



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0007]

Prescription Drug User Fee Rates for Fiscal Year 2015

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) 2015. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Prescription Drug User Fee Amendments of 2012 (PDUFA V), authorizes FDA to collect user fees for certain applications for the review of human drug and biological products, on establishments where the products are made, and on such products. This notice establishes the fee rates for FY 2015.

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 three different kinds of user fees. Fees are assessed on the following: (1) Certain types of applications and supplements for the review of human drug and biological products; (2) certain establishments where such products are made; and (3) certain products (section 736(a) of the FD&C Act). When certain conditions are met, FDA may waive or reduce fees (section 736(d) of the FD&C Act).

For FY 2013 through FY 2017, the base revenue amounts for the total revenues from all PDUFA fees are established by PDUFA V. The base revenue amount for FY 2013, which became the base amount for the remaining 4 FYs of PDUFA V, is \$718,669,000, as published in the Federal Register of August 1, 2012 (77 FR 45639). The FY 2013 base revenue amount is further adjusted each year after FY 2013 for inflation and workload. Fees for applications, establishments, and products are to be established each year by FDA so that revenues from each category will provide one-third of the total revenue to be collected each year.

This document provides fee rates for FY 2015 for an application requiring clinical data (\$2,335,200), for an application not requiring clinical data or a supplement requiring clinical data (\$1,167,600), for an establishment (\$569,200), and for a product (\$110,370). These fees are effective on October 1, 2014, and will remain in effect through September 30, 2015. For applications and supplements that are submitted on or after October 1, 2014, the new fee schedule must be used. Invoices for establishment and product fees for FY 2015 will be issued in August 2014 using the new fee schedule.

II. Fee Revenue Amount for FY 2015

The base revenue amount for FY 2015 is \$718,669,000 prior to adjustments for inflation and workload (see section 736(c)(1) and (c)(2) of the FD&C Act).

A. FY 2015 Statutory Fee Revenue Adjustments for Inflation

PDUFA V specifies that the \$718,669,000 is to be further adjusted for inflation increases for FY 2015 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 1 plus the average annual percent change in the cost of all PC&B paid per full-time equivalent (FTE) position at FDA for the first 3 of the preceding 4 FYs, multiplied by the proportion of PC&B costs to total

FDA costs of 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). The total PC&B paid and numbers of FTE paid, from which the average cost per FTE can be derived, are published in FDA's Justification of Estimates for Appropriations Committees.

Table 1 summarizes that 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 2015. The 3-year average is 1.8829 percent.

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

Fiscal Year	2011	2012	2013	3-Year Average
Total PC&B	\$1,761,655,000	\$1,824,703,000	\$1,927,703,000	
Total FTE	13,331	13,382	13,974	
PC&B per FTE	\$132,147	\$136,355	\$137,949	
Percent Change from Previous Year	1.2954%	3.1843%	1.1690%	1.8829%

The statute specifies that this 1.8829 percent should be multiplied by the proportion of PC&B costs to 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 3 FYs.

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

Fiscal Year	2011	2012	2013	3-Year Average
Total PC&B	\$596,627,595	\$ 592,642,252	\$568,206,210	
Total Costs	\$1,025,621,707	\$1,032,419,218	\$966,169,007	
PC&B Percent	58.1723%	57.4033%	58.8102%	58.1286%

The payroll adjustment is 1.8829 percent from table 1 multiplied by 58.1286 percent (or 1.0945 percent).

The statute specifies that the portion of the inflation adjustment for non-payroll costs is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Baltimore, DC-MD-VA-WV; not seasonally adjusted; all items; annual index) for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than PC&B costs to total costs of the process for the review of human drug applications for the first 3 years of the preceding 4 fiscal years (see section 736(c)(1)(C) 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 is published by the Bureau of Labor Statistics and can be found on their Web site at <http://data.bls.gov/cgi-bin/surveymost?cu> by checking the box marked “Washington-Baltimore All Items, November 1996=100 - CUURA311SA0” and then clicking on the “Retrieve Data” button.

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

Year	2011	2012	2013	3-Year Average
Annual CPI	146.975	150.212	152.500	
Annual Percent Change	3.3449%	2.2024%	1.5232%	2.3568%

To calculate the inflation adjustment for non-payroll costs, we multiply the 2.3568 percent 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 58.1286 percent was obligated for PC&B as shown in table 2, 41.8714 percent is the portion of costs other than PC&B (100 percent minus 58.1286 percent equals 41.8714 percent). The non-payroll adjustment is 2.3568 percent times 41.8714 percent, or 0.9868 percent.

Next, we add the payroll adjustment (1.0945 percent) to the non-payroll adjustment (0.9868 percent), for a total inflation adjustment of 2.0813 percent (rounded) for FY 2015.

PDUFA V provides for this inflation adjustment to be compounded after FY 2013 (see section 736(c)(1) of the FD&C Act). This factor for FY 2015 (2.0813 percent) is compounded by adding 1 and then multiplying by 1 plus the inflation adjustment factor for FY 2014 (2.20 percent), as published in the Federal Register of August 2, 2013 (78 FR 46980 at 46982), which equals to 1.043271 (rounded) (1.020813 times 1.0220) for FY 2015. We then multiply the base revenue amount for FY 2015 (\$718,669,000) by 1.043271, yielding an inflation-adjusted amount of \$749,766,526.

B. FY 2015 Statutory Fee Revenue Adjustments for Workload

The statute specifies that after the \$718,669,000 has been adjusted for inflation, the inflation-adjusted amount shall be further adjusted for workload (see section 736(c)(2) of the FD&C Act).

To calculate the FY 2015 workload adjustment, FDA calculated the average number of each of the four types of applications specified in the workload adjustment provision: (1) Human drug applications; (2) active commercial investigational new drug applications (INDs) (applications that have at least one submission during the previous 12 months); (3) efficacy supplements; and (4) manufacturing supplements received over the 3-year period that ended on June 30, 2012 (base years), and the average number of each of these types of applications over the most recent 3 year period that ended June 30, 2014.

The calculations are summarized in table 4. The 3-year averages for each application category are provided in column 1 ("3-Year Average Base Years 2010-2012") and column 2 ("3-Year Average 2012-2014"). Column 3 reflects the percent change in workload from column 1 to column 2. Column 4 shows the weighting factor for each type of application, estimating how much of the total FDA drug review workload was accounted for by each type of application in the table during the most recent 3 years. Column 5 is the weighted percent change in each

category of workload. This was derived by multiplying the weighting factor in each line in column 4 by the percent change from the base years in column 3. The sum of the values in column 5 is added, reflecting an increase in workload of 7.49 percent (rounded) for FY 2015 when compared to the base years.

Table 4.--Workload Adjuster Calculation for FY 2015

Application Type	Column 1	Column 2	Column 3	Column 4	Column 5
	3-Year Average Base Years 2010-2012	3-Year Average 2012-2014	Percent Change (Column 1 to Column 2)	Weighting Factor (percent)	Weighted Percent Change
New Drug Applications/Biologics License Applications	124.3	141.3	13.6766	37.3	5.10
Active Commercial INDs	6830.0	7141.3	4.5578	41.4	1.89
Efficacy Supplements	136.3	156.7	14.9670	7.5	1.12
Manufacturing Supplements	2548.3	2433.7	-4.4971	13.8	-0.62
FY 2015 Workload Adjuster					7.49

Table 5 shows the calculation of the revenue amount for FY 2015. The \$718,669,000 subject to adjustment on the first line is multiplied by the inflation adjustment factor of 1.043271, resulting in the inflation-adjusted amount on the third line, \$749,766,526. That amount is then multiplied by one plus the workload adjustment of 7.49 percent, resulting in the inflation and workload adjusted amount of \$805,924,000 on the fifth line, rounded to the nearest thousand dollars.

Table 5.--PDUFA Revenue Amount for FY 2015, Summary Calculation

FY 2013 Revenue Amount and Base Subsequent FYs as published in the <u>Federal Register</u> of August 1, 2012 (77 FR 45639) (Rounded to nearest thousand dollars)	\$718,669,000	Line 1
Inflation Adjustment Factor for FY 2015 (1 plus 4.3271 percent)	1.043271	Line 2
Inflation Adjusted Amount	\$749,766,526	Line 3
Workload Adjustment Factor for FY 2015 (1 plus 7.49 percent)	1.0749	Line 4
Inflation and Workload Adjusted Amount (Rounded to nearest thousand dollars)	\$805,924,000	Line 5

PDUFA specifies that one-third of the total fee revenue is to be derived from application fees, one-third from establishment fees, and one-third from product fees (see section 736(b)(2) of the FD&C Act). Accordingly, one-third of the total revenue amount (\$805,924,000), or a total of \$268,641,333, is the amount of fee revenue that will be derived from each of these fee categories: Application Fees, Establishment Fees, and Product Fees.

III. Application Fee Calculations

A. Application Fee Revenues and Application Fees

Application fees will be set to generate one-third of the total fee revenue amount, or \$268,641,333 in FY 2015.

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

For FY 2013 through FY 2017, FDA will estimate the total number of fee-paying full application equivalents (FAEs) it expects to receive the next FY by averaging the number of fee-paying FAEs received in the 3 most recently completed FYs.

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 an FAE, as does a supplement requiring clinical data. An application that is withdrawn, 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 6 shows, the average number of fee-paying FAEs received annually in the most recent 3-year period is 115.042 FAEs. FDA will set fees for FY 2015 based on this estimate as the number of full application equivalents that will pay fees.

Table 6.--Fee-Paying FAE 3-Year Average

FY	2011	2012	2013	3-Year Average
Fee-Paying FAEs	108.250	122.375	114.500	115.042

The FY 2015 application fee is estimated by dividing the average number of full applications that paid fees over the latest 3 years, 115.042, into the fee revenue amount to be derived from application fees in FY 2015, \$268,641,333. The result, rounded to the nearest hundred dollars, is a fee of \$2,335,200 per full application requiring clinical data, and \$1,167,600 per application not requiring clinical data or per supplement requiring clinical data.

IV. Fee Calculations for Establishment and Product Fees

A. Establishment Fees

At the beginning of FY 2014, the establishment fee was based on an estimate that 455 establishments would be subject to and would pay fees. By the end of FY 2014, FDA estimates that 509 establishments will have been billed for establishment fees, before all decisions on requests for waivers or reductions are made. FDA estimates that a total of 20 establishment fee waivers or reductions will be made for FY 2014. In addition, FDA estimates that another 17 full establishment fees will be exempted this year based on the orphan drug exemption in section 736(k) of the FD&C Act. Subtracting 37 establishments (20 waivers, plus the estimated 17 establishments under the orphan exemption) from 509 leaves a net of 472 fee-paying

establishments. FDA will use 472 to estimate the FY 2015 establishments paying fees. The fee per establishment is determined by dividing the adjusted total fee revenue to be derived from establishments (\$268,641,333) by the estimated 472 establishments, for an establishment fee rate for FY 2015 of \$569,200 (rounded to the nearest hundred dollars).

B. Product Fees

At the beginning of FY 2014, the product fee was based on an estimate that 2,425 products would be subject to and would pay product fees. By the end of FY 2014, FDA estimates that 2,545 products will have been billed for product fees, before all decisions on requests for waivers, reductions, or exemptions are made. FDA assumes that there will be 69 waivers and reductions granted. In addition, FDA estimates that another 42 product fees will be exempted this year based on the orphan drug exemption in section 736(k) of the FD&C Act. FDA estimates that 2,434 products will qualify for product fees in FY 2014, after allowing for an estimated 111 waivers and reductions, including the orphan drug products, and will use this number for its FY 2015 estimate. The FY 2015 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees (\$268,641,333) by the estimated 2,434 products for a FY 2015 product fee of \$110,370 (rounded to the nearest ten dollars).

V. Fee Schedule for FY 2015

The fee rates for FY 2015 are set out in table 7:

Table 7.--Fee Schedule for FY 2015

Fee Category	Fee Rates for FY 2015
Applications	
Requiring clinical data	\$2,335,200
Not requiring clinical data	\$1,167,600
Supplements requiring clinical data	\$1,167,600
Establishments	\$569,200
Products	\$110,370

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 or supplement subject to fees under PDUFA that is received on or after October 1, 2014. Payment must be made in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the Food and Drug Administration. Please include the user fee identification (ID) number on your check, bank draft, or postal money order. Your payment can be mailed to: Food and Drug Administration, P.O. Box 979107, St. Louis, MO 63197-9000.

If checks are to be sent by a courier that requests a street address, the courier can deliver the checks 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. Contact the U.S. Bank at 314-418-4013 if you have any questions concerning 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.

Wire transfer payment may also be used. 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: New York Federal Reserve Bank, 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.

Application fees can also be paid online with an electronic check (ACH). 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 Web site after the user fee ID number is generated.

The tax identification number of FDA is 53-0196965.

B. Establishment and Product Fees

FDA will issue invoices for establishment and product fees for FY 2015 under the new fee schedule in August 2014. Payment will be due on October 1, 2014. FDA will issue invoices in November 2015 for any products and establishments subject to fees for FY 2015 that qualify for fee assessments after the August 2014 billing.

Dated: July 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.