



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0007]

Prescription Drug User Fee Rates for Fiscal Year 2014

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) 2014. The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Prescription Drug User Fee Amendments of 2012, 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 2014 for application fees for an application requiring clinical data (\$2,169,100), for an application not requiring clinical data or a supplement requiring clinical data (\$1,084,550), for establishment fees (\$554,600), and for product fees (\$104,060). These fees are effective on October 1, 2013, and will remain in effect through September 30, 2014. For applications and supplements that are submitted on or after October 1, 2013, the new fee schedule must be used. Invoices for establishment and product fees for FY 2014 will be issued in August 2013 using the new fee schedule.

FOR FURTHER INFORMATION CONTACT: David Miller, Office of Financial Management (HFA-100), Food and Drug Administration, 1350 Piccard Dr., PI50, rm. 210J, Rockville, MD 20850, 301-796-7103.

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, which becomes the base amount for the remaining 4 FYs of PDUFA V, is \$718,699,000, as published in the Federal Register of August 1, 2012 (77 FR 45639). 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 2014

The base revenue amount for FY 2014 is \$718,699,000, prior to adjustment for inflation and workload (see section 736(c)(1) of the FD&C Act).

A. FY 2014 Statutory Fee Revenue Adjustments for Inflation

PDUFA V specifies that the \$718,699,000 is to be further adjusted for inflation increases for FY 2014 using 2 separate adjustments--one for payroll costs and one for non-pay 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 personnel compensation and benefits (PC&B) paid per full-time equivalent position (FTE) at FDA for the first 3 of the 4 preceding FYs, 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 FYs, and provides the percent change from the previous FY and the average percent change over the first 3 of the 4 FYs preceding FY 2014. The 3-year average is 2.05 percent.

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

| Fiscal Year                       | 2010            | 2011            | 2012            | 3-Year Average |
|-----------------------------------|-----------------|-----------------|-----------------|----------------|
| Total PC&B                        | \$1,634,108,000 | \$1,761,655,000 | \$1,824,703,000 |                |
| Total FTE                         | 12,526          | 13,331          | 13,382          |                |
| PC&B per FTE                      | \$130,457       | \$132,147       | \$136,355       |                |
| Percent Change from Previous Year | 1.67%           | 1.30%           | 3.18%           | 2.05%          |

The statute specifies that this 2.05 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&amp;B as a Percent of Fee Revenues Spent on the Process for the Review of Human Drug Applications

| Fiscal Year  | 2010          | 2011            | 2012            | 3-Year Average |
|--------------|---------------|-----------------|-----------------|----------------|
| Total PC&B   | \$573,603,582 | \$596,627,595   | \$592,642,252   |                |
| Total Costs  | \$931,845,581 | \$1,025,621,707 | \$1,032,419,218 |                |
| PC&B Percent | 62%           | 58%             | 57%             | 59%            |

The payroll adjustment is 2.05 percent multiplied by 59 percent (or 1.21 percent).

The statute specifies that the portion of the inflation adjustment for non-payroll costs for FY 2014 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 - CUURA311SA0" and then clicking on the "Retrieve Data" button.

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

| Year                  | 2010    | 2011    | 2012    | 3-Year Average |
|-----------------------|---------|---------|---------|----------------|
| Annual CPI            | 142.218 | 146.975 | 150.212 |                |
| Annual Percent Change | 1.72%   | 3.34%   | 2.20%   | 2.42%          |

To calculate the inflation adjustment for non-pay costs, we multiply the 2.42 percent by the proportion of costs of the process for the review of human drug applications obligated for costs other than PC&B. Since 59 percent was obligated for PC&B as shown in table 2 of this document, 41 percent is the portion of costs other than PC&B (100 percent minus 59 percent equals 41 percent). The non-payroll adjustment is 2.42 percent times 41 percent, or 0.99 percent.

To complete the inflation adjustment, we add the payroll component (1.21 percent) to the non-pay component (0.99 percent), for a total inflation adjustment of 2.20 percent (rounded), and then add one, making 1.0220. We then multiply the amount base revenue amount for FY 2014 (\$718,669,000) by 1.0220, yielding an inflation adjusted amount of \$734,479,718.

#### B. FY 2014 Statutory Fee Revenue Adjustments for Workload

Title I of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Public Law 112-144) specifies that after the \$718,699,000 has been adjusted for inflation, the inflation adjusted amount (\$734,479,718) shall be further adjusted for workload (see section 736(c)(2) of the FD&C Act). Title I also requires an independent accounting or consulting firm to review the adequacy of the adjustment for workload in FY 2013 and FY 2015 and publish the results of those reviews (see section 103(c)(2) of FDASIA). The reports must evaluate whether the adjustment reasonably represents actual changes in workload volume and complexity of human drug review and present recommendations to discontinue, retain, or modify any elements of the adjustment. After review of the reports and receipt of public comments, FDA may adopt appropriate changes to the workload adjustment methodology. FDA contracted with an independent consulting firm in FY 2013 to conduct the first required assessment of the workload adjuster. This assessment examined the performance of the workload adjuster and its ability to effectively measure changes in workload volume and complexity during the FY 2009-2013 period. The report is available online at

<http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM350567.pdf>

f. The report found that the current methodology reasonably represents workload volume associated with the human drug review process. However, the report concluded that the methodology is flawed with respect to measuring workload complexity, known as the adjustment

for changes in review activities ("Complexity Factor"), because it does not represent the total amount of work per submission. The report further notes that work complexity increased substantially during the evaluation period, but the Complexity Factor produced negative adjustments to the overall Workload Adjuster, indicating that human drug review became less complex over this period. Accordingly, the report recommends that FDA consider removing the current Complexity Factor. The report also found that the statute's use of 5-year rolling averages to measure changes in workload against the base years was not as sensitive to recent trends as 3-year rolling averages would be. After reviewing the report, FDA is removing the Complexity Factor from the workload adjustment methodology and adopting 3-year averages to measure changes in workload volume, rather than the 5-year averages used in prior adjustments. This is consistent with the use of 3-year averages for inflation adjustment calculations as called for under PDUFA V (section 736(c)(1) of the FD&C Act). The public comment received on the report indicated that changes to the workload adjuster methodology should be considered in the context of other aspects of the PDUFA financial model, including standard costs and time reporting in the human drug review process. FDA agrees with this point and will consider multiple aspects of the PDUFA financial model as the Agency investigates alternative methods to more accurately account for work complexity in the workload adjuster.

The statute specifies that changes FDA adopts are effective the first FY after FDA adopts the changes and each subsequent FY. Since FDA is adopting the changes in FY 2013, the changes are effective for FY 2014 fees.

To calculate the FY 2014 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 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, 2013.

The calculations are summarized in table 4 of this document. 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 2011-2013").

Column 3 of table 4 of this document reflects the percent change in workload from column 1 to column 2. 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 3 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 3.07 percent for FY 2014 when compared to the base years.

Table 4.--Workload Adjuster Calculation for FY 2014

| Application Type   | Column 1<br>3-Year Average<br>Base Years<br>2010-2012 | Column 2<br>3-Year<br>Average<br>2011-2013 | Column 3<br>Percent Change<br>(Column 1 to<br>Column 2) | Column 4<br>Weighting<br>Factor | Column 5<br>Weighted<br>Percent<br>Change |
|--|---|--|---|---------------------------------|---|
| New Drug<br>Applications/<br>Biologics License<br>Applications | 124.4   | 131.0                                      | 5.39%   | 38.6%                           | 2.08%                                     |
| Active Commercial<br>INDs                                      | 6830.0  | 6965.0                                     | 1.98%   | 41.4%                           | 0.82%                                     |
| Efficacy Supplements   | 136.3   | 140.3                                      | 2.93%   | 9.3%                            | 0.27%                                     |
| Manufacturing<br>Supplements                                   | 2548.3  | 2524.7                                     | -0.93%  | 10.7%                           | -0.10%                                    |
| FY 2014 Workload Adjuster                                      |   |  |   |                                 | 3.07%                                     |

The FY 2014 workload adjustment in the last line of Table 4 of this document is 3.07 percent.

Table 5 of this document shows the calculation of the revenue amount for FY 2014. The \$718,669,000 subject to adjustment on the first line is multiplied by the inflation adjustment factor of 1.0220, resulting in the inflation adjusted amount on the third line, \$734,479,718. That amount is then multiplied by one plus the workload adjustment of 3.07 percent, resulting in the inflation and workload adjusted amount of \$757,028,000 on the fifth line, rounded to the nearest thousand dollars.

Table 5.--PDUFA Revenue Amount for FY 2014, 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 |
| Inflation Adjustment Factor for FY 2014 (1 plus 2.20 percent)  | 1.0220        |
| Inflation Adjusted Amount  | \$734,479,718 |
| Workload Adjustment Factor for FY 2013 (1 plus 3.07 percent)   | 1.0307        |
| Inflation and Workload Adjusted Amount (rounded to nearest thousand dollars)   | \$757,028,000 |

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 (\$757,028,000), or a total of \$252,342,667, 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 \$252,342,667 in FY 2014, 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 FY by averaging the number of fee-paying FAEs received in the three most recently completed FYs. This will avoid having FDA try to estimate the number it expects to receive in the current 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 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 116.333 FAEs. FDA will set fees for FY 2014 based on this estimate as the number of full application equivalents that will pay fees.

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

| FY              | 2010    | 2011    | 2012    | 3-Year Average |
|-----------------|---------|---------|---------|----------------|
| Fee-Paying FAEs | 118.375 | 108.250 | 122.375 | 116.333        |

The FY 2014 application fee is estimated by dividing the average number of full applications that paid fees over the latest 3 years, 116.333, into the fee revenue amount to be derived from application fees in FY 2014, \$252,342,667. The result, rounded to the nearest \$100, is a fee of \$2,169,100 per full application requiring clinical data, and \$1,084,550 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 2013, the establishment fee was based on an estimate that 455 establishments would be subject to and would pay fees. By the end of FY 2013, FDA estimates that 490 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 2013. In addition, FDA estimates that another 15 full establishment fees will be exempted this year based on the orphan drug exemption in section 736(k) of the FD&C Act. Subtracting 35 establishments (20 waivers, plus the estimated 15 establishments under the orphan exemption) from 490 leaves a net of 455 fee-paying establishments. FDA will use 455 for its FY 2014 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 (\$252,342,667) by the estimated 455 establishments, for an establishment fee rate for FY 2014 of \$554,600 (rounded to the nearest \$100).

##### B. Product Fees

At the beginning of FY 2013, the product fee was based on an estimate that 2,435 products would be subject to and would pay product fees. By the end of FY 2013, FDA estimates that 2,510 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 45 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 section 736(k) of the FD&C Act. FDA estimates that 2,425 products will qualify for product fees in FY 2013, after allowing for waivers

and reductions, including the orphan drug products, and will use this number for its FY 2014 estimate. The FY 2014 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees (\$252,342,667) by the estimated 2,425 products for a FY 2014 product fee of \$104,060 (rounded to the nearest \$10).

#### V. Fee Schedule for FY 2014

The fee rates for FY 2014 are set out in table 7 of this document:

Table 7.--Fee Schedule for FY 2014

| Fee Category                        | Fee Rates for FY 2014 |
|-------------------------------------|-----------------------|
| Applications:                       |                       |
| Requiring clinical data             | \$2,169,100           |
| Not requiring clinical data         | \$1,084,550           |
| Supplements requiring clinical data | \$1,084,550           |
| Establishments                      | \$554,600             |
| Products                            | \$104,060             |

#### 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, 2013. 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 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 Drive, 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 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 2014 under the new fee schedule in August 2013. Payment will be due on October 1, 2013. FDA will issue invoices in November 2014 for any products and establishments subject to fees for FY 2014 that qualify for fee assessments after the August 2013 billing.

Dated: July 29, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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