Page 8 –Dr. Beigel, NIAID

U. All descriptive printed matter, advertising, and promotional material relating to the use of Jynneos under this authorization clearly and conspicuously shall state that:

- This product has not been approved or licensed by FDA for use in individuals less than 18 years of age, or as two 0.1 mL doses administered intradermally 4 weeks apart in individuals 18 years of age and older determined to be at high risk of monkeypox infection but has been authorized for emergency use by FDA, under an EUA to prevent monkeypox disease; and
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564(b)(1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner.

IV. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of vaccines for use to prevent monkeypox disease is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

/s/

Peter W. Marks, M.D., Ph.D.
Director
Center of Biologics Evaluation and Research
Food and Drug Administration

Enclosures

Dated: September 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21834 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–2355]

Prescription Drug User Fee Rates for Fiscal Year 2023

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the rates for prescription drug user fees for fiscal year (FY) 2023. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Prescription Drug User Fee Amendments of 2022 (PDUFA VII), 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 2023. 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 735 and 736 of the FD&C Act (21 U.S.C. 379g and 379h) 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). The statute also includes conditions under which such fees may be waived or reduced (section 736(d) of the FD&C Act), or under which fee exceptions, refunds, or exemptions apply (sections 736(a)(1)(C) through (G), 736(a)(2)(B) through (C), and 736(k) of the FD&C Act).

For FY 2023 through FY 2027, the base revenue amounts for the total revenues from all PDUFA fees are established by PDUFA VII. The base revenue amount for FY 2023 is $1,151,522,958. The FY 2023 base revenue amount is adjusted for inflation, strategic hiring and retention, and for the resource capacity needs for the process for the review of human drug applications (the capacity planning adjustment (CPA)). This amount is further adjusted to include the additional dollar amount as specified in the statute (see section 736(b)(1)(F) of the FD&C Act) to provide for additional full-time equivalent (FTE) positions to support PDUFA VII initiatives. If applicable, an operating reserve adjustment is added to provide sufficient operating reserves of carryover user fees. The amount from the preceding adjustments is then

adjusted to provide for additional direct costs to fund PDUFA VII 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 (see section 736(b)(2) of the FD&C Act).

This document provides fee rates for FY 2023 for an application requiring covered clinical data [1] ($3,242,026), for an application not requiring covered clinical data ($1,621,013), and for the prescription drug program fee ($393,933). 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, 2022, the new fee schedule must be used.

II. Fee Revenue Amount for FY 2023

The base revenue amount for FY 2023 is $1,151,522,958 (see section 736(b)(1)(A) and (b)(3) of the FD&C Act). This amount is prior to any adjustments made for inflation, the strategic hiring and retention adjustment, CPA, additional dollar amount, operating reserve adjustment (if applicable), and additional direct costs (see section 736(b)(1) of the FD&C Act).

A. FY 2023 Statutory Fee Revenue Adjustments for Inflation

PDUFA VII specifies that the $1,151,522,958 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 736(c)(1) of the FD&C Act).

The component of the inflation adjustment for payroll costs is 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)(i) of the FD&C Act).

Table 1 summarizes the actual cost and FTE data for the specified fiscal years, provides the percent changes from the previous fiscal years, and provides 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 Personnel Compensation and Benefits (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 payroll adjustment is 1.3918 percent from table 1 multiplied by 61.8539 percent resulting in 0.8609 percent.

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 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

	FY 2019	FY 2020	FY 2021	3-Year Average
Total PC&B	$872,087,636	$891,395,106	$959,387,333	
Total Costs	$1,430,338,888	$1,471,144,928	$1,499,064,056	
PC&B Percent	60.9707%	60.5919%	63.9991%	61.8539%

The payroll adjustment is 1.3918 percent from table 1 multiplied by 61.8539 percent resulting in 0.8609 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 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 personnel compensation and benefits costs to total costs of the process for the review of human drug applications (as defined in section 735(6)) for the first 3 years of the preceding 4 fiscal years (see section 736(c)(1)(A) and (B)(ii)). Table 3 provides the summary data for the percent changes in the specified CPI for the Washington-Arlington-Alexandria area.[2]

[1] As used herein, ''covered clinical data'' is ''clinical data (other than bioavailability or bioequivalence studies) with respect to safety or effectiveness [that] are required for approval'' (see section 736(a)(1)(A)) of the FD&C Act).

[2] 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

	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 human drug applications obligated. Because 61.8539 percent was obligated for PC&B (as shown in table 2), 38.1461 percent is the portion of costs other than PC&B (100 percent minus 61.8539 percent equals 38.1461 percent). The non-payroll adjustment is 2.0434 percent times 38.1461 percent, or 0.7795 percent.

Next, we add the payroll adjustment (0.8609 percent) to the non-payroll adjustment (0.7795 percent), for a total inflation adjustment of 1.6404 percent (rounded) for FY 2023.

We then multiply the base revenue amount for FY 2023 ($1,151,522,958) by 1.6404 percent which produces an inflation adjustment amount of 18,889,582. Adding this amount to the base revenue amount yields an inflation-adjusted base revenue amount of $1,170,412,541.

B. FY 2023 Strategic Hiring and Retention Adjustment

For each fiscal year, after the annual base revenue established in section II is adjusted for inflation in accordance with section II.A above, the statute directs FDA to further increase the fee revenue and fees to support strategic hiring and retention. For FY 2023, this amount is $9,000,000 (see section 736(c)(2)(A) of the FD&C Act).

C. FY 2023 Statutory Fee Revenue Adjustments for Capacity Planning

The statute specifies that after the base revenue amount for FY 2023 of $1,151,522,958 has been adjusted as described in sections II.A and II.B above, this 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)(3) of the FD&C Act). Following a process required in statute, FDA established a new CPA methodology and first applied it in the setting of FY 2021 fees. The establishment of this methodology is described in the **Federal Register** of August 3, 2020 (85 FR 46651). 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.

For FY 2023, updates were made to refine the time reporting categories included within the CPA. As such, the 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 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 prescription drug products.

The CPA methodology includes four steps:

1. Forecast workload volumes: predictive models estimate the volume of workload for the upcoming FY.

2. Forecast the resource needs: forecast algorithms are generated utilizing time reporting data. These algorithms estimate the required demand in FTEs [3] 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 FY, and the 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.

To determine the FY 2023 CPA, FDA calculated a 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 2023 PDUFA CPA. The following section outlines the major components of each Center's FY 2023 PDUFA CPA.

Table 4 summarizes the forecasted workload volumes for CDER in FY 2023 based on predictive models, as well as historical actuals from FY 2021 for comparison.

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

Table 4.--CDER Actual FY 2021 Workload Volumes and Predicted FY 2023 Workload Volumes

Workload Category	FY 2021 Actuals	FY 2023 Predictions
Efficacy Supplements	260	227
Labeling Supplements	1,072	1,063
Manufacturing Supplements	2,371	2,272
NDA/BLA[1] Original	171	158
PDUFA Industry Meetings (including WROs[2])	3,773	4,594
Active Commercial INDs[3]	9,045	10,389

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

Utilizing the resource forecast algorithms, the forecasted workload volumes for FY 2023 were then converted into estimated FTE needs for CDER's PDUFA direct review-related work. The resulting expected FY 2023 FTE need for CDER was compared to current resource capacity for direct review related work to determine the FY 2023 resource delta, as summarized in table 5. Refinement of the time reporting categories included in the CPA resulted in a lowering of both the resource capacity and resource forecast compared to prior years.

Table 5.--CDER FY23 PDUFA Resource Delta

Center	Current Resource Capacity	FY 2023 Resource Forecast	Predicted FY 2023 FTE Delta
CDER	1,682	1,833	151

The projected 151 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. CDER recognizes that FY 2023 presents significant hiring commitments for the Center, including the hiring goals set forth for FY 2023 per the PDUFA VII 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, CDER is opting to take a conservative adjustment for FY 2023.

CDER emphasizes that the limiting factor on the FY 2023 adjustment is its ability to net gain additional hires above and beyond the existing committed hires across its user fee programs. If a significant resource gap persists in future years and the Agency's ability to net gain additional hires above existing commitments improves, larger CPA adjustments should be expected.

After assessing current hiring capacity and existing funded vacancies, CDER adjusted the 151 FTE delta to 27 FTEs. The FY 2023 PDUFA CPA for CDER is therefore $8,541,423, as summarized in table 6.

Table 6.--CDER FY 2023 PDUFA CPA

Center	Additional FTEs for FY 2023	Cost for Each Additional FTE	CDER FY 2023 PDUFA CPA
CDER	27	$316,349	$8,541,423

To calculate the FY 2023 PDUFA CPA for CBER, FDA followed the approach outlined above. Table 7 summarizes the forecasted workload volumes for CBER in FY 2023 as well as the corresponding historical actuals from FY 2021 for comparison.

Table 7.--CBER Actual FY 2021 Workload Volumes and Predicted FY 2023 Workload Volumes

Workload Category	FY 2021 Actuals	FY 2023 Predictions
Efficacy Supplements	17	12
Labeling Supplements	39	44
Manufacturing Supplements	778	645
NDA/BLA Original	10	8
PDUFA Industry Meetings (including WROs)	695	645
Active Commercial INDs[1]	1,572	1,857

[1] For purpose of the CPA, 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 2023 was then converted into expected FTE resources and compared to current resource capacity for PDUFA direct review work, as summarized in table 8.

Table 8.--CBER FY 2023 PDUFA Resource Delta

Center	Current Resource Capacity	FY 2023 Resource Forecast	Predicted FY 2023 FTE Delta
CBER	370	379	10[4]

The projected 10 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 considering subject matter expert input on industry trends and ongoing workload impacts stemming from the COVID–19 pandemic, accounting for historical net FTE gains within CBER and the hiring necessary to meet the hiring commitments set forth for FY 2023 in the PDUFA VII commitment letter, subtracting previously funded PDUFA vacancies aligned with CPA-covered activities, CBER determined that an adjustment of 10 additional FTEs for FY 2023 is needed. The FY 2023 CPA for CBER is therefore $3,116,730, as summarized in table 9.

Table 9.--CBER FY 2023 PDUFA CPA

Center	Additional FTEs for FY 2023	Cost for Each Additional FTE	CBER FY 2023 CPA
CBER	10	$311,673	$3,116,730

The CDER and CBER CPA amounts were then added together to determine the PDUFA CPA for FY 2023 of $11,658,153, as outlined in table 10. FDA will track the utilization of the CPA funds to ensure they are supporting the organizational 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 2023 PDUFA CPA

Center	FY 2023 PDUFA CPA
CDER	$8,541,423
CBER	$3,116,730
Total	$11,658,153

D. FY 2023 Statutory Fee Revenue Adjustments for Additional Dollar Amounts

PDUFA VII provides an additional dollar amount for each of the 5 fiscal years covered by PDUFA VII for additional FTE to support enhancements outlined in the PDUFA VII commitment letter. The additional dollar amount for FY 2023 as outlined in statute is $65,773,693 (see section 736(b)(1)(F) of the FD&C Act). This amount will be added to the total FY 2023 PDUFA VII revenue amount.

Table 11.--Base Revenue Amount and Section 736(c)(1) through (3) Adjustment Amounts

Fee	Amount
Statutory Fee Revenue Base Amount (section 736(b)(3) of the FD&C Act)	$1,151,522,958
Statutory Fee Revenue Adjustments for Inflation (section 736(c)(1) of the FD&C Act)	$18,889,583
Strategic Hiring and Retention Adjustment (section 736(c)(2)(A) of the FD&C Act)	$9,000,000
Statutory Fee Revenue Adjustments for Capacity Planning (section 736(c)(3) of the FD&C Act)	$11,658,153
Statutory Fee Revenue Adjustments for Additional Dollar Amounts (section 736(b)(1)(F) of the FD&C Act)	$65,773,693
Cumulative Revenue Amount after Adjustments in sections 736(c)(1), (2), and (3) of the FD&C Act	**$1,256,844,387**

E. FY 2023 Statutory Fee Revenue Adjustments for Operating Reserve

PDUFA VII provides for an operating reserve that may result in an increase or decrease in fee revenue and fees for a given FY (see section 736(c)(4) of the FD&C Act). For FY 2023, FDA is required to further increase fee revenue and fees if an adjustment is necessary to provide for at least 8 weeks of operating reserves of carryover user fees (see section 736(c)(4)(A)(i) of the FD&C Act). If FDA has carryover balances of user fees in excess of 14 weeks of operating reserves, FDA is required to decrease fee revenue and fees to provide for not more than 14 weeks of operating reserves of

carryover user fees (see section 736(c)(4)(B) of the FD&C Act).

To determine the dollar amounts for the 8-week and 14-week operating reserve thresholds, the adjustments (inflation, strategic hiring and retention, capacity planning, and additional dollar amount) discussed in sections II.A, II.B, II.C, and II.D are applied to the FY 2023 base revenue (see section 736(c)(4)(A) of the FD&C Act), resulting in $1,256,844,387. This amount is then divided by 52 to generate the 1-week operating amount of $24,170,084. The one-week operating amount is then multiplied by 8 and 14. This results in an 8-week threshold amount of $193,360,675 and a 14-week threshold amount of $338,381,181.

To determine the FY 2022 end-of-year operating reserves of carryover user fees, the Agency assessed the operating reserve of carryover fees at the end of July 2022 and forecast collections and obligations in the fourth quarter of FY 2022 combined. This provides an estimated end-of-year FY 2022 operating reserve of carryover user fees, or $184,271,732, which equates to 7.6 weeks of operations.[5]

Because the estimated FY 2022 end-of-year operating reserves of carryover user fees does not exceed the 14-week threshold amount, FDA will not reduce the FY 2023 fees or fee revenue. However, because the estimated FY 2022 end-of-year operating reserves of carryover user fees of $184,271,732 is below the 8-week threshold amount of $193,360,675 by $9,088,943, FDA will apply an operating reserve adjustment of $9,088,943 to increase the fee revenue and fees for FY 2023.

With respect to target revenue for FY 2023, adding the operating reserve adjustment amount of $9,088,943 to the inflation, strategic hiring and retention, CPA, and additional dollar amount of $1,256,844,387 results in the cumulative revenue amount of $1,265,933,330.

Table 12.--Base Revenue Amount and Section 736(c)(1) through (4) Adjustment Amounts

Fee	Amount
Statutory Fee Revenue Base Amount (section 736(b)(3) of the FD&C Act)	$1,151,522,958
Statutory Fee Revenue Adjustments for Inflation (section 736(c)(1) of the FD&C Act)	$18,889,583
Strategic Hiring and Retention Adjustment (section 736(c)(2)(A) of the FD&C Act)	$9,000,000
Statutory Fee Revenue Adjustments for Capacity Planning (section 736(c)(3) of the FD&C Act)	$11,658,153
Statutory Fee Revenue Adjustments for Additional Dollar Amounts (section 736(b)(1)(F) of the FD&C Act)	$65,773,693
Operating Reserve Adjustment (section (736(c)(4) of the FD&C Act)	$9,088,943
Cumulative Revenue Amount after Adjustments in sections 736(c)(1), (2), (3), and (4) of the FD&C Act	**$1,265,933,330**

F. FY 2023 Statutory Fee Revenue Adjustments for Additional Direct Cost

PDUFA VII specifies that an additional direct cost of $44,386,150 is to be added to the total FY 2023 PDUFA revenue amount (see section 736(c)(5) of the FD&C Act). With respect to target revenue for FY 2023, adding the additional direct cost amount of $44,386,150 to the inflation, strategic hiring and retention, CPA, additional dollar amount, and operating reserve adjustment of $1,265,933,330 results in the total revenue amount of $1,310,319,000 (rounded to the nearest thousand dollars).

Table 12.--Total Estimated Adjusted Revenue Amount

Fee	Amount
Statutory Fee Revenue Base Amount (section 736(b)(3) of the FD&C Act)	$1,151,522,958
Statutory Fee Revenue Adjustments for Inflation (section 736(c)(1) of the FD&C Act)	$18,889,583
Strategic Hiring and Retention Adjustment (section 736(c)(2)(A) of the FD&C Act)	$9,000,000
Statutory Fee Revenue Adjustments for Capacity Planning (section 736(c)(3) of the FD&C Act)	$11,658,153
Statutory Fee Revenue Adjustments for Additional Dollar Amounts (section 736(b)(1)(F) of the FD&C Act)	$65,773,693
Operating Reserve Adjustment (section (736(c)(4) of the FD&C Act)	$9,088,943
Additional Direct Cost (section 736(c)(5) of the FD&C Act)	$44,386,150
Total Revenue Amount (rounded to the nearest thousand dollars) (sections 736(c)(1), (2), (3), (4), and (5) of the FD&C Act	**$1,310,319,000**

[5] For purposes of the operating reserve adjustment under PDUFA VII, the operating reserve of carryover user fees includes only user fee funds that are available for obligation. FDA does not consider part of the operating reserve of carryover user fees certain user fee funds that were collected prior to 2010 and that are held by FDA, but which are considered unavailable for obligation due to lack of an appropriation ($78,850,995).

III. Application Fee Calculations

A. Application Fee Revenues and Application Fees

Application fees will be set to generate 20 percent of the total revenue amount, amounting to $262,063,800 in FY 2023.

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 three most recently completed fiscal years. For FY 2023 fee setting, the three relevant fiscal years are FYs 2019, 2020,[6] and 2021. 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, an application requiring covered clinical data[7] counts as one FAE. An application not requiring covered 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.

As table 14 shows, the average number of fee-paying FAEs received annually in FY 2019 through FY 2021 is 80.8333. FDA will set fees for FY 2023 based on this estimate as the number of full application equivalents that will be subject to fees.

Table 14.--Fee-Paying FAEs

	FY 2019	FY 2020	FY 2021	3-Year Average
Fee-Paying FAEs	86.75	65.25	90.5	80.8333

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

The FY 2023 application fee is estimated by dividing the average number of full applications that paid fees from FY 2019 through FY 2021, 80.8333, into the fee revenue amount to be derived from application fees in FY 2023, $262,063,800. The result is a fee of $3,242,026 per full application requiring clinical data, and $1,621,013 per application not requiring clinical data.

IV. Fee Calculation for Prescription Drug Fees

PDUFA VII assesses prescription drug program fees for certain prescription drug products. Program fees will be set to generate 80 percent of the total target revenue amount amounting to $1,048,255,200 in FY 2023.

An applicant will not be assessed more than five program fees for a FY 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 for user fee eligible prescription drug products identified in a human drug application approved as of October 1 of such fiscal year. Additionally, applicants are assessed a program fee for a product that is not a prescription drug product on October 1 because it is included in the discontinued section of the Orange Book or the CDER/CBER Biologics List on that date, if the product becomes a fee-eligible prescription drug product during the fiscal year.

FDA estimates 2,876 program fees will be invoiced in FY 2023 before factoring in waivers, refunds, and exemptions. FDA approximates that there will be 70 waivers and refunds granted. In addition, FDA approximates that another 43 program fees will be exempted in FY 2023 based on the orphan drug exemption in section 736(k) of the FD&C Act.

PDUFA VII changes the definition of the same product exception for program fees. FDA determined that 93 products may be eligible for the pharmaceutical equivalence same product exception. An additional exception for program fees for skin-test diagnostic products is included in the PDUFA VII. FDA has determined that there are nine skin-test diagnostic application products that may be eligible for the exception for skin diagnostic tests. FDA estimates 2,661 program fees in FY 2023, after allowing for an estimated 215 waivers and reductions, including the orphan drug exemptions, excepted and exempted fee-liable products. The FY 2023 prescription drug program fee rate is calculated by dividing the adjusted total revenue from program fees ($1,048,255,200) by the estimated 2,661 program fees resulting in a FY 2023 program fee of $393,933 (rounded to the nearest dollar).

V. Fee Schedule for FY 2023

The fee rates for FY 2023 are displayed in table 15.

Table 15.--Fee Schedule for FY 2023

Fee Category	Fee Rates for FY 2023
Application	
Requiring clinical data	$3,242,026
Not requiring clinical data	$1,621,013
Program	$393,933

[6] FY 2020 data was omitted in FY 2022 methodology as FDA took into account the global COVID–19 pandemic situation at the time. However, after reviewing the data trend, FY 2020 data is included in this year's methodology given the higher FAE count for FY 2021. See table 13.

[7] As defined in section 736(a)(1)(A)(i) of the FD&C Act.

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 VII that is submitted on or after October 1, 2022. 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 2023 program fees under the new fee schedule in October 2022. Under section 736(a)(2)(A)(i) of the FD&C Act, prescription drug program fees are generally due on October 3, 2022. However, given the late date of the PDUFA reauthorization, invoices should be paid within 30 days of invoice.

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

C. Fee Waivers and Refunds

To qualify for consideration for a waiver or reduction under section 736(d) of the FD&C Act, an exemption under section 736(k) of the FD&C Act, or the return of an application or program fee paid under section 736 of the FD&C Act, including if the fee is claimed to have been paid in error, a person must submit to FDA a written request justifying such waiver, reduction, exemption or return not later than 180 days after such fee is due (section 736(i) of the FD&C Act). A request submitted under this paragraph must include any legal authorities under which the request is made.

Dated: October 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–21968 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–2013–N–0242]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practices for Positron Emission Tomography Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by November 7, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0667. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Current Good Manufacturing Practices for Positron Emission Tomography Drugs—21 CFR Part 212

OMB Control Number 0910–0667—Revision

FDA current good manufacturing practice (CGMP) regulations in part 212 (21 CFR part 212) are intended to ensure that positron emission tomography (PET) drug products meet the requirements of the Federal Food, Drug, and Cosmetic Act (FD&C Act) regarding