DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0339]

Prescription Drug User Fee Rates for Fiscal Year 2010

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) 2010. 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 2010 for application fees for an application requiring clinical data ($1,405,500), for an application not requiring clinical data or a supplement requiring clinical data ($702,750), for establishment fees ($457,200), and for product fees ($77,720). These fees are effective on October 1, 2009, and will remain in effect through September 30, 2010. For applications and supplements that are submitted on or after October 1, 2009, the new fee schedule must be used. Invoices for establishment and product fees for FY 2010 will be issued in August 2009, using the new fee schedule.

FOR FURTHER INFORMATION CONTACT: David Miller, Office of Financial Management (HFA–100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3917.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 735 and 736 of the 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 act). When certain conditions are met, FDA may waive or reduce fees (section 736(d) of the act).

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 fiscal years. That adjusted base revenue amount is increased for drug safety enhancements by $10,000,000 in each of the subsequent 4 fiscal years, and the increased total is further adjusted each year 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 notice uses the fee base revenue amount for FY 2008 published in the **Federal Register** of October 12, 2007 (72 FR 58103), adjusts it for the 2010 drug safety increase (see section 736(b)(4) of the act) for inflation, and for workload, and then establishes the application, establishment, and product fees for FY 2010. These fees are effective on October 1, 2009, and will remain in effect through September 30, 2010.

II. Fee Revenue Amount for FY 2010

The total fee revenue amount for FY 2010 is $569,207,000, based on the fee revenue amount specified in the statute, including additional fee funding for drug safety and adjustments for inflation and changes in workload. The statutory amount and a one-time base adjustment are described in sections II.A and II.B of this document. The adjustment for inflation is described in section II.C of this document, and the adjustment for changes in workload in section II.D of this document.

A. FY 2010 Statutory Fee Revenue Amounts Before Adjustments

PDUFA IV specifies that the fee revenue amount before adjustments for FY 2010 for all fees is $437,783,000 ($392,783,000 specified in section 736(b)(1) of the act plus an additional $45,000,000 for drug safety in FY 2010 specified in section 736(b)(4) of the act).

B. Base Adjustment to Statutory Fee Revenue Amount

The statute also specifies that $354,893,000 of the base amount is to be further adjusted for workload increases through FY 2007 (see section 736(b)(1)(B) of the act). The 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.

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 section 736(c)(2) of the act). 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 submissions specified in the workload adjustment provision (human drug applications, commercial INDs, 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 INDs with a submission in the previous 12 months is used for each 12-month period rather than the number of new commercial INDs submitted (see section 736(b) of the act, 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 WORKLOAD ADJUSTER CALCULATION TO BE APPLIED TO PDUFA IV STATUTORY BASE

Application Type	Column 1 5-Year Average Base Years (Ending 6/30/2002)	Column 2 5-Year Average (Ending 6/30/2007)	Column 3 Percent Change	Column 4 Weighting Factor	Column 5 Weighted Percent Change
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%
Workload adjuster to be applied to the statutory base					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 $437,783,000 statutorily specified amount from section II.A of this document, results in a total adjusted PDUFA IV base revenue amount of $479,412,000, before further adjustment for inflation and changes in workload after FY 2007.

C. Inflation Adjustment to FY 2010 Fee Revenue Amount

PDUFA IV provides that fee revenue amounts for each fiscal year after FY 2008 shall be adjusted for inflation. The adjustment must reflect the greater of the following amounts: (1) The total percentage change that occurred in the Consumer Price Index (CPI) (all items; U.S. city average) during the 12-month period ending June 30 preceding the fiscal year for which fees are being set; (2) the total percentage pay change for the previous fiscal year for Federal employees stationed in the Washington, DC metropolitan area; or (3) the average annual change in cost, per full time equivalent (FTE) FDA position, of all personnel compensation and benefits paid for the first 5 of the previous 6 fiscal years. PDUFA IV provides for this annual adjustment to be cumulative and compounded annually after FY 2008 (see section 736(c)(1) of the act).

The first factor is the CPI increase for the 12-month period ending in June 2009. The CPI for June 2009 was 215.693, and the CPI for June 2008 was 218.815. (These CPI figures are available on the Bureau of Labor Statistics Web site at *http://data.bls.gov/cgi-bin/surveymost?bls* by checking the first box under ''Price Indexes'' and then clicking ''Retrieve Data'' at the bottom of the page.) (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.) The CPI for June 2009 is 1.43 percent lower than the CPI for the previous 12-month period.

The second factor is the increase in pay for the previous fiscal year (FY 2009 in this case) for Federal employees stationed in the Washington, DC metropolitan area. This figure is published by the Office of Personnel Management, and found on their Web site at *http://www.opm.gov/flsa/oca/09tables/html/dcb.asp* above the salary table. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.) For FY 2009 it was 4.78 percent.

The third factor is the average change in FDA cost for compensation and benefits per FTE over the previous 5 of the most recent 6 fiscal years (FY 2003 through 2008). The data on total compensation 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 2 of this document summarizes that actual cost and FTE use data for the specified fiscal years, and provides the percent change from the previous fiscal year and the average percent change over the most 5 recent fiscal years, which is 5.54 percent.

TABLE 2.—FDA PERSONNEL COMPENSATION AND BENEFITS (PC&B) EACH YEAR AND PERCENT CHANGE

Fiscal Year	2004	2005	2006	2007	2008	Annual Average Increase for Latest 5 Years
Total PC&B	$1,042,749	$1,077,604	$1,114,704	$1,144,369	$1,215,627	
Total FTE	10,141	9,910	9,698	9,569	9,811	
PC&B per FTE	$102,825	$108,739	$114,942	$119,591	$123,905	
% Change from previous year	8.59%	5.75%	5.70%	4.05%	3.61%	5.54%

The inflation increase for FY 2010 is 5.54 percent. This is the greater of the CPI change during the 12-month period ending June 30 preceding the fiscal year for which fees are being set (-1.43 percent), the increase in pay for the previous fiscal year (FY 2009 in this case) for Federal employees stationed in the Washington, DC metropolitan area (4.78 percent), and the average annual change in cost, per FTE FDA position, of all personnel compensation and benefits paid for the first 5 of the previous 6 fiscal years (5.54 percent). Because the average change in pay per FTE (5.54 percent) is the highest of the three factors, it becomes the inflation

adjustment for total fee revenue for FY 2010.

The inflation adjustment for FY 2009 was 5.64 percent. This is the greater of the CPI increase during the 12-month period ending June 30 preceding the fiscal year for which fees were being set (June 30, 2008, which was 5.05 percent), the increase in pay for FY 2008 for Federal employees stationed in Washington, DC (4.49 percent), or the average annual change in cost, per FTE FDA position, of all personnel compensation and benefits paid for the first 5 of the previous 6 fiscal years (5.64 percent).

PDUFA IV provides for this inflation adjustment to be cumulative and compounded annually after FY 2008 (see section 736(c)(1) of the act). This factor for FY 2010 (5.54 percent) is compounded by adding one to it and then multiplying it by one plus the inflation adjustment factor for FY 2009 (5.64 percent). The result of this multiplication of the inflation factors for the 2 years since FY 2008 (1.0554 times 1.0564 percent) becomes the inflation adjustment for FY 2010. This inflation adjustment for FY 2010 is 11.15 percent.

Increasing the FY 2010 fee revenue base of $479,412,000, by 11.15 percent yields an inflation-adjusted fee revenue amount for FY 2010 of $532,866,000, rounded to the nearest thousand dollars, before the application of the FY 2010 workload adjustment.

D. Workload Adjustment to the FY 2010 Inflation Adjusted Fee Revenue Amount

PDUFA IV does not allow FDA to adjust the total revenue amount for workload beginning in FY 2010 unless the independent accounting firm study is complete (see section 736(c)(2)(C) of the act). That study, conducted by Deloitte Touche, LLP, was completed on March 31, 2009, and is available online at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm164339.htm*. The study found that the adjustment methodology used by FDA reasonably captures changes in workload for reviewing human drug applications under PDUFA IV. Accordingly, FDA continues to use the workload adjustment methodology that it utilized in FY 2009, and FDA intends to continue using this methodology through the end of PDUFA IV.

For each fiscal year 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 section 736(c)(2) of the act). PDUFA IV continues the PDUFA III workload adjustment with modifications, and provides for a new additional adjustment for changes in review activity.

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 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, 2009.

The calculations are summarized in of table 3 of this document. The 5-year averages for each application category are provided in Column 1 (''5-Year Average Base Years 2002–2007'') and Column 2a (''5 Year Average 2004–2009'').

PDUFA IV specifies that FDA make additional adjustments for changes in review activities to the first two categories (human drug applications and active commercial INDs). These adjustments, specified under PDUFA IV, are summarized in columns 2b and 2c in table 3 of this document. The number in the NDAs/BLAs line of column 2b of table 3 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 2002 through 2007 to the 5-year period 2004 through 2009. Likewise, the number in the ''Active commercial INDs'' line of column 2b of table 3 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 2002 through 2007 to the 5-year period 2004 through 2009. 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 3 of this document reflects the percent change in workload from column 1 to column 2c. 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 3 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 3 of this document is the sum of the values in column 5 that are added, reflecting an increase in workload of 6.82 percent for FY 2010 when compared to the base years.

TABLE 3.—WORKLOAD ADJUSTER CALCULATION FOR FY 2010

Application Type	Column 1 5-Year Average Base Years 2002–2007	Column 2a 5-Year Average 2004–2009	Column 2b Adjustment for Changes in Review Activity	Column 2c is Column 2a Increased by Column 2b	Column 3 Percent Change (Column 1 to Column 2c)	Column 4 Weighting Factor	Column 5 Weighted Percent Change
NDAs/BLAs	123.8	133.0	-0.73%	132.0	6.6%	34.8%	2.31%
Active commercial INDs[1]	5,528.2	6,078.0	-0.71%	6,035.0	9.2%	44.5%	4.08%
Efficacy supplements	163.4	169.4	NA	169.4	3.7%	8.7%	0.32%
Manufacturing supplements	2,589.2	2,613.6	NA	2,613.6	0.9%	12.0%	0.11%

TABLE 3.—WORKLOAD ADJUSTER CALCULATION FOR FY 2010—Continued

Application Type	Column 1 5-Year Average Base Years 2002–2007	Column 2a 5-Year Average 2004–2009	Column 2b Adjustment for Changes in Review Activity	Column 2c is Column 2a Increased by Column 2b	Column 3 Percent Change (Column 1 to Column 2c)	Column 4 Weighting Factor	Column 5 Weighted Percent Change
FY 2010 workload adjuster							6.82%

[1] Table 3 published in the **Federal Register** of August 1, 2008 (73 FR 45017), showed the average number of active INDs for the base years of 2002–2007 as 5,755.8. FDA discovered that a small subset of INDs had been double counted in the number reported last year. That error has been corrected in the revised number of 5528.2 reflected in the table this year. Had the error not been made, the workload adjustment in FY 2009 would have been 3.76 percent rather than the 2.98 percent published in the **Federal Register** last year.

The 2010 workload adjuster reflected in the calculations in table 3 of this document is 6.82 percent. Therefore the inflation-adjusted revenue amount of $532,866,000 from section II.C of this document will be increased by the 2010 workload adjuster of 6.82 percent, resulting in a total adjusted revenue amount in FY 2010 of $569,207,000, rounded to the nearest thousand dollars.

E. Rent and Rent-Related Adjustment to the FY 2010 Adjusted Fee Revenue Amount

PDUFA specifies that for FY 2010 and each subsequent fiscal year, the revenue amount will be decreased if the actual cost paid for rent and rent-related expenses for preceding fiscal years are less than estimates made for such fiscal years in FY 2006 (see section 736(c)(3) of the act). The only fiscal year which has been completed, and for which FDA has complete data at this time, is FY 2008. Table 4 of this document shows the estimates of rent and rent-related costs for FY 2008 made in 2006 and the actual costs at the end of the fiscal year.

TABLE 4.—COMPARISON OF ACTUAL AND ESTIMATED RENT AND RENT-RELATED EXPENSES FOR FY 2008

	Estimates Made in 2006	Actual FY 2008 Year-End Costs
Center for Drug Evaluation and Research rent & rent-related expenses	$46,732,000	$51,619,000
Center for Biologics Evaluation and Research rent & rent-related expenses	$22,295,000	$26,715,000
TOTAL	$69,027,000	$78,334,000

Because FY 2008 costs for rent and rent-related items exceeded the estimates of these costs made in 2006, no decrease in the FY 2010 estimated PDUFA revenues is required under this provision of PDUFA.

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 act). Accordingly, one-third of the total revenue amount ($569,207,000), i.e., $189,736,000 (rounded to the nearest thousand dollars), is the total amount of fee revenue that will be derived from each of these fee categories.

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 $189,736,000, rounded to the nearest thousand dollars, in FY 2010, as calculated previously in this document.

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 fiscal year by averaging the number of fee-paying FAEs received in the 5 most recent fiscal years. This use of the rolling average of the 5 most recent fiscal years is the same method that has applied for the last 6 years.

In estimating the number of fee-paying FAEs that FDA will receive in FY 2010, the 5-year rolling average for the most recent 5 years will be based on actual counts of fee-paying FAEs received for FY 2005 through FY 2009. For FY 2009, 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 7 years.

Table 5 of this document shows, in column 1, the total number of each type of FAE received in the first 9 months of FY 2009, 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, 2009. Column 4 estimates the 12-month total fee-paying FAEs for FY 2009 based on the applications received through June 30, 2009. 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 5.—FY 2009 FULL APPLICATION EQUIVALENTS RECEIVED THROUGH JUNE 30, 2009, AND PROJECTED THROUGH SEPTEMBER 30, 2009

Application or Action	Column 1 Total Received Through 6/30/2009	Column 2 Fee Exempt or Waived Through 6/30/2009	Column 3 Total Fee Paying Through 6/30/2009	Column 4 12-Month Fee-Paying Projection
Applications requiring clinical data	88.75	32.75	56	74.7
Applications not requiring clinical data	15.5	4.5	11	14.7
Supplements requiring clinical data	47.5	8.5	39	52
Withdrawn or refused to file	0.625	0	0.625	0.8
Total	153.375	45.75	106.25	142.2

In the first 9 months of FY 2009, FDA received 153.375 FAEs, of which 106.25 were fee-paying. Based on data from the last 10 fiscal years, on average, 25 percent of the applications submitted each year come in the final 3 months. Dividing 106.25 by 3 and multiplying by 4 extrapolates the amount to the full 12 months of the fiscal year and projects the number of fee-paying FAEs in FY 2008 at 142.2.

As table 6 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 2009, is 135.0 FAEs. FDA will set fees for FY 2010 based on this estimate as the number of full application equivalents that will pay fees.

TABLE 6.—FEE-PAYING FAE 5-YEAR AVERAGE

Fiscal Year	2005	2006	2007	2008	2009	5-Year Average
Fee-Paying FAEs	121.5	136.7	134.4	140.0	142.2	135.0

The FY 2010 application fee is estimated by dividing the average number of full applications that paid fees over the latest 5 years, 135.0, into the fee revenue amount to be derived from application fees in FY 2010, $189,736,000. The result, rounded to the nearest $100, is a fee of $1,405,500 per full application requiring clinical data, and $702,750 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 2009, the establishment fee was based on an estimate that 400 establishments would be subject to, and would pay, fees. By the end of FY 2009, FDA estimates that 450 establishments will have been billed for establishment fees, before all decisions on requests for waivers or reductions are made. FDA again estimates that a total of 20 establishment fee waivers or reductions will be made for FY 2009. In addition, FDA estimates that another 15 full establishment fees will be exempted this year based on the orphan drug exemption in FDAAA (see section 736(k) of the act). Subtracting 35 establishments (20 waivers plus the estimated 15 establishments under the orphan exemption) from 450 leaves a net of 415 fee-paying establishments. FDA will use 415 for its FY 2010 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 ($189,736,000) by the estimated 415 establishments, for an establishment fee rate for FY 2010 of $457,200 (rounded to the nearest $100).

B. Product Fees

At the beginning of FY 2009, the product fee was based on an estimate that 2,380 products would be subject to and would pay product fees. By the end of FY 2009, FDA estimates that 2,450 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 about 50 waivers and reductions granted. In addition, FDA estimates that another 20 product fees will be exempted this year based on the orphan drug exemption in FDAAA (see section 736(k) of the act). FDA estimates that 2,380 products will qualify for product fees in FY 2009, after allowing for waivers and reductions, including the orphan drug products eligible under the FDAAA exemption, and will use this number for its FY 2010 estimate. Accordingly, the FY 2010 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees ($189,736,000) by the estimated 2,380 products for a FY 2010 product fee of $79,720 (rounded to the nearest $10).

V. Fee Schedule for FY 2010

The fee rates for FY 2010 are set out in table 7 of this document:

TABLE 7.

Fee Category	Fee Rates for FY 2010
APPLICATIONS	
Requiring clinical data	$1,405,500
Not requiring clinical data	$702,750
Supplements requiring clinical data	$702,750
ESTABLISHMENTS	$457,200
PRODUCTS	$79,720

VIII. 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, 2009. 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 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, 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 usually charges 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, US Dept of Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No.: 75060099, Routing No.: 021030004, SWIFT: FRNYUS33, Beneficiary: FDA, 5600 Fishers Lane, Rockville, MD 20857.

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 2010 under the new fee schedule in August 2009. Payment will be due on October 1, 2009. FDA will issue invoices in November 2010 for any products and establishments subject to fees for FY 2010 that qualify for fees after the August 2009 billing.

Dated: July 28, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Privacy Act of 1974; Report of Altered Systems of Records

AGENCY: Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA).

ACTION: Notice of Altered Systems of Records (SOR).

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, the Health Resources and Services Administration (HRSA) is proposing to alter four existing systems of records (SORs) for the reasons indicated below:

09–15–0002: Records of Patient's Personal Valuables and Monies, HHS/HRSA/BPHC

HRSA is updating the system location, categories of individuals covered by the system, storage, retrievability, safeguards, retention and disposal, system manager, and notification procedure. HRSA is also adding a new routine use, number 3 (breach notification language).

09–15–0003: Contract Physicians and Consultants, HHS/HRSA/BPHC

HRSA is updating the system location, categories of individuals covered by the system, categories of records in the system, authority for maintenance of the system, retention and disposal, and system manager. HRSA is also adding a new routine use, number 6 (breach notification language).

09–15–0007: Patient's Medical Record System Public Health Service Hospitals, HHS/HRSA/BPHC

HRSA is updating the system location (Appendix 2—Federal Records Centers), categories of individuals covered by the system, categories of records in the system, authority for maintenance of the system, purpose of the system, physical safeguards, retention and disposal, system manager, and notification procedure. HRSA is deleting four routine uses, numbers 6 (Bureau of Prisons (BP) to report results of examination and treatment of patients examined and/or treated for and on behalf of the BP), 7 (Federal, state or private health benefit plans for billing purposes), 14 (Disclosure may be made to a private firm for the purpose of collating, analyzing, aggregating or otherwise refining records in this system. The contractor is required to maintain Privacy Act safeguards with respect to such records), and 19 (To organizations or individuals with agreements to provide photocopying or medical record data abstracting services. (a) PBS may inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, under the following circumstances:

1. The information has been obtained in the course of clinical activities at PHS facilities carried out by PHS personnel or contractors;

2. The PHS employee or contractor has made reasonable efforts to counsel and encourage the subject individual to provide the information to the individual's sexual or needle-sharing partner(s);

3. The PBS employee or contractor determines that the subject individual is unlikely to provide the information to the sexual or needle-sharing partner(s) or that the provision of such information cannot reasonably be verified; and

4. The notification of the partner(s) is made, whenever possible, by the subject individual's physician or by a professional counselor and shall follow standard counseling practices. (b) PHS may disclose information to State or local public health departments, to assist in the notification of the subject individual's sexual and/or needle-sharing partner(s), or in the verification that the subject individual has, notified such sexual or needle-sharing partner(s). HRSA is also adding one new routine use, number 16 (breach notification language).

09–15–0028: Public Health Service Clinical Affiliation Trainee Records, HHS/HRSA/BPHC

HRSA is updating the system location, authority for maintenance of the system, retrievability, safeguards, retention and disposal, and system manager. HRSA is also deleting one routine use, number 2 (to representatives of medical/allied health training program accreditation of PHS Training Programs), and adding a new routine use, number 6 (breach notification language).

DATES: HRSA filed an altered system report with the Chair of the House Committee on Government Reform and Oversight, the Chair of the Senate Committee on Homeland Security and Governmental Affairs, and the Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) on *July 23, 2009.* To ensure all parties have adequate time in which to comment, the altered systems, including the routine uses, will become effective 30 days from