most often found as a liquid solution, but it may be sold as a powder, tablet, blotter paper, or pellet. In 2018, flubromazolam, clonazolam, and dicalazepam were all identified by law enforcement in driving under the influence of drugs cases in the United States. Flubromazolam, clonazolam, and diclazepam are not approved for medical use in the United States and are not controlled substances under the CSA.

3-MeO-PCP (3-methoxyphencyclidine; chemical name: 1-(1-(3-methoxyphenyl)cyclohexyl)piperidine) is a novel N-methyl-D-aspartate (NMDA) receptor antagonist with structural and biochemical similarities to phencyclcycidine (PCP) and other arylcyclohexylamines. 3-MeO-PCP is classified as an arylcyclohexylamine and produces dissociative anesthetic and hallucinogenic effects. Use of this substance is associated with intoxication and published case reports of both fatal and non-fatal overdose. 3-MeO-PCP is encountered by law enforcement in drug seizure reports. 3-MeO-PCP is an analogue of the Schedule II hallucinogen PCP. There is no approved medical use for 3-MeO-PCP in the United States. 3-MeO-PCP is not a controlled substance under the CSA. If intended for human consumption, 3-MeO-PCP may be treated as a ''controlled substance analogue'' under the CSA pursuant to 21 U.S.C 802(32) (A) and 813.

DIPHENIDINE (chemical name: 1-(1,2-diphenylethyl) piperidine) is a non-competitive NMDA receptor antagonist classified as a diarylethylamine and produces dissociative anesthetic and hallucinogenic effects. It was originally synthesized in the 1920s, but reports of abuse started in the last decade. Use of this substance is associated with intoxication and published case reports of both fatal and non-fatal overdose outside of the United States. DIPHENIDINE is encountered by law enforcement in drug seizure reports. DIPHENIDINE is not approved for medical use in the United States and is not a controlled substance under the CSA.

2-MeO-DIPHENIDINE (2-methoxy-diphenidine, methoxphenidine) is a non-competitive NMDA receptor antagonist classified as a diarylethylamine and produces dissociative anesthetic and hallucinogenic effects that may produce effects similar to high doses of dextromethorphan. Use of this substance is associated with intoxication and non-fatal overdose in published case reports outside the United States. 2-MeO-DIPHENIDINE is encountered by law enforcement in drug seizure reports. There is no approved medical use for 2-MeO-DIPHENIDINE in the United States and 2-MeO-DIPHENIDINE is not a controlled substance under the CSA.

5-MeO-DALT (chemical name: *N,N*-Diallyl-5-methoxytryptamine) is a tryptamine hallucinogen and is an agonist of the serotonin (5–HT) 5–HT_{2A} receptor. 5-MeO-DALT appears to produce hallucinogenic effects similar to other tryptamine hallucinogens and fully substituted for 2,5-dimethoxy-4-methylamphetamine (DOM) in DOM-trained rats. 5-MeO-DALT is an analogue of the Schedule I controlled substance 5methoxy-*N,N*-diisopropyltryptamine (5-MeO-DiPT). 5-MeO-DALT has been encountered by law enforcement in drug seizure reports. 5-MeO-DALT is not approved for medical use in the United States and is not controlled under the CSA.

3-FLUOROPHENMETRAZINE (3-FPM) (chemical name: 1-(3-fluorophenyl)-2-(methylamino)propan-1-one) shares substantial chemical structural similarity to phenmetrazine, a Schedule II controlled substance that was prescribed as an appetite suppressant before being withdrawn from the pharmaceutical drug market in the United States because of its abuse potential. 3-FPM, which is similar to phenmetrazine and other stimulant drugs of abuse, increases extracellular concentrations of the neurotransmitter dopamine by inhibiting the uptake of this neurotransmitter at the dopamine transporter. Elevated extracellular dopamine concentrations have been implicated in the mechanism of action of stimulant drugs of abuse. There is no approved medical use for 3-FPM in the United States and 3-FPM is not a controlled substance under the CSA.

IV. Opportunity To Submit Domestic Information

As required by paragraph (d)(2)(A) of the CSA, FDA, on behalf of HHS, invites interested persons to submit comments regarding the 11 drug substances. Any comments received will be considered by HHS when it prepares a scientific and medical evaluation for drug substances that is responsive to the WHO Questionnaire for these drug substances. HHS will forward such evaluation of these drug substances to WHO, for WHO's consideration in deciding whether to recommend international control/decontrol of any of these drug substances. Such control could limit, among other things, the manufacture and distribution (import/export) of these drug substances and could impose certain recordkeeping requirements on them.

Although FDA is, through this notice, requesting comments from interested persons, which will be considered by HHS when it prepares an evaluation of these drug substances, HHS will not now make any recommendations to WHO regarding whether any of these drugs should be subjected to international controls. Instead, HHS will defer such consideration until WHO has made official recommendations to the Commission on Narcotic Drugs, which are expected to be made in late-2020. Any HHS position regarding international control of these drug substances will be preceded by another **Federal Register** notice soliciting public comments, as required by paragraph (d)(2)(B) of the CSA.

Dated: July 29, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–16905 Filed 8–3–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3560]

Biosimilar User Fee Rates for Fiscal Year 2021

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) 2021. 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, 2020, through September 30, 2021.

FOR FURTHER INFORMATION CONTACT: Andrew Bank, Office of Financial

Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 62019A, Beltsville, MD 20705–4304, 301–796–0292.

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 2021, the base revenue amount is the FY 2020 inflation adjusted fee revenue amount of $41,922,873. The FY 2021 base revenue amount is to be adjusted for inflation and may be reduced, as appropriate, for long-term financial planning purposes. Beginning in FY 2021, the inflation-adjusted base revenue amount is also adjusted to reflect changes in the resource capacity needs for the process for the review of biosimilar biological product applications.

This document provides fee rates for FY 2021 for the initial and annual BPD fee ($102,494), for the reactivation fee ($204,988), 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, 2020, and will remain in effect through September 30, 2021. For applications that are submitted on or after October 1, 2020, the new fee schedule must be used.

II. Fee Revenue Amount for FY 2021

The base revenue amount for FY 2021 is $41,922,873 prior to adjustments for inflation, resource capacity, and operating reserves (see section 744H(c)(1), (c)(2), and (c)(3) of the FD&C Act).

A. FY 2021 Statutory Fee Revenue Adjustments for Inflation

BsUFA II specifies that the $41,922,873 is to be adjusted for inflation increases for FY 2021 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 2021. The 3-year average is 1.2644 percent.

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

Fiscal year	2017	2018	2019	3-Year average
Total PC&B	$2,581,551,000	$2,690,678,000	$2,620,052,000	
Total FTE	17,022	17,023	17,144	
PC&B per FTE	$151,660	$158,061	$152,826	
Percent Change From Previous Year	2.8845%	4.2206%	−3.3120%	1.2644%

The statute specifies that this 1.2644 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	2017	2018	2019	3-Year average
Total PC&B	$30,707,050	$35,477,032	$32,946,252	
Total Costs	$55,814,043	$62,604,122	$65,210,467	

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

Fiscal year	2017	2018	2019	3-Year average
PC&B Percent	55.0167%	56.6688%	50.5230%	54.0695%

The payroll adjustment is 1.2644 percent from Table 1 multiplied by 54.0695 percent (or 0.6837 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 THREE-YEAR AVERAGE PERCENT CHANGE IN CPI FOR WASHINGTON-ARLINGTON-ALEXANDRIA AREA

Year	2017	2018	2019	3-Year average
Annual CPI	256.221	261.445	264.777	
Annual Percent Change	1.1045%	2.0389%	1.2745%	1.4726%

The statute specifies that this 1.4726 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 54.0695 percent was obligated for PC&B (as shown in Table 2), 45.9305 percent is the portion of costs other than PC&B (100 percent minus 54.0695 percent equals 45.9305 percent). The non-payroll adjustment is 1.4726 percent times 45.9305 percent, 0.6764 percent.

Next, we add the payroll adjustment (0.6837 percent) to the non-payroll adjustment (0.6764 percent), for a total inflation adjustment of 1.3601 percent (rounded) for FY 2021.

We then multiply the base revenue amount for FY 2021 ($41,922,873) by one plus the inflation adjustment (1.013601), yielding an inflation-adjusted amount of $42,493,000 (rounded to the nearest thousand).

B. FY 2021 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).

As a first step toward implementing the new methodology, FDA committed to establish modernized time reporting and a resource capacity planning capability. Modernized time reporting was implemented in CBER in 2018 and in CDER in 2019. A resource capacity planning capability was established in both CDER and CBER in 2020. In the statute, FDA was directed to commission an independent report evaluating options and recommendations for a methodology to accurately assess changes in the resource and capacity needs of the process for the review of biosimilar biological product applications, informed by personnel time reporting data as an input, and to publish the report for public comment. The evaluation was conducted by Booz Allen Hamilton and published on the FDA website in April 2020.[2] A docket was then opened to receive public comment.[3] After having reviewed the evaluation and the public comment, FDA is establishing and implementing the CPA methodology for the setting of FY 2021 fee amounts.

The new CPA methodology consists of four steps:

1. Forecast workload volumes: Predictive models estimate the volume of workload for the upcoming fiscal year. Workload categories for BsUFA include biosimilar biological product applications, participating BPD programs, supplements, and formal industry meetings scheduled (biosimilar initial advisory (BIA) and BPD Type 1–4 meetings,[4] including BIA and BPD Type 2 written-response only meetings)

2. Forecast the resource needs: Forecast algorithms are generated utilizing time reporting data. These algorithms estimate the required demand in FTEs for direct review-related efforts. This is then compared to current available resources for the direct review 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

[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.*

[2] See: *https://www.fda.gov/media/136606/download.*

[3] See: *https://www.regulations.gov/docketBrowser?rpp=50&so=DESC&sb=postedDate&po=0&dct=PS&D=FDA-2020-N-0989.*

[4] The BsUFA II commitment letter defines these meeting types in section 1.I.: *https://www.fda.gov/media/100573/download.*

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.

Further, FDA is adopting an iterative, continuous improvement approach as part of its CPA methodology. For FY 2021, FDA is applying the methodology to core review activities, for which significant data collection and analysis has been completed. Going forward, the Agency intends to refine its data and estimates for the core review activities to improve their accuracy, and also, as feasible, to apply the new methodology to all major activities that impact the resource needs of the process for the review of biosimilar biological product applications under BsUFA, potentially including, for example, post-market safety activities and some subsets of policy and guidance development. This iterative, continuous improvement approach to the CPA methodology was recommended by the independent evaluation and in the public comments. FDA believes that its estimates will be continuously improved over time as more robust data becomes available to more fully account for total BsUFA program resource needs.

The following section outlines the major components of the FY 2021 BsUFA CPA. Table 4 summarizes the forecasted workload volumes for BsUFA in FY 2021 based on predictive models, as well as historical actuals from FY 2019 for comparison.

TABLE 4—BSUFA ACTUAL FY 2019 WORKLOAD VOLUMES & PREDICTED FY 2021 WORKLOAD VOLUMES

Workload category	FY 2019 actuals	FY 2021 predictions
Efficacy Supplements	12	8
Labeling Supplements	10	7
Manufacturing Supplements	58	90
Biosimilar Biological Product Applications	6	8
BsUFA Industry Meetings (BIA, BPD Type 1–4)	114	102
Participating BPD Programs	95	119

Utilizing the resource forecast algorithms, the forecasted workload volumes for FY 2021 were then converted into estimated FTE needs for FDA's BsUFA direct review-related work. The resulting expected FY 2021 FTE need for BsUFA was compared to current onboard capacity for BsUFA direct review-related work to determine the FY 2021 resource delta, as summarized in Table 5.

TABLE 5—FY 2021 BSUFA RESOURCE DELTA

Current resource capacity	FY 2021 resource forecast	Predicted FY 2021 FTE delta
61.7	88.3	26.5

The projected 26.5 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. After accounting for the range of recent years' historical net FTE gains and one remaining previously funded BsUFA vacancy, FDA determined that the realistic expected net FTE gains could be funded through the expected FY 2021 collections amount without a further adjustment from the CPA. In summary, after accounting for these internal factors, FDA determined that in FY 2021 the BsUFA fee amounts did not need adjustment from the CPA to provide funds for the realistic estimated net FTE gains.

TABLE 6—FY 2021 BSUFA CPA

Additional FTEs for FY 2021	Cost for each additional FTE	FY 2021 BsUFA CPA
26.5	$301,701	$0

Although an adjustment to the fee amounts for resource needs by the CPA will not be made in FY 2021, FDA will evaluate the need for a fee adjustment from the CPA in future fiscal years and will make adjustments as warranted.

C. FY 2021 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,*[5] FDA is committed to reducing the BsUFA carryover reserve to an

[5] See: *https://www.fda.gov/media/100573/download.*

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 2021 target revenue amount as FDA appears on track to reduce the carryover reserve to the committed level.

III. Fee Amounts for FY 2021

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 fourth 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 2021, FDA utilized an average of the 3 most recently completed fiscal years (*i.e.,* fiscal years 2017–2019) of biosimilar biological product application submissions. Based on the available information, FDA estimates it will receive 8 biosimilar biological product applications requiring clinical data for approval in FY 2021.

FDA will maintain the biosimilar biological product application fee for FY 2021 at the same level as FY 2020, which is $1,746,745. This is estimated to provide a total of $13,973,960 representing 33 percent (rounded to the nearest whole number) of the FY 2021 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 54 program fees will be invoiced for FY 2021, including currently approved products and products with the potential to be approved in pending applications with goal dates in FY 2020. For products invoiced in the FY 2021 regular billing cycle, FDA anticipates that zero program fees will be refunded.

FDA will maintain the biosimilar biological product program fee for FY 2021 at the same level as FY 2020, which is $304,162. This is estimated to provide a total of $16,424,748, representing 39 percent (rounded to the nearest whole number) of the FY 2021 target revenue amount.

C. Initial and Annual BPD Fees, Reactivation Fees

To estimate the number of BPD fees to be paid in FY 2021, 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 2021. In FY 2021, FDA estimates 32 new BPD programs, no reactivations (a single reactivation is weighted as two BPD fees), and 86 BPD programs to be invoiced for the annual BPD fee, for a total equivalent of 118 BPD fees assessed in FY 2021.

The remainder of the target revenue of $12,094,292, or 28 percent (rounded to the nearest whole number), is to be collected from the BPD fees. Dividing this amount by the estimated 118 BPD fees to be paid equals an initial BPD and annual BPD fee amount of $102,494. The reactivation fee is set at twice the initial/annual BPD amount at $204,988. This represents a reduction of the BPD fees from the FY 2020 levels.

IV. Fee Schedule for FY 2021

The fee rates for FY 2021 are displayed in Table 7.

TABLE 7—FEE SCHEDULE FOR FY 2021

Fee category	Fee rates for FY 2021
Initial BPD	$102,494
Annual BPD	102,494
Reactivation	204,988
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 2021, *i.e.,* the period from October 1, 2020, through September 30, 2021. 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 five 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 five 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 2021 annual BPD and program fees under the new fee schedule in August 2020. Payment will be due on October 1, 2020. If sponsors join the BPD program after the annual BPD invoices have been issued in August 2020, FDA will issue invoices in December 2020 to firms subject to fees for FY 2021 that qualify for the annual BPD fee after the August 2020 billing. FDA will issue invoices in December 2020 for any annual program fees for FY 2021 that qualify for fee assessments and were not issued in August 2020.

Dated: July 29, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–16858 Filed 7–30–20; 4:15 pm]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1693]

Outsourcing Facility Fee Rates for Fiscal Year 2021

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fiscal year (FY) 2021 rates for the establishment and re-inspection fees related to entities that compound human drugs and elect to register as outsourcing facilities under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FD&C Act authorizes FDA to assess and collect an annual establishment fee from outsourcing facilities, as well as a re-inspection fee for each re-inspection of an outsourcing facility. This document establishes the FY 2021 rates for the small business establishment fee ($5,695), the non-small business establishment fee ($18,837), and the re-inspection fee ($17,085) for outsourcing facilities; provides information on how the fees for FY 2021 were determined; and describes the payment procedures outsourcing facilities should follow. These fee rates are effective October 1, 2020, and will remain in effect through September 30, 2021.

FOR FURTHER INFORMATION CONTACT:

For more information on human drug compounding and outsourcing facility fees: Visit FDA's website at: *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm.*

For questions relating to this notice: Lola Olajide, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61077B, Beltsville, MD 20705–4304, 240–402–4244.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Quality and Security Act contains important provisions relating to the oversight of compounding human drugs. Title I of this law, the Compounding Quality Act, created a new section 503B in the FD&C Act (21 U.S.C. 353b). Under section 503B of the FD&C Act, a human drug compounder can become an ''outsourcing facility.''

Outsourcing facilities, as defined in section 503B(d)(4) of the FD&C Act, are facilities that meet all of the conditions described in section 503B(a), including registering with FDA as an outsourcing facility and paying an annual establishment fee. If the conditions of section 503B are met, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from three sections of the FD&C Act: (1) Section 502(f)(1) (21 U.S.C. 352(f)(1)) concerning the labeling of drugs with adequate directions for use; (2) section 505 (21 U.S.C. 355) concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs); and (3) section 582 (21 U.S.C. 360eee–1) concerning drug supply chain security requirements. Drugs compounded in outsourcing facilities are not exempt from the requirements of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) concerning current good manufacturing practice requirements for drugs.

Section 744K of the FD&C Act (21 U.S.C. 379j–62) authorizes FDA to assess and collect the following fees associated with outsourcing facilities: (1) An annual establishment fee from each outsourcing facility and (2) a re-inspection fee from each outsourcing facility subject to a re-inspection (see section 744K(a)(1) of the FD&C Act). Under statutorily defined conditions, a qualified applicant may pay a reduced small business establishment fee (see section 744K(c)(4) of the FD&C Act).

FDA announced in the **Federal Register** of November 24, 2014 (79 FR 69856), the availability of a final guidance for industry entitled ''Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act.'' The guidance provides additional information on the annual fees for outsourcing facilities and adjustments required by law, re-inspection fees, how to submit payment, the effect of failure to pay fees, and how to qualify as a small business to obtain a reduction of the annual establishment fee. This guidance can be accessed on FDA's website at: *https://www.fda.gov/media/136683/download.*