special review process. In addition, the Federal Travel Regulation (FTR) allows for actual expense reimbursement as provided in §§ 301–11.300 through 301–11.306.

For FY 2022, all current non-standard area (NSA) maximum lodging allowance rates will remain at FY 2021 levels. The standard lodging rate will also remain unchanged at $96. The M&IE reimbursement rates were revised for FY 2022; they were last revised in FY 2019. The M&IE NSA tiers are revised from $56–$76 to $59–$79, and the standard M&IE rate is revised from $55 to $59.

Notices published periodically in the **Federal Register** now constitute the only notification of revisions in CONUS per diem reimbursement rates to agencies, other than the changes posted on the GSA website.

Krystal J. Brumfield,

Associate Administrator, Office of Government-wide Policy.

[FR Doc. 2021–17491 Filed 8–13–21; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Needs and Challenges in Personal Protective Equipment (PPE) Use for Underserved User Populations; Extension of Comment Period

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Extension of comment period.

SUMMARY: On June 24, 2021, NIOSH opened a notice to request information on the Needs and Challenges in Personal Protective Equipment (PPE) Use for Underserved User Populations. Written comments were to be received by August 23, 2021. NIOSH is extending the public comment period to October 15, 2021.

DATES: The comment period for the document published on June 24, 2021 (86 FR 33296), is extended. Comments must be received by October 15, 2021.

ADDRESSES: Interested parties should submit information to: NIOSH, Attn: Sherri Diana, National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C–34, Cincinnati, Ohio 45226–1998, Email address: *ppeconcerns@cdc.gov.*

FOR FURTHER INFORMATION CONTACT: N. Katherine Yoon, Ph.D., National Institute for Occupational Safety and Health Centers for Disease Control and Prevention Email Address: *NYoon@cdc.gov,* Phone number: 412–386–6752 [non-toll-free number].

SUPPLEMENTARY INFORMATION: NIOSH published a notice and request for information in the **Federal Register** on June 24, 2021 (86 FR 33296) regarding the *Needs and Challenges in Personal Protective Equipment (PPE) Use for Underserved User Populations.* This notice announces the extension of the comment period until October 15, 2021.

Frank J. Hearl,

Chief of Staff, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2021–17485 Filed 8–13–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0709]

Prescription Drug 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) is announcing the rates for prescription drug user fees for fiscal year (FY) 2022. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Prescription Drug User Fee Amendments of 2017 (PDUFA VI), authorizes FDA to collect application fees for certain applications for the review of human drug and biological products, and prescription drug program fees for certain approved products. This notice establishes the fee rates for FY 2022.

FOR FURTHER INFORMATION CONTACT: Misbah Tareen, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61077A, Beltsville, MD 20705–4304, 301–796–3997.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 735 and 736 of the FD&C Act (21 U.S.C. 379g and 379h, respectively) establish two different kinds of user fees. Fees are assessed as follows: (1) Application fees are assessed on certain types of applications for the review of human drug and biological products and (2) prescription drug program fees are assessed on certain approved products (section 736(a) of the FD&C Act). When specific conditions are met, FDA may waive or reduce fees (section 736(d) of the FD&C Act) or exempt certain prescription drug products from fees (section 736(k) of the FD&C Act).

For FY 2018 through FY 2022, the base revenue amounts for the total revenues from all PDUFA fees are established by PDUFA VI. The base revenue amount for FY 2022 is $1,098,077,960. The FY 2022 base revenue amount is adjusted for inflation and for the resource capacity needs for the process for the review of human drug applications (the capacity planning adjustment (CPA)). An additional dollar amount specified in the statute (see section 736(b)(1)(F) of the FD&C Act) is then added to provide for additional full-time equivalent (FTE) positions to support PDUFA VI initiatives. The FY 2022 revenue amount may be adjusted further, if necessary, to provide for sufficient operating reserves of carryover user fees. Finally, the amount is adjusted to provide for additional direct costs to fund PDUFA VI initiatives. Fee amounts are to be established each year so that revenues from application fees provide 20 percent of the total revenue, and prescription drug program fees provide 80 percent of the total revenue.

This document provides fee rates for FY 2022 for an application requiring clinical data ($3,117,218), for an application not requiring clinical data ($1,558,609), and for the prescription drug program fee ($369,413). 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 $1,098,077,960 prior to adjustments for inflation, capacity planning, additional FTE, operating reserve, and additional direct costs (see section 736(b)(1) of the FD&C Act).

A. FY 2022 Statutory Fee Revenue Adjustments for Inflation

PDUFA VI specifies that the $1,098,077,960 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 736(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 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 human drug applications for the first 3 of the preceding 4 fiscal years (see section 736(c)(1)(A) and (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 PERSONNEL COMPENSATION AND BENEFITS (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 human drug applications. Table 2 shows the PC&B and the total obligations for the process for the review of human drug 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 HUMAN DRUG APPLICATIONS

Fiscal year	2018	2019	2020	3-Year average
Total PC&B	$792,900,647	$872,087,636	$891,395,106	.....
Total Costs	$1,374,508,527	$1,430,338,888	$1,471,144,928	.....
PC&B Percent	57.6861	60.9707	60.5919	59.7496

The payroll adjustment is 2.7383 percent from table 1 multiplied by 59.7496 percent (or 1.6361 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 human drug applications for the first 3 years of the preceding 4 fiscal years (see section 736(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 that best reflects the geographic region in which FDA is headquartered and that provides the most current data available, the Washington-Arlington-Alexandria index will be used in calculating the relevant adjustment factors for FY 2020 and subsequent years. Table 3 provides the summary data for the percent changes in the specified CPI for the Washington-Arlington-Alexandria area. The data are published by the Bureau of Labor Statistics and can be found on its website at: *https://data.bls.gov/pdq/SurveyOutputServlet?data_tool=dropmap&series_id=CUURS35ASA0,CUUSS35ASA0.*

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

Year	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 human drug applications obligated. Because 59.7496 percent was obligated for PC&B (as shown in table 2), 40.2504 percent is the portion of costs other than PC&B (100 percent minus 59.7496 percent equals 40.2504 percent). The non-payroll adjustment is 1.4041 percent times 40.2504 percent, or 0.5652 percent.

Next, we add the payroll adjustment (1.6361 percent) to the non-payroll adjustment (0.5652 percent), for a total inflation adjustment of 2.2013 percent (rounded) for FY 2022.

We then multiply the base revenue amount for FY 2022 ($1,098,077,960) by 1.022013, yielding an inflation-adjusted amount of $1,122,249,950.

B. FY 2022 Statutory Fee Revenue Adjustments for Capacity Planning

The statute specifies that after $1,098,077,960 has been adjusted for inflation, the inflation-adjusted amount shall be further adjusted to reflect changes in the resource capacity needs for the process of human drug application reviews (see section 736(c)(2) of the FD&C Act). Following a process required in statute, the FDA

[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.*

established a new 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 46651.

The CPA methodology includes 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 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.

To determine the FY 2022 capacity planning adjustment, FDA calculated a PDUFA CPA for the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) individually. The final Center-level results were then combined to determine the total FY 2022 PDUFA CPA. The following section outlines the major components of each Center's FY 2022 PDUFA CPA.

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

TABLE 4—CDER ACTUAL FY 2020 WORKLOAD VOLUMES AND PREDICTED FY 2022 WORKLOAD VOLUMES

Workload category	FY 2020 actuals	FY 2022 predictions
Efficacy Supplements	293	316
Labeling Supplements	1,122	1,043
Manufacturing Supplements	2,350	2,388
NDA/BLA [1] Original	150	161
PDUFA Industry Meetings (including WROs [2])	3,950	4,534
Active Commercial INDs [3]	8,243	9,549

[1] New drug applications (NDA)/biological license applications (BLA).
[2] Written responses only (WRO).
[3] For purpose of the capacity planning adjustment, this is defined as an active commercial investigational new drugs (IND) for which a document has been received in the past 18 months.

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

TABLE 5—CDER FY22 PDUFA RESOURCE DELTA

Center	Current resource capacity	FY 2022 resource forecast	Predicted FY 2022 FTE delta
CDER	1,686	1,861	175

The projected 175 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 that can be utilized in the fiscal year and for which funds are required to support additional review capacity. With recent enhancements to its hiring capability, CDER's ability to net gain PDUFA FTEs moving forward is expected to outpace recent years' net gains. As such, hiring capacity is not expected to be a significant impediment to onboarding the needed net gains for the PDUFA program.

After assessing current hiring capacity and existing funded vacancies, CDER adjusted the 175 FTE delta to 78 FTEs. The FY 2022 PDUFA CPA for CDER is therefore $24,350,430, as summarized in table 6.

FDA recognizes that this adjustment for CDER is significantly larger than in the previous year's capacity planning adjustment. A relatively small adjustment of 13 FTEs was made for CDER in the capacity planning adjustment in FY 2021 fee-setting. FDA took a conservative approach to the capacity planning adjustment for CDER in FY 2021 until the pace of net gains increased and was sustained. CDER is now experiencing a sustained increase in its ability to increase its staffing. In addition, the capacity planning adjustment has now demonstrated a sustained gap in the number of CDER staff needed to deliver on the expected forecasted workload. CDER has been performing its mission with a staffing level less than that required of its increasing submission workload. The FTEs enabled through this adjustment should significantly reduce this gap, once fully onboarded.

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

TABLE 6—CDER FY 2022 PDUFA CPA

Center	Additional FTEs for FY 2022	Cost for each additional FTE	CDER FY22 PDUFA CPA
CDER	78	$312,185	$24,350,430

To calculate the FY 2022 PDUFA CPA for CBER, FDA followed the same approach outlined above. Table 7 summarizes the forecasted workload volumes for CBER in FY 2022 as well as the corresponding historical actuals from FY 2020 for comparison.

TABLE 7—CBER ACTUAL FY 2020 WORKLOAD VOLUMES AND PREDICTED FY 2022 WORKLOAD VOLUMES

Workload category	FY 2020 actuals	FY 2022 predictions
Efficacy Supplements	29	16
Labeling Supplements	57	63
Manufacturing Supplements	677	647
NDA/BLA Original	8	9
PDUFA Industry Meetings (including WROs)	701	657
Active Commercial INDs [1]	1,436	1,770

[1] For purpose of the capacity planning adjustment, this is defined as an active commercial IND for which a document has been received in the past 18 months.

The forecasted CBER PDUFA workload for FY 2022 was then converted into expected FTE resources and compared to current onboard capacity for PDUFA direct review work, as summarized in table 8.

TABLE 8—CBER FY 2022 PDUFA RESOURCE DELTA

Center	Current resource capacity	FY 2022 resource forecast	Predicted FY 2022 FTE delta
CBER	334	394	60

The projected 60 FTE delta for CBER was also assessed in the context of other operational and financial factors that may impact the need and/or feasibility of obtaining the additional resources. After accounting for historical net FTE gains within CBER and subtracting previously funded PDUFA vacancies, an adjustment of 7 additional FTEs within CBER for FY 2022 was determined to be needed. The FY 2022 PDUFA CPA for CBER is therefore $2,152,969, as summarized in table 9.

TABLE 9—CBER FY 2022 PDUFA CPA

Center	Additional FTEs for FY 2022	Cost for each additional FTE	CBER FY 2022 PDUFA CPA
CBER	7	$307,567	$2,152,969

The CDER and CBER CPA amounts were then added together to determine the PDUFA CPA for FY 2022 of $26,503,399, as outlined in table 10. FDA will track the utilization of the CPA funds to ensure they are supporting the organizational review components engaged in PDUFA direct review work to enhance resources and expand staff capacity and capability. Should FDA be unable to utilize any amounts of the CPA funds during the fiscal year, it will not spend those funds and the unspent funds will be transferred to the carryover balance at the end of the fiscal year.

TABLE 10—FY 2022 PDUFA CPA

Center	FY 2022 PDUFA CPA
CDER	$24,350,430
CBER	$2,152,969
Total	$26,503,399

Table 11 shows the calculation of the inflation and capacity planning adjusted amount for FY 2022. The FY 2022 base revenue amount, $1,098,077,960, shown on line 1 is multiplied by the inflation adjustment factor of 1.022013, resulting in the inflation-adjusted amount of $1,122,249,950 shown on line 3. The FY 2022 CPA of $26,503,399 is then added on line 4, resulting in the inflation and capacity planning adjusted amount of $1,148,753,349 shown on line 5.

TABLE 11—PDUFA INFLATION AND CAPACITY PLANNING ADJUSTED AMOUNT FOR FY 2022, SUMMARY CALCULATION

FY 2021 Revenue Amount	$1,098,077,960	Line 1.
Inflation Adjustment Factor for FY 2022 (1 plus 1.022013 percent)	1.022013	Line 2.
Inflation-Adjusted Amount	$1,122,249,950	Line 3.
Capacity Planning Adjustment for FY 2022	$26,503,399	Line 4.
Inflation and Capacity Planning Adjusted Amount	$1,148,753,349	Line 5.

Per the commitments made in PDUFA VI, this increase in the revenue amount will be allocated to and used by organizational review components engaged in direct review work to enhance resources and expand staff capacity and capability (see II.A.4 on p. 37 of the PDUFA VI commitment letter [3]).

C. FY 2022 Statutory Fee Revenue Adjustments for Additional Dollar Amounts

PDUFA VI provides an additional dollar amount for each of the 5 fiscal years covered by PDUFA VI for additional FTE to support enhancements outlined in the PDUFA VI commitment letter. The amount for FY 2022 is $2,769,609 (see section 736(b)(1)(F) of the FD&C Act). Adding this amount to the inflation and capacity planning adjusted revenue amount, $1,148,753,349, equals $1,151,522,958.

D. FY 2022 Statutory Fee Revenue Adjustments for Operating Reserve

PDUFA VI provides for an operating reserve adjustment to allow FDA to increase the fee revenue and fees for any given fiscal year during PDUFA VI to maintain up to 14 weeks of operating reserve of carryover user fees. If the carryover balance exceeds 14 weeks of operating reserves, FDA is required to decrease fees to provide for not more than 14 weeks of operating reserves of carryover user fees.

To determine the 14-week operating reserve amount, the FY 2022 annual base revenue adjusted for inflation, capacity planning, and additional dollar amounts, $1,151,522,958 is divided by 52, and then multiplied by 14. The 14-week operating reserve amount for FY 2022 is $310,025,412.

To determine the end of year operating reserve amount, the Agency must assess the operating reserve at the end of the third quarter of FY 2021 and forecast collections and obligations in the fourth quarter of FY 2021. The estimated end of year FY 2021 operating reserve of carryover user fees is $225,724,631. Note that under PDUFA VI, this amount includes both user fee funds available for obligation $126,873,636 and funds that are considered unavailable due to a lack of appropriations $98,850,995.[4]

Because the estimated end of year FY 2021 PDUFA operating reserve does not exceed the 14-week operating reserve for FY 2022, FDA will not reduce the FY 2022 PDUFA fee revenue in FY 2022. However, FDA will apply an operating reserve adjustment to increase the fee revenue and fees for FY 2022. The statute authorizes FDA to raise the fee revenue by up to $84,300,781 ($310,025,412 minus $225,724,631) for the operating reserve adjustment. FDA has decided to exercise its discretion to make a smaller operating reserve adjustment, of $39,402,923.

In making this decision, FDA focused on the amount of available operating reserves. Maintaining an appropriate level of available operating reserves enables FDA to mitigate financial risks to the program, including for example, the risk of under collecting fees and the risk of a lapse in appropriations. FDA considers maintaining an operating reserve balance of between 8–10 weeks of available funds as a reasonable range to mitigate these risks. FDA has decided to make an available operating reserve adjustment that is intended to increase the amount of available funds to approximately 7 weeks by the end of FY 2022 as an incremental step toward the 8–10 week range while mitigating the impact on fee amounts. FDA estimates the cost of operations per week is $22,144,672. Before the operating adjustment, the estimated end of year FY 2022 available operating reserve is $125,677,240, which equates to just over 5 weeks of available operating reserves. Adding the FY 2022 operating reserve adjustment of $39,402,923 to this amount is expected to provide approximately 7 weeks of available operating reserve, or $165,080,162, and an operating reserve (including unavailable funds) of $263,931,157.

With respect to target revenue for FY 2022, adding the operating reserve adjustment amount of $39,402,923 to the inflation, capacity planning adjustment and additional dollar amount, $1,151,522,958 equals $1,190,925,881.

E. FY 2022 Statutory Fee Revenue Adjustments for Additional Direct Cost

PDUFA VI specifies that $8,730,000, adjusted for inflation, be added after the operating reserve adjustment to account for additional direct costs in FY 2022. This additional direct cost adjustment is adjusted for inflation by multiplying $8,730,000 by the CPI for urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All Items; Annual Index) for the most recent year of available data, divided by such index for 2016 (see section 736(c)(4)(B) of the FD&C Act). Because of the geographical revision made by the Bureau of Labor and Statistics, the Washington-Arlington-Alexandria index will be used in calculating the direct cost adjustment inflation factor for FY 2021 and subsequent years. The annual index for 2020, 267.157, divided by such index for 2016, 253.422, results in an adjustment factor of 1.054198, making the additional direct cost adjustment equal to $9,203,149.

The final FY 2022 PDUFA target revenue is $1,200,129,000 (rounded to the nearest thousand dollars).

III. Application Fee Calculations

A. Application Fee Revenues and Application Fees

Application fees will be set to generate 20 percent of the total target revenue amount, or $240,025,800 in FY 2022.

B. Estimate of the Number of Fee-Paying Applications and Setting the Application Fees

Historically, FDA has estimated the total number of fee-paying full application equivalents (FAEs) it expects to receive during the next fiscal year by averaging the number of fee-paying FAEs received in the 3 most recently completed fiscal years. For estimating the FY 2022 FAEs, FDA decided to average the number of FAEs from FY 2017 through FY 2019 instead of FY 2018 through FY 2020. FDA made this adjustment because the FY 2020 FAE count (62.77) is abnormally low,

[3] The PDUFA VI commitment letter can be viewed at *https://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm511438.pdf.*

[4] Please refer to the PDUFA Financial Reports for details on unavailable carryover amounts at *https://www.fda.gov/about-fda/user-fee-financial-reports/pdufa-financial-reports.*

potentially due to the impact of the COVID–19 pandemic on sponsor submissions. Thus, FDA changed the estimate for FY 2022 to remove this potential outlier from the 3-year moving average forecast method. FDA believes that this change will result in a more realistic FAE estimate for FY 2022. Prior year FAE totals are updated annually to reflect refunds and waivers processed after the close of the fiscal year.

In estimating the number of fee-paying FAEs, a full application requiring clinical data counts as one FAE. An application not requiring clinical data counts as one-half of an FAE. An application that is withdrawn before filing, or refused for filing, counts as one-fourth of an FAE if the applicant initially paid a full application fee, or one-eighth of an FAE if the applicant initially paid one-half of the full application fee amount. Prior to PDUFA VI, the FAE amount also included supplements; supplements have been removed from the FAE calculation as the supplement fee has been discontinued in PDUFA VI.

As table 12 shows, the average number of fee-paying FAEs received annually in FY 2017 through FY 2019 is 77.00. FDA will set fees for FY 2022 based on this estimate as the number of full application equivalents that will be subject to fees.

TABLE 12—FEE-PAYING FAEs

FY	2017	2018	2019	3-Year average
Fee-Paying FAEs	79.75	68.87	82.38	77.00

Note: Prior year FAE totals are updated annually to reflect refunds and waivers processed after the close of the fiscal year.

The FY 2022 application fee is estimated by dividing the average number of full applications that paid fees from FY 2017 through FY 2019, 77.00, into the fee revenue amount to be derived from application fees in FY 2022, $240,025,800. The result is a fee of $3,117,218 per full application requiring clinical data, and $1,558,609 per application not requiring clinical data.

IV. Fee Calculations for Prescription Drug Program Fees

PDUFA VI assesses prescription drug program fees for certain prescription drug products. An applicant will not be assessed more than five program fees for a fiscal year for prescription drug products identified in a single approved NDA or BLA (see section 736(a)(2)(C) of the FD&C Act). Applicants are assessed a program fee for a fiscal year only for user fee eligible prescription drug products identified in a human drug application approved as of October 1 of such fiscal year.

FDA estimates 2,806 program fees will be invoiced in FY 2022 before factoring in waivers, refunds, and exemptions. FDA approximates that there will be 161 waivers and refunds granted. In addition, FDA approximates that another 46 program fees will be exempted in FY 2022 based on the orphan drug exemption in section 736(k) of the FD&C Act. FDA estimates 2,599 program fees in FY 2022, after allowing for an estimated 207 waivers and reductions, including the orphan drug exemptions. The FY 2022 prescription drug program fee rate is calculated by dividing the adjusted total revenue from program fees ($960,103,200) by the estimated 2,599 program fees, for a FY 2022 program fee of $369,413 (rounded to the nearest dollar).

V. Fee Schedule for FY 2022

The fee rates for FY 2022 are displayed in table 13.

TABLE 13—FEE SCHEDULE FOR FY 2022

Fee category	Fee rates for FY 2022
Application:	
Requiring clinical data	$3,117,218
Not requiring clinical data	1,558,609
Program	369,413

VI. Fee Payment Options and Procedures

A. Application Fees

The appropriate application fee established in the new fee schedule must be paid for any application subject to fees under PDUFA that is submitted on or after October 1, 2021. Payment must be made in U.S. currency by electronic check, check, bank draft, wire transfer, or U.S. postal money order payable to the order of the Food and Drug Administration. 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 completing the Prescription Drug User Fee Cover Sheet and generating the user fee ID number. 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 an invoice is located, ''Pay Now'' should be selected 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 979107, 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 979107, 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 the 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 979107) 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, which could result in FDA not filing an application and other penalties. Note: The originating financial institution may charge a wire

transfer fee, especially for international wire transfers. Applicable wire transfer fees must be included with payment to ensure fees are paid in full. Questions about wire transfer fees should be addressed to the financial institution. The account information for wire transfers is as follows: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53–0196965.

B. Prescription Drug Program Fees

FDA will issue invoices and payment instructions for FY 2022 program fees under the new fee schedule in August 2021. Payment will be due on October 1, 2021. FDA will issue invoices in December 2021 for products that qualify for FY 2022 program fee assessments after the August 2021 billing.

Dated: August 11, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–17505 Filed 8–13–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0739]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; 4F–MDMB–BICA (4F–MDMB–BUTICA); Brorphine; Metonitazene; Eutylone (bk-EBDB); BMDP (3,4-Methylenedioxy-N-benzylcathinone); Kratom (mitragynine, 7-hydroxymitragynine); Phenibut; Reopening Comment Period

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

ACTION: Notice; reopening comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is reopening the comment period for the notice entitled ''International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; 4F–MDMB–BICA (4F–MDMB–BUTICA); Brorphine; Metonitazene; Eutylone (bk-EBDB); BMDP (3,4-Methylenedioxy-N-benzylcathinone); Kratom (mitragynine, 7-hydroxymitragynine); Phenibut'' that appeared in the **Federal Register** of July 23, 2021. The Agency is taking this action to allow interested persons additional time to submit comments. These comments will be considered in preparing a response from the United States to the World Health Organization (WHO) regarding the abuse liability and diversion of these drugs. WHO will use this information to consider whether to recommend that certain international restrictions be placed on these drug substances.

DATES: FDA is reopening the comment period for the notice published July 23, 2021 (86 FR 39038). Submit either electronic or written comments by August 24, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 24, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of August 24, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2021–N–0739 for ''International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; 4F–MDMB–BICA (4F–MDMB–BUTICA); Brorphine; Metonitazene; Eutylone (bk-EBDB); BMDP (3,4-Methylenedioxy-N-benzylcathinone); Kratom (mitragynine, 7-hydroxymitragynine); Phenibut; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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