DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Prescription Drug User Fee Rates for Fiscal Year 2008

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) 2008. The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Prescription Drug User Fee Amendments of 2007 (Title 1 of the Food and Drug Administration Amendments Act of 2007 (FDAAA)) (PDUFA IV), 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 IV, 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 notice establishes fee rates for FY 2008 for application fees for an application requiring clinical data ($1,178,000), for an application not requiring clinical data or a supplement requiring clinical data ($589,000), for establishment fees ($392,700), and for product fees ($65,030). These fees are effective on October 1, 2007, and will remain in effect through September 30, 2008. For applications and supplements that are submitted on or after October 1, 2007, the new fee schedule must be used. Invoices for establishment and product fees for FY 2008 will be issued in October 2007, using the new fee schedule.

FOR FURTHER INFORMATION CONTACT: Yanming Chae, Office of Financial Management (HFA–120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5042.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 735 and 736 of the act (21 U.S.C. 379g and h), 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 (21 U.S.C. 379h(a)). When certain conditions are met, FDA may waive or reduce fees (21 U.S.C. 379h(d)).

For FY 2008 through FY 2012, the base revenue amounts for the total revenues from all PDUFA fees are established by PDUFA IV. The base revenue amount for FY 2008 is to be adjusted for workload, and that adjusted amount becomes the base amount for the remaining 4 FYs. That adjusted base revenue amount is subject to further adjustments for inflation and workload each year. 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 notice establishes the fee base revenue amount for FY 2008 after adjustment for workload, and then establishes the application, establishment, and product fees for FY 2008. These fees are effective on October 1, 2007, and will remain in effect through September 30, 2008.

II. Fee Revenue Amount for FY 2008, Including Adjustments for Workload

The total fee revenue amount for FY 2008 is $459,412,000, based on the fee revenue amount specified in the statute, including additional fee funding for drug safety and adjusted for inflation and changes in workload. The statutory amounts and these adjustments are described in the following paragraphs. Section II.A of this document provides the fee amounts specified in the statute. Section II.B of this document describes the one-time base adjustment to the statutory fee revenue amount under the FY 2007 method. Section II.C of this document describes the inflation adjustment to the adjusted fee revenue base amount. Section II.D of this document describes the workload adjustment to the inflation-adjusted fee revenue amount.

A. Statutory Fee Revenue Amounts

PDUFA IV specifies that the fee revenue amount for FY 2008 for all fees is $417,783,000 ($392,783,000 specified in 21 U.S.C. 379h(b)(1) plus an additional $25,000,000 for drug safety specified in 21 U.S.C. 379h(b)(4)).

The statute specifies that $354,893,000 of the amount specified in 21 U.S.C. 379h(b)(1) is to be further adjusted for workload. The workload adjustment on this amount is to be made in accordance with the workload adjustment provisions that were in effect for FY 2007, except that the adjustment for investigational new drug (IND) workload is based on the number of INDs with a submission in the previous 12 months rather than on the number of new commercial INDs submitted in the same 12-month period.

B. One-time Base Adjustment to Statutory Fee Revenue Amount Under FY 2007 Method

For each FY beginning in FY 2004, the Prescription Drug User Fee Amendments of 2002 (PDUFA III) provided that fee revenue amounts, after they had been adjusted for inflation, should be further adjusted to reflect changes in workload for the process for the review of human drug applications (see 21 U.S.C. 379h(c)(2)).

The conference report accompanying PDUFA III, House of Representatives Report number 107–481, provides guidance on how the workload adjustment provision of PDUFA III is to be implemented. Following that guidance, FDA calculated the average number of each of the four types of applications specified in the workload adjustment provision (human drug applications, commercial IND applications, efficacy supplements, and manufacturing supplements) received over the 5-year period that ended on June 30, 2002 (base years), and the average number of each of these types of applications over the most recent 5-year period that ended June 30, 2007. PDUFA IV directs that this same method be used in making the workload adjustment apply to the 2008 statutory revenue amount, except that for this calculation the number of commercial IND applications with a submission in the previous 12 months is used for each 12-month period rather than the number of commercial IND applications submitted (see 21 U.S.C. 379h(b), as amended by PDUFA IV).

The results of these calculations are presented in the first two columns of table 1 of this document. Column 3 reflects the percent change in workload over the two 5-year periods. 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 5 years. Column 5 of table 1 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 the table the sum of the values in column 5 is added, reflecting a total increase in workload of 11.73 percent when compared to the base years.

TABLE 1.—SUMMARY BASE WORKLOAD ADJUSTER CALCULATION TO BE APPLIED IN FY 2008

Application Type	Column 1 5-Year AverageBase Years	Column 2 Latest 5-YearAverage	Column 3 Percent Change	Column 4 Weighting Factor	Column 5 Weighted PercentChange
New drug applications (NDAs)/biologics license applications (BLAs)	119.6	123.8	3.5%	35.2%	1.24%
Active INDs	4,751.8	5,528.2	16.3%	44.2%	7.22%
Efficacy supplements	159.2	163.4	2.6%	7.4%	0.20%
Manufacturing supplements	2,100.6	2,589.2	23.3%	13.2%	3.07%
FY 2008 workload adjuster					11.73%

Increasing the PDUFA IV statutorily-specified amount of $354,893,000 by the specified workload adjuster (11.73 percent) results in an increase of $41,629,000, rounded to the nearest thousand. Adding this amount to the $417,783,000 statutorily-specified amount, before adjustment, results in a total adjusted PDUFA IV base revenue amount of $459,412,000. This figure is the adjusted PDUFA IV base revenue amount that will be adjusted in future years for inflation and workload.

C. Inflation Adjustment to Adjusted Fee Revenue Base Amount

PDUFA IV provides that fee revenue amounts for each FY after 2008 shall be adjusted for inflation. Since no inflation adjustment is applicable in FY 2008, no further adjustment is made to the revenue amount derived in section II.B of this document.

D. Workload Adjustment to Inflation-Adjusted Fee Revenue Amount

For each FY beginning in FY 2009, PDUFA IV provides that fee revenue amounts, after they have been adjusted for inflation, shall be further adjusted to reflect changes in workload for the process for the review of human drug applications (see 21 U.S.C. 379h(c)(2)). Because no further workload adjustment, other than the adjustment to the base amount in section II.B of this document, is applicable in FY 2008, no further adjustment is made to the revenue amount derived in section II.B of this document.

III. Application Fee Calculations

PDUFA IV provides that the rates for application, product, and establishment fees be established so that they will generate the fee revenue amounts specified in the statute, as adjusted for inflation and workload.

A. Application Fee Revenues and Application Fees

The application fee revenue amount that PDUFA IV establishes for each year is one third of the total adjusted fee revenue amount. The total fee revenue amount for FY 2008 is $459,412,000, as calculated in section II.B of this document. Application fees will be set to generate one-third of this amount, or $153,137,000, rounded to the nearest $1,000, in FY 2008.

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

For FY 2008 through FY 2012, 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 5 most recent FYs. This use of the rolling average of the 5 most recent FYs is the same method that was applied during PDUFA III.

In estimating the number of fee-paying FAEs that FDA will receive in FY 2008, the 5-year rolling average for the most recent 5 years will be based on actual counts of fee-paying FAEs received for FY 2003 through FY 2007. For FY 2007, FDA is estimating the number of fee-paying FAEs for the full year based on the actual count for the first 9 months and estimating the number for the final 3 months, as we have done for the past 5 years.

Table 2 of this document shows in column 1 the total number of each type of FAE received in the first 9 months of FY 2007, whether fees were paid or not. Column 2 shows the number of FAEs for which fees were waived or exempted during this period, and column 3 shows the number of fee-paying FAEs received through June 30, 2007. Column 4 estimates the 12-month total fee-paying FAEs for FY 2007 based on the applications received through June 30, 2007. All of the counts are in 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.

TABLE 2.—FY 2007 FAES RECEIVED THROUGH JUNE 30, 2007, AND PROJECTED THROUGH SEPTEMBER 30, 2007

Application or Action	Column 1 Total Received ThroughJune 30, 2007	Column 2 Fee Exempt or WaivedThrough June 30, 2007	Column 3 Total Fee Paying Through June 30, 2007	Column 4 12-Month Fee-Paying Projection
Applications requiring clinical data	71.8	18.8	53	70.7
Applications not requiring clinical data	7	3.5	3.5	4.7
Supplements requiring clinical data	43.5	5	38.5	51.3

TABLE 2.—FY 2007 FAEs RECEIVED THROUGH JUNE 30, 2007, AND PROJECTED THROUGH SEPTEMBER 30, 2007—Continued

Application or Action	Column 1 Total Received ThroughJune 30, 2007	Column 2 Fee Exempt or WaivedThrough June 30, 2007	Column 3 Total Fee Paying Through June 30, 2007	Column 4 12-Month Fee-Paying Projection
Withdrawn or refused to file	.4	0	0.4	0.5
Total	122.7	27.3	95.4	127.2

In the first 9 months of FY 2007, FDA received 122.7 FAEs, of which 95.4 were fee-paying. Based on data from the last 8 FYs, on average, 25 percent of the applications submitted each year come in the final 3 months. Dividing 95.4 by 3 and multiplying by 4 extrapolates the amount to the full 12 months of the FY and projects the number of fee-paying FAEs in FY 2007 at 127.2.

As table 3 of this document shows, the average number of fee-paying FAEs received annually in the most recent 5-year period, and including our estimate for FY 2007, is 130 FAEs. FDA will set fees for FY 2008 based on this estimate as the number of FAEs that will pay fees.

TABLE 3.—FEE-PAYING FAEs—5-YEAR AVERAGE

Fiscal Year	2003	2004	2005	2006	2007	5-Year Average
Fee-paying FAEs	119.5	145.1	121.5	136.7	127.2	130

The FY 2008 application fee is estimated by dividing the average number of full applications that paid fees over the latest 5 years, 130, into the fee revenue amount to be derived from application fees in FY 2008, $153,137,000. The result, rounded to the nearest $100, is a fee of $1,178,000 per full application requiring clinical data, and $589,000 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 2007, the establishment fee was based on an estimate that 375 establishments would be subject to, and would pay, fees. By the end of FY 2007, FDA estimates that 425 establishments will have been billed for establishment fees, before all decisions on requests for waivers or reductions are made. As in previous years, FDA again estimates that a total of 25 establishment fee waivers or reductions will be made for FY 2007. In addition to the previous year estimates, FDA estimates that another 10 full establishment fees will be exempted this year based on the new orphan drug exemption in FDAAA (see 21 U.S.C. 379h(k)). Subtracting 35 (25 plus the estimated 10 establishments under the new orphan exemption) establishments from 425 leaves a net of 390 fee-paying establishments. FDA will use 390 for its FY 2008 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 ($153,137,000 by the estimated 390 establishments, for an establishment fee rate for FY 2008 of $392,700 (rounded to the nearest $100).

B. Product Fees

At the beginning of FY 2007, the product fee was based on an estimate that 2,400 products would be subject to and pay product fees. By the end of FY 2007, FDA estimates that 2,425 products will have been billed for product fees, before all decisions on requests for waivers or reductions are made. FDA assumes that there will be about 40 waivers and reductions granted, the same amount estimated last year. In addition to the previous year estimates, FDA estimates that another 30 product fees will be exempted this year based on the new orphan drug exemption in FDAAA (see 21 U.S.C. 379h(k)). FDA estimates that 2,355 products will qualify for product fees in FY 2007, after allowing for waivers and reductions, including the orphan drug products eligible under the new FDAAA exemption, and will use this number for its FY 2008 estimate. Accordingly, the FY 2008 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees ($153,137,000) by the estimated 2,355 products for a FY 2008 product fee of $65,030 (rounded to the nearest $10).

V. Fee Schedule for FY 2008

The fee rates for FY 2008 are set out in table 4 of this document:

TABLE 4.

Fee Category	Fee Rates for FY 2008
APPLICATIONS	
Requiring clinical data	$1,178,000
Not requiring clinical data	$589,000
Supplements requiring clinical data	$589,000
ESTABLISHMENTS	$392,700
PRODUCTS	$65,030

VI. Implementation of Adjusted Fee Schedule

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, 2007. 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 ID number on your check. Your payment can be mailed to: Food and Drug Administration, P.O. Box 70963, Charlotte, NC 28272–0963.

If checks are to be sent by a courier that requests a street address, the courier can deliver the checks to: Wachovia Bank, Attn: Food and Drug Administration Lockbox 70963, 1525 West WT Harris Blvd., rm. NC0810, Charlotte, NC 28262. (Note: This Wachovia Bank address is for courier delivery only.)

Please make sure that the FDA post office box number (P.O. Box 70963) is written on the check. The tax identification number of the Food and Drug Administration is 53–0196965.

Wire transfer payment may also be used. The routing and transit number is 021030004 and the account number is 75060099. Please include, as the reference, the NDA/BLA number and the user fee ID number.

FDA is in the process of implementing alternate Web-based payment methods. For more information on these payment options and when they will be available, please visit FDA's Web site at *http://www.fda.gov*, select the appropriate user fee type, and click on ''User Fee Cover Sheet.''

B. Establishment and Product Fees

FDA will issue invoices for establishment and product fees for FY 2008 under the new fee schedule in October 2007. Payment will be due 30 days from the date of the invoice. FDA will issue invoices in November 2008 for any products and establishments subject to fees for FY 2008 that qualify for fees after the October 2007 billing.

Dated: October 4, 2007.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. 07–5052 Filed 10–9–07; 12:06 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0309]

Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Electrocardiograph Electrodes; Availability; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of October 4, 2007 (72 FR 56771). The document announced the availability of a draft guidance entitled ''Class II Special Controls Guidance Document: Electrocardiograph Electrodes.'' The document was published with an incorrect docket number. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce A. Strong, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. E7–19578, appearing on page 56771 in the **Federal Register** of Thursday, October 4, 2007, the following correction is made:

1. On page 56771, in the third column, in the heading of the document, ''[Docket No. 2007N–0309]'' is corrected to read ''[Docket No. 2007D–0309]''.

Dated: October 5, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–20183 Filed 10–11–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Availability of Draft Policy Documents for Comment

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Extension of requests for comments deadline.

SUMMARY: The Health Resources and Services Administration published a notice in the **Federal Register** of August 29, 2007, requesting comments on draft Agency Guidance (Policy Information Notices (PINS)) to describe the policy and processes pertaining to requests from federally-funded health centers to change the scope of their Federal project. The PINS, ''Defining Scope of Project and Policy for Requesting Changes,'' ''Changes in Scope Requests: Policy for Adding a New Target Population,'' and ''Specialty Services and Health Centers' Scope of Project,'' are available on the Internet at *http://bphc.hrsa.gov.*

Correction: In the **Federal Register** of August 29, 2007, FR Doc. E7–17092, on page 49724, in the first column, under **DATES**, the deadline for comments has been extended to October 19, 2007.

Dated: October 5, 2007.

Dennis P. Williams,

Deputy Administrator.

[FR Doc. E7–20171 Filed 10–11–07; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories currently certified to meet the standards of Subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908), on September 30, 1997 (62 FR 51118), and on April 13, 2004 (69 FR 19644).

A notice listing all currently certified laboratories is published in the **Federal Register** during the first week of each month. If any laboratory's certification is suspended or revoked, the laboratory will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.