person otherwise would be subject to user fees under AGDUFA based only on the submission of the supplemental abbreviated application (21 U.S.C. 379j–21(d)(2).

VIII. Procedures for Paying FY 2021 Generic New Animal Drug User Fees

A. Abbreviated Application Fees and Payment Instructions

The FY 2021 fee established in the new fee schedule must be paid for a generic new animal drug application subject to fees under AGDUFA III that is submitted on or after October 1, 2020. The payment must be made in U.S. currency from a U.S. bank by one of the following methods: Wire transfer, electronically, check, bank draft, or U.S. postal money order made payable to the Food and Drug Administration. The preferred payment method is online using an electronic check (Automated Clearing House (ACH), also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay* or the *Pay.gov* payment option is available to you after you submit a cover sheet. (Note: Only full payments are accepted. No partial payments can be made online.) Once you have found your invoice, select ''Pay Now'' to be redirected to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available only for balances 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.

When paying by check, bank draft, or U.S. postal money order, please write your application's unique Payment Identification Number (PIN), beginning with the letters ''AG'', on the upper right-hand corner of your completed Animal Generic Drug User Fee Cover Sheet. Also write FDA's post office box number (P.O. Box 979033) and PIN on the enclosed check, bank draft, or money order. Mail the payment and a copy of the completed Animal Generic Drug User Fee Cover Sheet to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000. Note: In no case should the payment for the fee be submitted to FDA with the application.

When paying by wire transfer, it is required that the invoice number is included; without the invoice number the payment may not be applied, and the invoice amount would be referred to collections. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required to add that amount to the payment to ensure that the invoice is paid in full. Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account Name: Food and Drug Administration, Account No.: 75060099, Routing No.: 021030004, SWIFT No.: FRNYUS33.

To send a check by a courier such as Federal Express, the courier must deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 979033, 1005 Convention Plaza, St. Louis, MO 63101. (*Note:* This address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314–418–4013. This phone number is only for questions about courier delivery.)

It is important that the fee arrives at the bank at least a day or two before the abbreviated application arrives at FDA's CVM. FDA records the official abbreviated application receipt date as the later of the following: The date the application was received by CVM, or the date U.S. Bank notifies FDA that your payment in the full amount has been received, or when the U.S. Department of the Treasury notifies FDA of payment. U.S. Bank and the United States Treasury are required to notify FDA within 1 working day, using the PIN described previously.

The tax identification number of FDA is 53–0196965.

B. Application Cover Sheet Procedures

Step One—Create a user account and password. Log onto the AGDUFA website at *https://www.fda.gov/ForIndustry/UserFees/AnimalGenericDrugUserFeeActAGDUFA/ucm137049.htm* and scroll down the page until you find the link ''Create AGDUFA User Fee Cover Sheet.'' Select that link and follow the directions. For security reasons, each firm submitting an application will be assigned an organization identification number, and each user will also be required to set up a user account and password the first time you use this site. Online instructions will walk you through this process.

Step Two—Create an Animal Generic Drug User Fee Cover Sheet, transmit it to FDA, and print a copy. After logging into your account with your user name and password, complete the steps required to create an Animal Generic Drug User Fee Cover Sheet. One cover sheet is needed for each abbreviated application for a generic new animal drug. Once you are satisfied that the data on the cover sheet is accurate and you have finalized the cover sheet, you will be able to transmit it electronically to FDA and you will be able to print a copy of your cover sheet showing your unique PIN.

Step Three—Send the payment for your application as described in section VIII.A.

Step Four—Please submit your application and a copy of the completed Animal Generic Drug User Fee Cover Sheet to the following address: Food and Drug Administration, Center for Veterinary Medicine, Document Control Unit (HFV–199), 7500 Standish Pl., Rockville, MD 20855.

C. Product and Sponsor Fees

By December 31, 2020, FDA will issue invoices and payment instructions for product and sponsor fees for FY 2021 using this fee schedule. Fees will be due by January 31, 2021. FDA will issue invoices in November 2021 for any products and sponsors subject to fees for FY 2021 that qualify for fees after the December 2020 billing.

Dated: July 28, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–16688 Filed 7–29–20; 4:15 pm]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1700]

Prescription Drug 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 prescription drug user fees for fiscal year (FY) 2021. 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 2021.

FOR FURTHER INFORMATION CONTACT: Melissa Hurley, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 61075, Beltsville, MD 20705–4304, 240–402–4585.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 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 2021 is $1,065,707,676. The FY 2021 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 or 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 2021 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 2021 for an application requiring clinical data ($2,875,842), for an application not requiring clinical data ($1,437,921), and for the prescription drug program fee ($336,432). 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 $1,065,707,676 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 2021 Statutory Fee Revenue Adjustments for Inflation

PDUFA VI specifies that the $1,065,707,676 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 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 FYs, 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 FYs (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 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 PERSONNEL COMPENSATION AND BENEFITS (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 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 FYs.

TABLE 2—PC&B AS A PERCENT OF TOTAL COST OF THE PROCESS FOR THE REVIEW OF HUMAN DRUG APPLICATIONS

Fiscal year	2017	2018	2019	3-Year average
Total PC&B	$711,016,627	$792,900,647	$872,087,636	
Total Costs	$1,206,657,269	$1,374,508,527	$1,430,338,888	
PC&B Percent	58.9245%	57.6861%	60.9707%	59.1938%

The payroll adjustment is 1.2644 percent from table 1 multiplied by 59.1938 percent (or 0.7484 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 FYs (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-

[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.

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	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 human drug applications obligated. Because 59.1938 percent was obligated for PC&B (as shown in table 2), 40.8062 percent is the portion of costs other than PC&B (100 percent minus 59.1938 percent equals 40.8062 percent). The non-payroll adjustment is 1.4726 percent times 40.8062 percent, or 0.6009 percent.

Next, we add the payroll adjustment (0.7484 percent) to the non-payroll adjustment (0.6009 percent), for a total inflation adjustment of 1.3493 percent (rounded) for FY 2021.

We then multiply the base revenue amount for FY 2021 ($1,065,707,676) by 1.013493, yielding an inflation-adjusted amount of $1,080,087,270.

B. FY 2021 Statutory Fee Revenue Adjustments for Capacity Planning

The statute specifies that after $1,065,707,676 has been adjusted for inflation, the inflation-adjusted amount shall be further adjusted to reflect changes in the resource capacity needs for the process for human drug application reviews (see section 736(c)(2) of the FD&C Act). The statute directed FDA to utilize an interim capacity planning adjustment until a new methodology could be developed and made effective.

As a first step toward the new methodology, FDA committed to establish modernized time reporting and a resource capacity planning capability. Modernized time reporting was implemented in the Center for Biologics Evaluation and Research (CBER) in 2018 and in the Center for Drug Evaluation and Research (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 new methodology to accurately assess changes in the resource and capacity needs of the process for the review of human drug 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 new CPA methodology for the setting of FY 2021 fee amounts.

The new CPA methodology is intended to resolve issues with the previous interim methodology.[4] First, the interim methodology was a lagging indicator as it utilized changes in average workload volumes during prior years—specifically, the adjustment was based on the change in the 3-year average ending in the most recent year for which data is available over the 3-year average for the previous year. The new methodology replaces the comparison of prior 3-year averages with predictive models to forecast future workload volumes, where feasible. Second, the interim CPA methodology did not convert the volume of workload into resource demands; its adjustments simply reflected changes in average number of workload units. The new methodology translates the expected workload volumes into forecasted staffing needs in terms of FTEs, facilitating a more straightforward calculation of both future resource and funding needs.

The new CPA methodology includes four steps:

(1) Forecast workload volumes: Predictive models estimate the volume of workload for the upcoming fiscal year. Workload categories in the CPA for PDUFA include original new drug applications (NDAs)/biologics license applications (BLAs), commercial investigational new drug applications (INDs) with activity, supplements (efficacy, labeling and manufacturing), and formal industry meetings scheduled (Type A–C meetings ,[5] including written-response only (WRO) 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 effort. 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 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.

Further, FDA is adopting an iterative, continuous improvement approach as part of its new CPA methodology. For FY 2021, FDA is applying the new methodology to core review activities, for which significant data collection and analysis has been completed. Going forward, the Agency intends to refine its

[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] Under the interim methodology, the capacity planning adjustment for a fiscal year was based on the product of the annual base revenue for the year, as adjusted for inflation, and an adjustment percentage. The adjustment percentage was a weighted change in the 3-year average ending in the most recent year for which data are available, over the 3-year average in the previous year, for: (1) The total number of human drug applications, efficacy supplements, and manufacturing supplements submitted to FDA; (2) the total number of active commercial investigational new drug applications; and (3) the total number of formal meetings scheduled by FDA and written responses issued by the Agency in lieu of such formal meetings, as set forth in section 1.H. of the PDUFA commitment letter.

[5] The PDUFA VI commitment letter defines these meeting types in section 1.H.: *https://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm511438.pdf.*

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 human drug applications under PDUFA, potentially including, for example, postmarket 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 PDUFA program resource needs, and that this new methodology represents a significant improvement over the previous CPA methodology.

To determine the FY 2021 capacity planning adjustment, FDA calculated a PDUFA CPA for CDER and CBER individually. The final Center-level results were then combined to determine the total FY 2021 PDUFA CPA. The following section outlines the major components of each Center's FY 2021 PDUFA CPA.

Table 4 summarizes the forecasted workload volumes for CDER in FY 2021 based on predictive models, as well as historical actuals from FY 2019 for comparison.

TABLE 4—CDER ACTUAL FY 2019 WORKLOAD VOLUMES AND PREDICTED FY 2021 WORKLOAD VOLUMES

Workload category	FY 2019 actuals	FY 2021 predictions
Efficacy Supplements	287	322
Labeling Supplements	1,320	1,584
Manufacturing Supplements	2,024	2,187
NDA/BLA Original	156	171
PDUFA Industry Meetings Scheduled and WROs	3,186	3,249
Active Commercial INDs [1]	8,233	8,565

[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.*

[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.

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

TABLE 5—CDER FY21 PDUFA RESOURCE DELTA

Center	Current resource capacity	FY 2021 resource forecast	Predicted FY 2021 FTE delta
CDER	1,594.1	1,859.7	265.6

The projected 265.6 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. After accounting for the range of recent years historical net FTE gains within CDER and subtracting previously funded PDUFA vacancies, a range of 6 to 59 FTEs was established as a realistic adjustment for FY 2021. CDER adjusted to the lower portion of this range until the pace of net gains increases and is sustained. CDER also recognized that some resources may be required to sustain increases in PDUFA workload resulting from the impacts of the COVID–19 pandemic. In summary, after accounting for these internal factors, FDA determined that an adjustment for $3,922,113 to fund an equivalent of 13 FTEs in FY 2021 was needed and realistic.

TABLE 6—CDER FY 2021 PDUFA CPA

Center	Additional FTEs for FY 2021	Cost for each additional FTE	CDER FY21 PDUFA CPA
CDER	13	$301,701	$3,922,113

To calculate the FY 2021 PDUFA CPA for CBER, FDA followed the same approach outlined above. Table 7 summarizes the forecasted workload volumes for CBER in FY 2021 as well as the corresponding historical actuals from FY 2019 for comparison.

TABLE 7—CBER ACTUAL FY 2019 WORKLOAD VOLUMES AND PREDICTED FY 2021 WORKLOAD VOLUMES

Workload category	FY 2019 Actuals	FY 2021 predictions
Efficacy Supplements	12	15
Labeling Supplements	66	64
Manufacturing Supplements	541	576
NDA/BLA Original	7	7
PDUFA Industry Meetings Scheduled and WROs	541	738
Active Commercial INDs[1]	1,361	1,571

The forecasted CBER PDUFA workload for FY 2021 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 2021 PDUFA RESOURCE DELTA

Center	Current resource capacity	FY 2021 resource forecast	Predicted FY 2021 FTE delta
CBER	322.7	385.1	62.4

The projected 62.4 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 29 additional FTEs within CBER for FY 2021 was determined to be both needed and realistic to support significant growth in some PDUFA products and PDUFA workload stemming from the COVID–19 pandemic. The FY 2021 PDUFA CPA for CBER is therefore $8,641,681, as summarized in table 9.

TABLE 9—CBER FY 2021 PDUFA CPA

Center	Additional FTEs for FY 2021	Cost for each additional FTE	CBER FY 2021 PDUFA CPA
CBER	29	$297,989	$8,641,681

The CDER and CBER CPA amounts were then added together to determine the PDUFA CPA for FY 2021 of $12,563,794, as outlined in table 10.

TABLE 10—FY 2021 PDUFA CPA

Center	FY 2021 PDUFA CPA
CDER	$3,922,113
CBER	$8,641,681
Total	$12,563,794

Table 11 shows the calculation of the inflation and capacity planning adjusted amount for FY 2021. The FY 2021 base revenue amount, $1,065,707,676, shown on line 1 is multiplied by the inflation adjustment factor of 1.013493, resulting in the inflation-adjusted amount of $1,080,087,270 shown on line 3. The FY 2021 CPA of $12,563,794 is then added on line 4, resulting in the inflation and capacity planning adjusted amount of $1,092,651,064 shown on line 5.

TABLE 11.—PDUFA INFLATION AND CAPACITY PLANNING ADJUSTED AMOUNT FOR FY 2021, SUMMARY CALCULATION

FY 2021 Revenue Amount	$1,065,707,676	Line 1
Inflation Adjustment Factor for FY 2021 (1 plus 1.3493 percent)	1.013493	Line 2
Inflation-Adjusted Amount	$1,080,087,270	Line 3
Capacity Planning Adjustment for FY 2021	$12,563,794	Line 4
Inflation and Capacity Planning Adjusted Amount	$1,092,651,064	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[6]).

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

C. FY 2021 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 PDUFA VI

enhancements outlined in the PDUFA VI commitment letter. The amount for FY 2021 is $5,426,896 (see section 736(b)(1)(F) of the FD&C Act). Adding this amount to the inflation and capacity planning adjusted revenue amount, $1,092,651,064, equals $1,098,077,960.

D. FY 2021 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 2021 annual base revenue adjusted for inflation, capacity planning, and additional dollar amounts, $1,098,077,960 is divided by 52, and then multiplied by 14. The 14-week operating reserve amount for FY 2021 is $295,636,374.

To determine the end of year operating reserve amount, the Agency must assess actual operating reserve at the end of the third quarter of FY 2020 and forecast collections and obligations in the fourth quarter of FY 2020. The estimated end of year FY 2020 operating reserve is $217,070,092.

Because the estimated end of year FY 2021 PDUFA operating reserve does not exceed the 14-week operating reserve for FY 2021, FDA will not reduce the FY 2021 PDUFA fee revenue in FY 2021.

E. FY 2021 Statutory Fee Revenue Adjustments for Additional Direct Cost

PDUFA VI specifies that $8,730,000, adjusted for inflation, be added in addition to the operating reserve adjustment to account for additional direct costs in FY 2021. This additional direct cost adjustment is adjusted for inflation by multiplying $8,730,000 by the Consumer Price Index 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 2020 and subsequent years. The annual index for 2019, 264.777, divided by such index for 2016, 253.422, results in an adjustment factor of 1.044807, making the additional direct cost adjustment equal to $9,121,165.

The final FY 2021 PDUFA target revenue is $1,107,199,000 (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 $221,439,800 in FY 2021.

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

FDA will estimate the total number of fee-paying full application equivalents (FAEs) it expects to receive during the next FY by averaging the number of fee-paying FAEs received in the 3 most recently completed FYs. Prior year FAE totals are updated annually to reflect refunds and waivers processed after the close of the FY.

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 the most recent 3-year period is 77 FAEs. FDA will set fees for FY 2021 based on this estimate as the number of full application equivalents that will pay 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 FY.

The FY 2021 application fee is estimated by dividing the average number of full applications that paid fees over the latest 3 years, 77, into the fee revenue amount to be derived from application fees in FY 2021, $221,439,800. The result is a fee of $2,875,842 per full application requiring clinical data, and $1,437,921 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; in addition, 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 2,793 program fees will be invoiced in FY 2021 before factoring in waivers, refunds, and exemptions. FDA approximates that there will be 124 waivers and refunds granted. In addition, FDA approximates that another 36.2 program fees will be exempted in FY 2021 based on the orphan drug exemption in section 736(k) of the FD&C Act. FDA estimates 2,632.8 program fees in FY 2021, after allowing for an estimated 160.2 waivers and reductions, including the orphan drug exemptions. The FY 2021 prescription drug program fee rate is calculated by dividing the adjusted total revenue from program fees ($885,759,200) by the estimated 2,632.8 program fees, for a FY 2021 program fee of $336,432 (rounded to the nearest dollar).

V. Fee Schedule for FY 2021

The fee rates for FY 2021 are displayed in table 13.

TABLE 13—FEE SCHEDULE FOR FY 2021

Fee Category	Fee rates for FY 2021
Application:	
Requiring clinical data	$2,875,842
Not requiring clinical data	$1,437,921
Program	$336,432

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, 2020. 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. The originating financial institution may charge a wire transfer fee. Applicable wire transfer fees must be included with payment to ensure fees are fully paid. 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 2021 program fees under the new fee schedule in August 2020. Payment will be due on October 1, 2020. FDA will issue invoices in December 2020 for FY 2021 program fees that qualify for fee assessments after the August 2020 billing.

Dated: July 29, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–16833 Filed 7–29–20; 4:15 pm]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3723]

Watson Laboratories, Inc.; Withdrawal of Approval of an Abbreviated New Drug Application for Oxycodone Hydrochloride and Ibuprofen Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) is withdrawing approval of an abbreviated new drug application (ANDA) for oxycodone hydrochloride and ibuprofen tablets. The basis for the withdrawal is that the holder of the ANDA has repeatedly failed to submit the required data to support a finding of bioequivalence for this ANDA. The holder of the ANDA has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of August 3, 2020.

FOR FURTHER INFORMATION CONTACT: Jennifer Forde, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6228, Silver Spring, MD 20993–0002, 301–348–3035.

SUPPLEMENTARY INFORMATION: FDA's Office of Generic Drugs (OGD) approved ANDA 078394, held by Watson Laboratories, Inc. (Watson),[1] for a generic version of oxycodone hydrochloride and ibuprofen tablets, 5 milligrams (mg)/400 mg, under the requirements of section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) and FDA's implementing regulations. The OGD approved ANDA 078394 on November 26, 2007. In a notice of opportunity for a hearing (NOOH) published in the **Federal Register** of October 28, 2019 (84 FR 57739), CDER notified Watson of CDER's proposal to issue an order, under section 505(e) of the FD&C Act and § 314.150 (21 CFR 314.150), withdrawing approval of ANDA 078394 and all amendments and supplements to it on the grounds that Watson has failed to submit the required bioequivalence data necessary to demonstrate the bioequivalence of its drug product.

As noted in the October 28, 2019, NOOH, FDA issued a letter to Watson on August 9, 2011, regarding ANDA 078394 because this drug product application was supported by bioequivalence studies with the bioanalytical analysis conducted by Cetero Research at the Houston, TX, site between April 1, 2005, and June 15, 2010. As FDA noted in its August 9, 2011 correspondence, inspection findings regarding Cetero Research's bioequivalence studies raised significant concerns about the validity of the reported results of the analytical studies conducted between April 2005 and June 2010 in support of drug applications. Accordingly, FDA informed Watson that ANDA 078394 needed to be supplemented by conducting new bioequivalence studies or re-assaying

[1] In correspondence dated February 23, 2017, Watson notified FDA that Watson is an indirect, wholly-owned subsidiary of Teva Pharmaceuticals USA, Inc.