needed, FDA's tax identification number is 53–0196965.

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Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0007]

Prescription Drug User Fee Rates for Fiscal Year 2019

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) 2019. 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 2019.

FOR FURTHER INFORMATION CONTACT: Lola Olajide, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE–14541B, Silver Spring, MD 20993–0002, 240–402–4244.

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).

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 2019 is $935,903,507. The FY 2019 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). 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 2019 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 2019 for an application requiring clinical data ($2,588,478), for an application not requiring clinical data ($1,294,239), and for the prescription drug program fee ($309,915). These fees are effective on October 1, 2018, and will remain in effect through September 30, 2019. For applications that are submitted on or after October 1, 2018, the new fee schedule must be used.

II. Fee Revenue Amount for FY 2019

The base revenue amount for FY 2019 is $935,903,507 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 2018 Statutory Fee Revenue Adjustments for Inflation

PDUFA VI specifies that the $935,903,507 is to be adjusted for inflation increases for FY 2019 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 (c)(1)(B) of the FD&C Act).

Table 1 summarizes the actual cost and FTE data for the specified FYs and provides the percent changes from the previous FYs and the average percent changes over the first three of the four FYs preceding FY 2019. The 3-year average is 2.4152 percent.

TABLE 1—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGES

Fiscal year	2015	2016	2017	3-year average
Total PC&B	$2,232,304,000	$2,414,728,159	$2,581,551,000	
Total FTE	15,484	16,381	17,022	
PC&B per FTE	$144,168	$147,408	$151,660	
Percent Change From Previous Year	2.1136	2.2474	2.8845	2.4152

The statute specifies that this 2.4152 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 three of the preceding four FYs.

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

Fiscal year	2015	2016	2017	3-year average
Total PC&B	$615,483,892	$652,508,273	$711,016,627	
Total Costs	$1,127,664,528	$1,157,817,695	$1,206,657,269	
PC&B Percent	54.5804	56.3567	58.9245	56.6205

The payroll adjustment is 2.4152 percent from table 1 multiplied by 56.6205 percent (or 1.3675 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). Table 3 provides the summary data for the percent changes in the specified CPI for the Washington-Baltimore 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=CUURA311SA0, CUUSA311SA0.*

TABLE 3—ANNUAL AND THREE-YEAR AVERAGE PERCENT CHANGE IN CPI FOR WASHINGTON-BALTIMORE AREA

Year	2015	2016	2017	3-year average
Annual CPI	155.353	157.180	159.202	.....
Annual Percent Change	0.3268	1.1760	1.2864	0.9297

The statute specifies that this 0.9297 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. Since 56.6205 percent was obligated for PC&B (as shown in table 2), 43.3795 percent is the portion of costs other than PC&B (100 percent minus 56.6205 percent equals 43.3795 percent). The non-payroll adjustment is 0.9297 percent times 43.3795 percent, or 0.4033 percent.

Next, we add the payroll adjustment (1.3675 percent) to the non-payroll adjustment (0.4033 percent), for a total inflation adjustment of 1.7708 percent (rounded) for FY 2019.

We then multiply the base revenue amount for FY 2019 ($935,903,507) by 1.017708, yielding an inflation-adjusted amount of $952,476,486.

B. FY 2019 Statutory Fee Revenue Adjustments for Capacity Planning

The statute specifies that after $935,903,507 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). The statute prescribes an interim capacity planning adjustment be utilized until a new methodology can be developed through a process involving an independent evaluation as well as obtaining public comment. The interim capacity planning adjustment is applied to FY 2019 fee setting.

To determine the FY 2019 capacity planning adjustment, FDA calculated the average number of each of the five elements specified in the capacity planning adjustment provision: (1) Human drug applications (new drug applications (NDAs)/biologics license applications (BLAs)); (2) active commercial investigational new drug applications (INDs) (IND applications that have at least one submission during the previous 12 months); (3) efficacy supplements; (4) manufacturing supplements; and (5) formal meetings, type A, B, B(EoP), C, and written responses only (WRO) issued in lieu of such formal meetings, over the 3-year period that ended on June 30, 2017, and the average number of each of these elements over the most recent three-year period that ended June 30, 2018.

The calculations are summarized in table 4. The three-year averages for each element are provided in column 1 (''Three-Year Average Ending 2017'') and column 2 (''Three-Year Average Ending 2018''). Column 3 reflects the percent change from column 1 to column 2. Column 4 shows the weighting factor for each element. The weighting factor methodology has been updated for PDUFA VI. The previous methodology relied on the relative value of the standard costs for the elements included in the adjuster, and summed to 100 percent. The weighting factor now is the time invested in activities related to the element expressed as a percentage of total time invested in PDUFA activities, and will adjust only the costs attributed to the elements included in the model (hence the weighting factor does not now sum to 100 percent). Column 5 is the weighted percent change in each element. This is calculated by multiplying the weighting factor in each line in column 4 by the percent change in column 3. The values in column 5 are summed, reflecting an adjustment of 2.9067 percent (rounded).

TABLE 4—CAPACITY PLANNING ADJUSTER (INTERIM METHODOLOGY) CALCULATION FOR FY 2019

Element	Column 1	Column 2	Column 3	Column 4	Column 5
	3-year average ending 2017	3-year average ending 2018	Percent change (column 1 to column 2)	Weighting factor (percent)	Weighted percent change
NDAs/BLAs	153.0000	162.0000	5.8824	20.5015	1.2060
Active Commercial INDs	7,846.6667	8,057.0000	2.6805	22.2771	0.5971
Efficacy Supplements	212.3333	234.3333	10.3611	5.2439	0.5433
Manufacturing Supplements	2,482.6667	2,561.6667	3.1821	3.7243	0.1185
Meetings Scheduled and WROs	2,940.0000	3,136.3333	6.6780	6.6156	0.4418
FY 2019 Capacity Planning Adjuster	.....	.....	.....	.....	2.9067

Table 5 shows the calculation of the inflation and capacity planning adjusted amount for FY 2019. The FY 2019 base revenue amount, $935,903,507, shown on line 1 is multiplied by the inflation adjustment factor of 1.017708, resulting

in the inflation-adjusted amount of $952,476,486 shown on line 3. That amount is then multiplied by one, plus the capacity planning adjustment of 2.9067 percent, resulting in the inflation and capacity planning adjusted amount of $980,162,120 shown on line 5.

TABLE 5—PDUFA INFLATION AND CAPACITY PLANNING ADJUSTED AMOUNT FOR FY 2019, SUMMARY CALCULATION

FY 2019 Revenue Amount	$935,903,507	Line 1.
Inflation Adjustment Factor for FY 2019 (1 plus 1.7708 percent)	1.017708	Line 2.
Inflation Adjusted Amount	952,476,486	Line 3.
Capacity Planning Adjustment Factor for FY 2019 (1 plus 2.9067 percent)	1.029067	Line 4.
Inflation and Capacity Planning Adjusted Amount	980,162,120	Line 5.

The capacity planning adjustment adds $27,685,634 to the fee revenue amount for FY 2019. This increase is driven by the fact that the counts of elements for 2018 (year ending June 30) are at or near the highest levels since the first incorporation of the workload adjuster in 2003. The NDA/BLA count in 2018 is equal to the highest annual number recorded since the advent of the workload adjuster methodology in 2003. Active commercial INDs, efficacy supplements, and meetings/WROs are higher in 2018 than in any previous year recorded in the workload adjuster (note: Meetings/WROs are only counted back to 2014 while the other elements are counted back to 2003). The manufacturing supplement count is approximately 2 percent below the highest number recorded in the history of the workload adjuster. Comparing 2018 to 2015, the first year included in the average in column 1 in the adjustment, NDA/BLAs are 17 percent higher, active commercial INDs are 8 percent higher, efficacy supplements are 36 percent higher, manufacturing supplements are 10 percent higher, and meetings scheduled and WROs are 21 percent higher. This significant and across the board increase in submission activity is the driver of the $27,685,634 upward adjustment to the fee revenue amount.

Per the commitments made in PDUFA VI, this increase in the revenue amount will be allocated 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 [1]).

C. FY 2019 Statutory Fee Revenue Adjustments for Additional Dollar Amounts

PDUFA VI provides an additional dollar amount for each of the five 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 2019 is $21,317,472 (see section 736(b)(1)(F) of the FD&C Act). Adding this amount to the inflation and capacity planning adjusted revenue amount, $980,162,120, equals $1,001,479,592.

D. FY 2019 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 2019 annual base revenue adjusted for inflation and capacity planning, $980,162,120, is divided by 52, and then multiplied by 14. The 14-week operating reserve amount for FY 2019 is $263,889,802.

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 2018, and forecast collections and obligations in the fourth quarter of FY 2018. The estimated end of year FY 2018 operating reserve is $235,128,646.

Because the estimated end of year FY 2019 PDUFA operating reserve does not exceed the 14-week operating reserve for FY 2019, FDA will not reduce the FY 2019 PDUFA fee revenue in FY 2019.

E. FY 2019 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 2019. 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 2017, which is 159.202, and then divided by such Index for 2016, 157.180 (see section 736(c)(4)(B) of the FD&C Act). This results in an adjustment factor of 1.012864, making the additional direct cost adjustment equal to $8,842,303.

The final FY 2019 PDUFA target revenue is $1,010,322,000 (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 $202,064,400 in FY 2019.

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 three 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 6 shows, the average number of fee-paying FAEs received annually in the most recent three-year period is 78.063013 FAEs. FDA will set fees for

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

FY 2019 based on this estimate as the number of full application equivalents that will pay fees.

TABLE 6—FEE-PAYING FAEs

FY	2015	2016	2017	3-year average
Fee-Paying FAEs	81.955603	70.483437	81.750000	78.063013

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

The FY 2019 application fee is estimated by dividing the average number of full applications that paid fees over the latest three years, 78.063013, into the fee revenue amount to be derived from application fees in FY 2019, $202,064,400. The result is a fee of $2,588,478 per full application requiring clinical data, and $1,294,239 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)). Applicants are assessed a program fee for a fiscal year only for prescription drug products identified in a human drug application approved as of October 1 of such fiscal year.

FDA estimates 2,683 program fees will be invoiced in FY 2019 before factoring in waivers, refunds, and exemptions. FDA approximates that there will be 40 waivers and refunds granted. In addition, FDA approximates that another 35 program fees will be exempted in FY 2019 based on the orphan drug exemption in section 736(k) of the FD&C Act. FDA estimates 2,608 program fees in FY 2019, after allowing for an estimated 75 waivers and reductions, including the orphan drug exemptions. The FY 2019 prescription drug program fee rate is calculated by dividing the adjusted total revenue from program fees ($808,257,600) by the estimated 2,608 program fees, for a FY 2019 program fee of $309,915.

V. Fee Schedule for FY 2019

The fee rates for FY 2019 are displayed in table 7:

TABLE 7—FEE SCHEDULE FOR FY 2019

Fee category	Fee rates for FY 2019
Application:	
Requiring clinical data	$2,588,478
Not requiring clinical data	1,294,239
Program:	309,915

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 received on or after October 1, 2018. 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). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay* (Note: Only full payments are accepted. No partial payments can be made online). Once you search for your invoice, select ''Pay Now'' to be redirected to *Pay.gov.* Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S bank accounts as well as U.S. credit cards.

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.

Please include the user fee (ID) number on your check, bank draft, or postal money order. Mail your payment 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.

If paying by wire transfer, please reference your unique user fee ID number when completing your transfer. The originating financial institution may charge a wire transfer fee. Please ask your financial institution about the fee and add it to your payment to ensure that your fee is fully paid. 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 2019 program fees under the new fee schedule in August 2018. Payment will be due on October 1, 2018. FDA will issue invoices in December 2018 for FY 2019 program fees that qualify for fee assessments after the August 2018 billing.

Dated: July 26, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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