4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0007]

Prescription Drug User Fee Rates for Fiscal Year 2013

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) 2013. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Prescription Drug User Fee Amendments of 2012 (Title 1 of the Food and Drug Administration Safety and Innovation Act (FDASIA), Public Law 112-144, which was signed by the President on July 9, 2012) (PDUFA V)), authorizes FDA to collect user fees for certain applications for approval of drug and biological products, on establishments where the products are made, and on such products. Base revenue amounts to be generated from PDUFA fees were established by PDUFA V, with provisions for certain adjustments. Fee revenue amounts for applications, establishments, and products are to be established each year by FDA so that one-third of the PDUFA fee revenues FDA collects each year will be generated from each of these categories. This document establishes fee rates for FY 2013 for application fees for an application requiring clinical data ($1,958,800), for an application not requiring clinical data or a supplement requiring clinical data ($979,400), for establishment fees ($526,500), and for product fees ($98,380). These fees are effective on October 1, 2012, and will remain in effect through September 30, 2013. For applications and supplements that are submitted on or after October 1, 2012, the new fee schedule must be used. Invoices for

establishment and product fees for FY 2013 will be issued in August 2012 using the new fee schedule.

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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 approval of 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 is to be adjusted for inflation and workload, and that adjusted FY 2013 amount becomes the base amount for the remaining 4 FYs of PDUFA V. That 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.

II. Fee Revenue Amount for FY 2013

The statutory fee revenue amount for FY 2013 is $693,099,000, prior to adjustment for inflation and workload (see section 736(b)(1) of the FD&C Act). Of this amount, $652,709,000 will be further adjusted for inflation and workload, and $40,390,000, for new initiatives, will not be adjusted in FY 2013.

A. FY 2013 Statutory Fee Revenue Adjustments for Inflation

PDUFA V specifies that $652,709,000 of the amount for FY 2013 is to be further adjusted for inflation increases for FY 2013 using 2 separate adjustments--one for payroll costs and one for non-pay costs (see section 736(b)(3)(A) 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 personnel compensation and benefits (PC&B) paid per full-time equivalent position (FTE) at FDA for the first 3 of the 4 preceding fiscal years multiplied by the proportion of PC&B costs to total FDA costs of the review of human drug applications for the first 3 of the preceding 4 FYs (see section 736(c)(1)(B) of the FD&C Act). The data on 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 of this document summarizes that actual cost and FTE data for the specified fiscal years, and provides the percent change from the previous fiscal year and the average percent change over the first 3 of the 4 FYs preceding FY 2013. The 3 year average is 2.17 percent.

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

Fiscal Year	2009	2010	2011	3-Year Average
Total PC&B	$1,464,445,000	$ 1,634,108,000	$1,761,655,000	
Total FTE	11,413	12,526	13,331	
PC&B per FTE	$128,314	$130,457	$132,143	
Percent Change from Previous Year	3.56%	1.67%	1.29%	2.17%

The statute says that this 2.17 percent should be multiplied by the proportion of PC&B for the review of human drug applications. Table 2 of this document shows the amount of PC&B and the total amount obligated for the process for the review of human drug applications for the same 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	2009	2010	2011	3-Year Average
Total PC&B	$514,874,163	$573,603,582	$596,627,595	
Total Costs	$855,426,294	$931,845,581	$1,025,621,707	
PC&B percent	60%	62%	58%	60%

The payroll adjustment is 2.17 percent multiplied by 60 percent (or 1.30 percent).

The statute specifies that the portion of the inflation adjustment for non-payroll costs for FY 2013 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 of the preceding 4 years of available data multiplied by the proportion of all costs of the process for the review of human drug applications other than PC&B (see section 736(c)(1)(C) of the FD&C Act). Table 3 of this document provides the summary data for the percent change in the specified CPI for the Baltimore-Washington 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 - CUURA311SAO" and the clicking on the retrieve data button.

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

Year	2009	2010	2011	3-Year Average
Annual CPI	140.718	142.915	146.975	
Annual Percent Change	0.23%	1.72%	3.34%	1.76%

To complete the inflation adjustment for non-pay costs, we multiply the 1.76 percent by the proportion of costs of the process for the review of human drug applications obligated for costs other than PC&B. Since 60 percent was obligated for PC&B as shown in table 2 of this document, 40 percent is the portion of costs other than PC&B (100 percent minus 60 percent equals 40 percent). The non-payroll adjustment is 2.5 percent times 40 percent, or 0.71 percent.

To complete the inflation adjustment, we add the payroll component (1.30 percent) to the non-pay component (0.71 percent), for a total inflation adjustment of 2.01 percent (rounded), and then add one, making 1.0201. We then multiply the amount specified in the statute ($652,709,000) by 1.0201 percent, yielding an inflation adjusted amount of $665,828,451.

B. FY 2013 Statutory Fee Revenue Adjustments for Workload

PDUFA V specifies that after the $652,709,000 has been adjusted for inflation, the inflation adjusted amount ($665,828,451) shall be further adjusted for workload (see section 736(b)(3)(B) of the FD&C Act). For FY 2013 the workload adjustment will be the percentage by which the workload adjustment for FY 2013 exceeds the workload adjuster for FY 2012, if both such adjustments were calculated using the 5 year base period consisting of FYs 2003 through 2007. As published in the Federal Register of August 1, 2011 (76 FR 45831), the FY 2012 workload calculated as directed was 8.12 percent.

To calculate the FY 2013 adjustment factor, 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 5-year period that ended on June 30, 2007 (base years), and the average number of each of these types of applications over the most recent 5-year period that ended June 30, 2012.

The calculations are summarized in table 4 of this document. The 5-year averages for each application category are provided in column 1 ("5-Year Average Base Years 2003-2007") and column 2a ("5-Year Average 2008-2012").

PDUFA specifies that FDA make additional adjustments for changes in review activities to human drug applications and active commercial INDs. These adjustments, started under PDUFA IV, are summarized in columns 2b and 2c in table 4 of this document. The number in the new drug applications/biologics license applications (NDAs/BLAs) line of column 2b of table 4 of this document is the percent by which the average workload for meetings, annual reports, and labeling supplements for NDAs and BLAs has changed from the 5-year period 2003 through 2007, to the 5-year period 2008 through 2012. Likewise, the number in the "Active commercial INDs" line of column 2b of table 4 of this document is the percent by which the workload for meetings and special protocol assessments for active commercial INDs has changed from the 5-year period 2003 through 2007, to the 5-year period 2008 through 2012. There is no entry in the last two lines of column 2b because the adjustment for changes in review workload does not apply to the workload for efficacy supplements and manufacturing supplements.

Column 3 of table 4 of this document reflects the percent change in workload from column 1 to column 2c. Column 4 of table 4 of this document 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 5 years. Column 5 of table 4 of this document 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. At the bottom right of table 4 of this document is the sum of the values in column 5 that are added, reflecting an increase in workload of 9.99 percent for FY 2013 when compared to the base years.

Table 4.--Workload Adjuster Calculations for FY 2013

Application Type	Column 1	Column 2a	Column 2b	Column 2c	Column 3	Column 4	Column 5
	5-Year Average Base Years 2003-2007	5-Year Average 2008-2012	Adjustment for Changes in Review Activity	Column 2a increased by Column 2b	Percent Change (Column 1 to Column 2c)	Weighting Factor	Weighted Percent Change
NDAs/BLAs	123.8	134.4	0.08%	134.5	8.6%	39.6%	3.42%
Active commercial INDs	5,528.2	6724.2	-3.13%	6513.7	17.8%	40.3%	7.18%
Efficacy Supplements	163.4	153.8	NA	153.8	-5.9%	9.5%	-0.56%
Manufacturing Supplements	2589.2	2575.4	NA	2575.4	-0.5%	10.6%	-0.06%
FY 2013 Workload Adjuster							9.99%

Since the calculated workload adjustment for 2013 (9.99 percent) is greater than the 8.12 percent that was calculated last year for FY 2012 the difference between the two, 1.87 percent (9.99 percent minus 8.12 percent), and that is the amount of the workload adjustment for FY 2013 (see section 736(b)(3)(B) of the FD&C Act).

Table 5 of this document shows the calculation of the revenue amount for FY 2013. The $652,709,000 subject to adjustment on the first line is multiplied by the combined inflation adjustment factor of 1.0201, resulting in the inflation adjusted amount on the third line. That

amount is then multiplied by one plus the workload adjustment of 1.87 percent, resulting in the inflation and workload adjusted amount of $678,279,443 on the fifth line. Finally the portion of the FY 2013 fees not subject to adjustment ($40,390,000) is added, resulting in the total FY 2013 fee revenue amount of $718,669,000 on the last line of table 5 of this document.

Table 5.--PDUFA Revenue Amount for FY 2013 and Base for Subsequent Years

Portion of FY 2013 Revenues Subject to Adjustments	$652,709,000
Amount of Inflation Adjustment Factor for FY 2013	1.0201
Inflation Adjusted Amount (1 plus 2.01 percent)	$665,828,451
Workload Adjustment Factor for FY 2013 (1 plus 1.87 percent)	1.0187
Inflation and Workload Adjusted Amount	$678,279,443
Portion of 2013 Revenues Not Subject to Adjustment	$40,390,000
FY 2013 Revenue Amount and Base for Subsequent Years (Rounded to nearest thousand dollars)	$718,669,000

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 ($718,669,000), or a total of $239,556,333, is the amount of fee revenue that will be derived from each of these fee categories: Application Fees, Establishment Fees, and Product Fees.

While the fee revenue amount anticipated in FY 2013 is $718,669,000, as the previous paragraph shows, FDA assumes that the fee appropriation for FY 2013 will be 5 percent higher, or $754,602,000, rounded to the nearest thousand dollars. The latest PDUFA 5-Year Financial Plan (which can be found at http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm153456.htm) states in Assumption 14 (Fee Revenue and Annual Appropriation Amount) that the PDUFA workload adjuster is a lagging adjustment dampened by averages over 5 years, and will not help FDA keep up with workload if there are sudden increases in the number of applications to be reviewed in the current fiscal year. Appropriated amounts for PDUFA fee revenue each year are estimated at

5 percent higher than estimated fee revenues for each year, to provide FDA with the ability to cope with surges in application review workload should that occur. If FDA collects less than the fee estimate at the beginning of the year and less than the fee appropriation, then collections rather than appropriations set the upper limit on how much FDA may actually keep and spend. If, however, FDA collects more than fee estimates at the beginning of the year, due to a workload surge, a slightly higher fee appropriation will permit FDA to keep and spend the higher collections in order to respond to a real surge in review workload that caused the increased collections--an unexpected increase in the number of applications that FDA must review in accordance with PDUFA goals. For this reason, in most fiscal years since 1993, actual appropriations have slightly exceeded PDUFA fee revenue estimates made each year.

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 $239,556,333 in FY 2013, as calculated previously in this document.

B. Estimate of the Number of Fee-Paying Applications and the Establishment of 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 fiscal year by averaging the number of fee-paying FAEs received in the 3 most recently completed fiscal years. This will avoid having FDA try to estimate the number it expects to receive in the current fiscal year.

In estimating the number of fee-paying FAEs, 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 of this document shows, the average number of fee-paying FAEs received annually in the most recent 3-year period is 122.3 FAEs. FDA will set fees for FY 2013 based on this estimate as the number of full application equivalents that will pay fees.

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

Fiscal Year	2009	2010	2011	3-Year Average
Fee-Paying FAEs	140.3	118.4	108.25	122.3

The FY 2013 application fee is estimated by dividing the average number of full applications that paid fees over the latest 3 years, 122.3, into the fee revenue amount to be derived from application fees in FY 2013, $239,556,333. The result, rounded to the nearest $100, is a fee of $1,958,800 per full application requiring clinical data, and $979,400 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 2012, the establishment fee was based on an estimate that 450 establishments would be subject to, and would pay, fees. By the end of FY 2012, FDA estimates that 480 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 10 establishment fee waivers or reductions will be made for FY 2012. In addition, FDA estimates that another 15 full establishment fees will be exempted this year based on the orphan drug exemption in the Food and Drug Administration Amendments Act (FDAAA) (see section 736(k) of the FD&C Act). Subtracting 25 establishments (10 waivers, plus the estimated 15 establishments under the

orphan exemption) from 480 leaves a net of 455 fee-paying establishments. FDA will use 455 for its FY 2013 estimate of establishments paying fees, after taking waivers and reductions into account. The fee per establishment is determined by dividing the adjusted total fee revenue to be derived from establishments ($239,556,333) by the estimated 455 establishments, for an establishment fee rate for FY 2013 of $526,500 (rounded to the nearest $100).

B. Product Fees

At the beginning of FY 2012, the product fee was based on an estimate that 2,365 products would be subject to and would pay product fees. By the end of FY 2012, FDA estimates that 2,525 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 50 waivers and reductions granted. In addition, FDA estimates that another 40 product fees will be exempted this year based on the orphan drug exemption in FDAAA (see section 736(k) of the FD&C Act). FDA estimates that 2,435 products will qualify for product fees in FY 2012, after allowing for waivers and reductions, including the orphan drug products eligible under the FDAAA exemption, and will use this number for its FY 2013 estimate. The FY 2013 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees ($239,556,333) by the estimated 2,435 products for a FY 2013 product fee of $98,380 (rounded to the nearest $10).

V. Fee Schedule for FY 2013

The fee rates for FY 2013 are set out in table 7 of this document:

Table 7.--Fee Schedule for FY 2013

Fee Category	Fee Rates for FY 2013
Applications	
Requiring clinical data	$1,958,800
Not requiring clinical data	$ 979,400
Supplements requiring clinical data	$ 979,400
Establishments	$ 526,500

Products	$ 98,380

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 after September 30, 2012. 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 between $15.00 and $35.00. Please ask your financial institution about the fee and include it with your payment to ensure that your fee is fully paid. The account information 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, 1350 Piccard Dr., Rockville, MD.

Application fees can also be paid online with an electronic check (ACH). FDA has partnered with the U.S. Department of the Treasury to utilize 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 the Food and Drug Administration is 53-0196965.

B. Establishment and Product Fees

FDA will issue invoices for establishment and product fees for FY 2013 under the new fee schedule in August 2012. Payment will be due on October 1, 2012. FDA will issue invoices in November 2013 for any products and establishments subject to fees for FY 2013 that qualify for fee assessments after the August 2012 billing.

Dated: July 24, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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