



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0007]

Prescription Drug User Fee Rates for Fiscal Year 2018

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) 2018. The Federal Food, Drug, and Cosmetic Act (the 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 2018.

FOR FURTHER INFORMATION CONTACT: Robert J. Marcarelli, Office of Financial Management, Food and Drug Administration, 8455 Colesville Rd., COLE-14202F, Silver Spring, MD 20993-0002, 301-796-7223.

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 on the following: (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 2018 is \$878,590,000. The FY 2018 base revenue amount is to be 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 2018 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 2018 for an application requiring clinical data (\$2,421,495), for an application not requiring clinical data (\$1,210,748), and for the prescription drug program fee (\$304,162). These fees are effective on October 1, 2017, and will remain in effect through September 30, 2018. For applications that are submitted on or after October 1, 2017, the new fee schedule must be used.

II. Fee Revenue Amount for FY 2018

The base revenue amount for FY 2018 is \$878,590,000 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 \$878,590,000 is to be adjusted for inflation increases for FY 2018 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 three of the preceding four 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 three of the preceding four 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 2018. The 3-year average is 2.2354 percent.

Table 1.--FDA Personnel Compensation and Benefits (PC&B) Each Year and Percent Changes

Fiscal Year	2014	2015	2016	3-Year Average
Total PC&B	\$2,054,937,000	\$2,232,304,000	\$2,414,728,159	
Total FTE	14,555	15,484	16,381	
PC&B per FTE	\$141,184	\$144,168	\$147,408	
Percent Change From Previous Year	2.3451	2.1136	2.2474	2.2354

The statute specifies that this 2.2354 percent should 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 three FYs.

Table 2.--PC&B as a Percent of Fee Revenues Spent on the Process for the Review of Human Drug Applications

Fiscal Year	2014	2015	2016	3-Year Average
Total PC&B	\$585,260,720	\$615,483,892	\$652,508,273	
Total Costs	\$1,077,263,695	\$1,127,664,528	\$1,157,817,695	
PC&B Percent	54.3285	54.5804	56.3567	55.0885

The payroll adjustment is 2.2354 percent from table 1 multiplied by 55.0885 percent (or 1.2314 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 three years of the preceding four 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: <http://data.bls.gov/cgi-bin/surveymost?cu>. The data can be viewed by checking the box marked “Washington-Baltimore All Items, November 1996=100 - CUURA311SA0” and then selecting “Retrieve Data”.

Table 3.--Annual and Three-Year Average Percent Change in CPI for Washington-Baltimore Area

Year	2014	2015	2016	3-Year Average
Annual CPI	154.847	155.353	157.180	
Annual Percent Change	1.5390	0.3268	1.1760	1.0139

The statute specifies that this 1.0139 percent should 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 55.0885 percent was obligated for PC&B (as shown in table 2), 44.9115 percent is the portion of costs other than PC&B (100 percent minus 55.0885 percent equals 44.9115 percent). The non-payroll adjustment is 1.0139 percent times 44.9115 percent, or 0.4554 percent.

Next, we add the payroll adjustment (1.2314 percent) to the non-payroll adjustment (0.4554 percent), for a total inflation adjustment of 1.6868 percent (rounded) for FY 2018.

We then multiply the base revenue amount for FY 2018 (\$878,590,000) by 1.016868, yielding an inflation-adjusted amount of \$893,410,056.

B. FY 2018 Statutory Fee Revenue Adjustments for Capacity Planning

The statute specifies that after \$878,590,000 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 2018 fee setting.

To determine the FY 2018 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, 2016, and the average number of each of these elements over the most recent 3-year period that ended June 30, 2017.

The calculations are summarized in table 4. The 3-year averages for each element are provided in column 1 (“3-Year Average Ending 2016”) and column 2 (“3-Year Average Ending 2017”). 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 2.5090 percent (rounded).

Table 4.--Capacity Planning Adjuster (Interim Methodology) Calculation for FY 2018

Element	Column 1	Column 2	Column 3	Column 4	Column 5
	3-Year Average Ending 2016	3-Year Average Ending 2017	Percent Change (column 1 to column 2)	Weighting Factor (percent)	Weighted Percent Change
NDA/BLAs	147.3333	153.0000	3.8462	18.0915	0.6958
Active Commercial INDs	7,598.0000	7,846.6667	3.2728	23.3890	0.7655
Efficacy Supplements	196.3333	212.3333	8.1494	4.1848	0.3410
Manufacturing Supplements	2,368.0000	2,482.6667	4.8423	4.3690	0.2116
Meetings Scheduled and WROs	2,720.6667	2,940.0000	8.0617	6.1417	0.4951
FY 2018 Capacity Planning Adjuster					2.5090

Table 5 shows the calculation of the inflation and capacity planning adjusted amount for FY 2018. The FY 2018 base revenue amount, \$878,590,000, shown on line 1 is multiplied by the inflation adjustment factor of 1.016868, resulting in the inflation-adjusted amount of \$893,410,056 shown on line 3. That amount is then multiplied by one plus the capacity planning adjustment of 2.5090 percent, resulting in the inflation and capacity planning adjusted amount of \$915,825,714 shown on line 5.

Table 5.--PDUFA Inflation and Capacity Planning Adjusted Amount for FY 2018, Summary Calculation

FY 2018 Revenue Amount	\$878,590,000	Line 1
Inflation Adjustment Factor for FY 2018 (1 plus 1.6868 percent)	1.016868	Line 2
Inflation Adjusted Amount	\$893,410,056	Line 3
Capacity Planning Adjustment Factor for FY 2018 (1 plus 2.5090 percent)	1.025090	Line 4
Inflation and Capacity Planning Adjusted Amount	\$915,825,714	Line 5

The capacity planning adjustment adds \$22,415,658 to the fee revenue amount for FY 2018. This increase is driven by the fact that the counts of elements for 2017 (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 2017 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 2017 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 2017 to 2014, the first year included in the average in column 1 in the adjustment, NDA/BLAs are 12 percent higher, active commercial INDs are 10 percent higher, efficacy supplements are 25 percent higher, manufacturing supplements are 15 percent higher, and meetings scheduled and WROs are 27 percent higher. This significant and across the board increase in submission activity is the driver of the \$22,415,658 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 letter¹).

C. FY 2018 Statutory Fee Revenue Adjustments for Additional Dollar Amounts

PDUFA VI provides an additional dollar amount for each of the next five fiscal years for additional FTE to support PDUFA VI enhancements outlined in the PDUFA VI commitment letter. The amount for FY 2018 is \$20,077,793 (see section 736(b)(1)(F) of the FD&C Act).

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

Adding this amount to the inflation and capacity planning adjusted revenue amount, \$915,825,714, equals \$935,904,000 (rounded to the nearest thousand dollars).

D. FY 2018 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 2018 annual base revenue adjusted for inflation and capacity planning, \$915,825,714, is divided by 52, and then multiplied by 14. The 14-week operating reserve amount for FY 2018 is \$246,568,461.

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 2017, and forecast collections and obligations in the fourth quarter of FY 2017. The estimated end of year FY 2017 operating reserve is \$279,856,044.

Because the estimated end of year FY 2017 PDUFA operating reserve exceeds the 14-week operating reserve for FY 2018, FDA will reduce the FY 2018 PDUFA fee revenue of \$935,903,507 by \$33,287,582, resulting in an adjusted fee revenue of \$902,615,925.

E. FY 2018 Statutory Fee Revenue Adjustments for Additional Direct Cost

PDUFA VI specifies that \$8,730,000 be added in addition to the operating reserve adjustment to account for additional direct costs in FY 2018. This additional direct cost adjustment will be adjusted for inflation each year beginning in FY 2019.

The final FY 2018 PDUFA fee revenue is \$911,346,000 (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 revenue amount, or \$182,269,200 in FY 2018.

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 3-year period is 75.271347 FAEs. FDA will set fees for FY 2018 based on this estimate as the number of full application equivalents that will pay fees.

Table 6.--Fee-Paying FAEs

FY	2014	2015	2016	3-Year Average
Fee-Paying FAEs	73.375000	81.955603	70.483437	75.271347

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

The FY 2018 application fee is estimated by dividing the average number of full applications that paid fees over the latest 3 years, 75.271347, into the fee revenue amount to be derived from application fees in FY 2018, \$182,269,200. The result is a fee of \$2,421,495 per full application requiring clinical data, and \$1,210,748 per application not requiring clinical data.

IV. Fee Calculations for Prescription Drug Program Fees

PDUFA VI renamed the product fee the “prescription drug program fee”; in addition, PDUFA VI introduced a limitation that 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)). The program fee was also modified so that applicants are assessed a program fee only for prescription drug products identified in a human drug application approved as of October 1 of such fiscal year.

FDA estimates 2,461 program fees will be invoiced in FY 2018 before factoring in waivers, refunds, and exemptions. FDA approximates that there will be 27 waivers and refunds granted. In addition, FDA approximates that another 37 program fees will be exempted in FY 2018 based on the orphan drug exemption in section 736(k) of the FD&C Act. FDA estimates 2,397 program fees in FY 2018, after allowing for an estimated 64 waivers and reductions, including the orphan drug exemptions. The FY 2018 prescription drug program fee rate is calculated by dividing the adjusted total revenue from program fees (\$729,076,800) by the estimated 2,397 program fees, for a FY 2018 program fee of \$304,162.

V. Fee Schedule for FY 2018

The fee rates for FY 2018 are displayed in table 7:

Table 7.--Fee Schedule for FY 2018

Fee Category	Fee Rates for FY 2018
Application	
Requiring clinical data	\$2,421,495
Not requiring clinical data	\$1,210,748

Program	\$304,162
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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, 2017. 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. 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 the user fee ID number is generated.

Please include the user fee identification (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, Beneficiary: FDA, 8455 Colesville Rd., 14th Floor, Silver Spring, MD 20993-0002. If needed, FDA's tax identification number is 53-0196965.

B. Prescription Drug Program Fees

FDA plans to issue invoices and payment instructions for FY 2018 program fees under the new fee schedule in September 2017. Payment will be due on October 1, 2017. FDA plans to issue invoices in December 2017 for FY 2018 program fees that qualify for fee assessments after the initial 2017 billing.

Dated: September 8, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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