to provide funds for the realistic estimated net FTE gains.

Table 6.--FY 2023 BsUFA III CPA

Additional FTEs for FY 2023	Cost for Each Additional FTE	FY 2023 BsUFA III CPA
0	$316,349	$0

Although an adjustment to the fee amounts for resource needs by the CPA will not be made in FY 2023, FDA will evaluate the need for a fee adjustment from the CPA in future fiscal years and will make adjustments as warranted.

D. FY 2023 Additional Dollar Amount

For FY 2023 and FY 2024, BsUFA III provides an additional dollar amount for additional FTE for the biosimilar biological product review program to support enhancements outlined in the BsUFA III Commitment Letter. For FY 2023, the statute directs FDA to further increase the fee revenue and fees by the additional dollar amount, which is $4,428,886 for FY 2023 (see section 744H(b)(1)(F) of the FD&C Act).

E. FY 2023 Statutory Fee Revenue Adjustments for Operating Reserve

BsUFA III sets forth an operating reserve adjustment to the fee revenue and fees. Specifically, for FY 2023, the statute directs FDA: (1) to increase the fee revenue and fees if such an adjustment is necessary to provide for at least 10 weeks of operating reserves of carryover user fees for the process for the review of biosimilar biological product applications and (2) if FDA has carryover balances for such process in excess of 33 weeks of such operating reserves, to decrease such fee revenue and fees to provide for not more than 33 weeks of such operating reserves (see section 744H(c)(4) of the FD&C Act).

To determine whether the operating reserve adjustment will be applied, FDA uses an estimated adjusted revenue amount which estimates FDA's costs of operations for BsUFA for FY 2023. To calculate the estimated adjusted revenue amount, the FY 2023 annual base revenue is adjusted for inflation, strategic hiring and retention, capacity planning, and the additional dollar amount. The annual base revenue amount for FY 2023 is $43,376,922. This amount is then multiplied by 1.7162 percent yielding an inflation-adjusted revenue amount of $44,121,357. The next adjustment is the strategic hiring and retention adjustment of $150,000. Adding the strategic hiring and retention adjustment of $150,000 to the inflation-adjusted revenue amount results in $44,271,357. Next, adding the FY 2023 CPA of $0 results in the capacity planning-adjusted revenue amount of $44,271,357. Next, adding the additional dollar amount of $4,428,886 generates the estimated adjusted revenue amount. For FY 2023, the BsUFA estimated adjusted revenue amount is $48,700,243.

To calculate the 10-week and 33-week threshold amounts for the FY 2023 operating reserve adjustment, the estimated adjusted revenue amount is divided by 52, resulting in a $936,543 cost of operation for 1 week. The unrounded 1-week value is then multiplied by 10 weeks to generate the 10-week operating reserve threshold amount for FY 2023 of $9,365,431. The unrounded 1-week value is multiplied by 33 to generate the 33-week operating reserve threshold amount for FY 2023 of $30,905,923.

To calculate the estimated operating reserve of carryover user fees at the end of FY 2022, FDA estimated the operating reserves of carryover fees at the end of July 2022. The balance of operating reserves of carryover fees at the end of July 2022 is combined with the forecasted collections and obligations for the remainder of FY 2022 to generate a full year estimate for FY 2022. The estimated operating reserve of

carryover user fees at the end of FY 2022 is $38,005,821.

The estimated operating reserve of carryover user fees at the end of FY 2022 of $38,005,821 exceeds the 33-week threshold allowable operating reserve of carryover user fees for FY 2023 of $30,905,923. As such, FDA is applying a downward operating reserve adjustment of $7,099,898 (rounded to the nearest dollar), an amount equivalent to a reduction of approximately 8 weeks of operations, to bring the operating reserve of carryover user fees to $30,905,923 or 33 weeks of operations at the start of FY2023. With this Operating Reserve Adjustment, the estimated adjusted revenue amount of $48,700,243 will be lowered by $7,099,898, yielding the FY 2023 target revenue amount of $41,600,000 (rounded to the nearest thousand).

III. Fee Amounts for FY 2023

Under section 744H(b)(2)(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. As described above, a downward operating reserve adjustment is required for FY 2023. The operating reserve adjustment in subsequent years may not be as large. As such, the target revenue in FY 2023 may be lower than in prior or future years, and thereby the fee amounts may also be lower than in prior or future years.

A. Application Fees

In establishing the biosimilar biological product application fee amount for FY 2023, FDA utilized an average of the three most recently completed fiscal years (*i.e.,* FY 2019 to 2022) of biosimilar biological product application submissions. Based on the available information, FDA estimates it will receive eight biosimilar biological product applications requiring clinical data for approval in FY 2023 and zero applications that do not require clinical data.

For FY 2023, FDA will maintain the biosimilar biological product application fee at the same level as FY 2022, which is $1,746,745 for applications requiring clinical data. Applications not requiring clinical data pay half that fee, or $873,373. This is estimated to provide a total of $13,973,960 representing 34 percent (rounded to the nearest whole number) of the FY 2023 target revenue amount.

B. Biosimilar Biological Product Program Fee

Under BsUFA III, 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 for biosimilar biological products that are identified in a biosimilar biological product application approved as of October 1 of such fiscal year; that may be dispensed only under prescription pursuant to section 503(b) of the FD&C Act; and that, as of October 1 of such fiscal year, do not appear on a list developed and maintained by FDA of discontinued biosimilar biological products. An approved biosimilar biological product that appears on the list of discontinued biosimilar biological products as of October 1 of a fiscal year would also be assessed the program fee if it is removed from the discontinued list during the fiscal year and the other statutory criteria for fee assessment are satisfied (see section 744H(a)(3)(E)(ii) of the FD&C Act).

Based on available information, FDA estimates that 72 program fees will be invoiced for FY 2023. For products invoiced in the FY 2023 regular billing cycle, FDA anticipates that zero program fees will be refunded.

For FY 2023, the biosimilar biological product program fee is $304,162. This is estimated to provide a total of $21,899,664, representing 53 percent (rounded to the nearest whole number) of the FY 2023 target revenue amount.

C. Initial and Annual BPD Fees, and Reactivation Fees

To estimate the number of BPD fees to be paid in FY 2023, 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 analyzed available data to estimate the total number of BPD programs for FY 2023. In FY 2023, FDA estimates approximately 23.5 new BPD programs, no reactivations (a single reactivation is weighted as two BPD fees), and approximately 97.75 BPD programs to pay the annual BPD fee, yielding a rounded total estimated equivalent of 121 BPD fees to be collected in FY 2023. The remainder of the target revenue of $5,726,376 or 14 percent (rounded to the nearest whole number), is to be collected from the BPD fees. Dividing this amount by the estimated 121 BPD fees to be paid equals an initial BPD and annual BPD fee amount of $47,325. The reactivation fee is set at twice the initial/annual BPD amount at $94,650 (rounded to the nearest dollar).

IV. Fee Schedule for FY 2023

The fee rates for FY 2023 are displayed in table 7.

Table 7.--Fee Schedule for FY 2023

Fee Category	Fee Rates for FY 2023
Initial BPD	$47,325
Annual BPD	$47,325
Reactivation	$94,650
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 2023, *i.e.,* the period from October 1, 2022, through September 30, 2023. 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 7 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 or have been administratively removed from the BPD program for a product, and seek to resume participation in such program must pay all annual biosimilar biological product development fees previously assessed for such product and still owed and the reactivation fee by the earlier of the following dates: no later than 7 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 *www.pay.gov,* a web-based payment application, for online electronic payment. The *www.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 *www.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 2023 annual BPD and program fees under the new fee schedule in October 2022. Under sections 744H(a)(1)(B)(ii) and 744H(a)(3)(B) of the FD&C Act, annual BPD and program fees are generally due on October 3, 2022. However, given the late date of the BsUFA reauthorization, invoices should be paid within 30 days of invoice.

FDA will issue invoices in December 2023 for any products that qualify for the annual program fee after the October 2022 billing.

C. Waivers and Refunds

To qualify for consideration for a waiver under section 744H(d) of the FD&C Act, or the return of any fee paid under section 744H of the FD&C Act, including if the fee is claimed to have been paid in error, a person shall submit to FDA a written request justifying such waiver or return and, except as otherwise specified in section 744H of the FD&C Act, such written request shall be submitted to FDA not later than

180 days after such fee is due. Such written request shall include any legal authorities under which the request is made. See section 744H(h) of the FD&C Act.

Dated: October 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21965 Filed 10–5–22; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–1981]

Facility Readiness: Goal Date Decisions Under Generic Drug User Fee Amendments; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Facility Readiness: Goal Date Decisions Under GDUFA.'' This draft guidance provides information to applicants on how FDA will use information related to a facility's readiness for inspection as certified on Form FDA 356h to set a goal date for an original abbreviated new drug application (ANDA) submitted under the Federal Food, Drug, and Cosmetic Act. This guidance incorporates a program enhancement agreed upon by the Agency and industry as part of the negotiations relating to reauthorization of the Generic Drug User Fee Amendments (GDUFA) and as described in ''GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023–2027'' (GDUFA III commitment letter).

DATES: Submit either electronic or written comments on the draft guidance by December 6, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2022–D–1981 for ''Facility Readiness: Goal Date Decisions Under GDUFA.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission.

You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Karen Takahashi, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6686, Silver Spring, MD 20993–0002, 301–796–3191.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Facility Readiness: Goal Date Decisions Under GDUFA.'' This draft guidance provides information to applicants on how FDA intends to assign a goal date based on a facility's readiness for inspection as certified on Form FDA 356h submitted as part of an original ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)). This guidance explains how FDA incorporates a performance enhancement in the