DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Establishment of Prescription Drug User Fee Rates for Fiscal Year 2006

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) 2006. The Federal Food, Drug, and Cosmetic Act (the FD& C Act), as amended by the Prescription Drug User Fee Amendments of 2002 (Title 5 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (PHSBPRA or PDUFA III)), 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 for application fees, establishment fees, and product fees for FY 2006 were established by PDUFA III. Fees for applications, establishments, and products are to be established each year by FDA so that revenues from each category will approximate the revenue levels established in the statute, after those amounts have been first adjusted for inflation and workload. This notice establishes fee rates for FY 2006 for application fees for an application requiring clinical data ($767,400), for an application not requiring clinical data or a supplement requiring clinical data ($383,700), for establishment fees ($264,000), and for product fees ($42,130). These fees are effective on October 1, 2005, and will remain in effect through September 30, 2006. For applications and supplements that are submitted on or after October 1, 2005, the new fee schedule must be used. Invoices for establishment and product fees for FY 2006 will be issued in August 2005, using the new fee schedule.

FOR FURTHER INFORMATION CONTACT: Frank Claunts, Office of Management (HFA–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4427.

SUPPLEMENTARY INFORMATION:

I. Background

The FD&C Act, sections 735 and 736 (21 U.S.C. 379g and 379h), establishes three different kinds of user fees. Fees are assessed on: (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 2003 through FY 2007 base revenue amounts for application fees, establishment fees, and product fees are established by PDUFA III. Base revenue amounts established for years after FY 2003 are subject to adjustment 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 approximate the revenue levels established in the statute, after those amounts have been first adjusted for inflation and workload. The revenue levels established by PDUFA III continue the arrangement under which one-third of the total user fee revenue is projected to come from each of the three types of fees: Application fees, establishment fees, and product fees.

This notice establishes fee rates for FY 2006 for application, establishment, and product fees. These fees are effective on October 1, 2005, and will remain in effect through September 30, 2006.

II. Revenue Amounts for FY 2006, and Adjustments for Inflation and Workload

A. Statutory Fee Revenue Amounts

PDUFA III specifies that the fee revenue amount for FY 2006 for application fees is $86,434,000 and for both product and establishment fees is $86,433,000, for a total of $259,300,000 from all 3 categories of fees (21 U.S.C. 379h(b)), before any adjustments are made.

B. Inflation Adjustment to Fee Revenue Amount

PDUFA III provides that fee revenue amounts for each FY after 2003 shall be adjusted for inflation. The adjustment must reflect the greater of the following percentage change: (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 FY for which fees are being set, or (2) the total percentage pay change for the previous FY for Federal employees stationed in the Washington, DC metropolitan area. PDUFA III provides for this annual adjustment to be cumulative and compounded annually after FY 2003 (see 21 U.S.C. 379h(c)(1)).

The inflation increase for FY 2004 was 4.27 percent. This was the greater of the CPI increase during the 12-month period ending June 30 preceding the FY for which fees are being set (June 30, 2003—which was 2.11 percent) or the increase in pay for the previous FY (2003 in this case) for Federal employees stationed in the Washington, DC metropolitan area (4.27 percent).

The inflation increase for FY 2005 was 4.42 percent. This was the greater of the CPI increase during the 12-month period ending June 30 preceding the FY for which fees are being set (June 30, 2004—which was 3.27 percent) or the increase in pay for the previous FY (2004 in this case) for Federal employees stationed in the Washington, DC metropolitan area (4.42 percent).

The inflation adjustment for FY 2006 is 3.71 percent. This is the greater of the CPI increase during the 12-month period ending June 30 preceding the FY for which fees are being set (June 30, 2005—which was 2.53 percent) or the increase in pay for FY 2005 for Federal employees stationed in the Washington, DC metropolitan area (3.71 percent).

Compounding these amounts (1.0427 times 1.0442 times 1.0371) yields a total compounded inflation adjustment of 12.92 percent for FY 2006.

The inflation adjustment for each category of fees for FY 2006 is the statutory fee amount increased by 12.92 percent, the inflation adjuster for FY 2006. The FY 2006 inflation-adjusted revenue amount for application fees is $97,601,273 ($86,434,000 times 1.1292). For both product and establishment fees the inflation-adjusted revenue amount is $97,600,144 ($86,433,000 times 1.1292). The total inflation-adjusted fee revenue amount for all three fee categories combined is $292,801,561 in FY 2006.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

For each FY beginning in FY 2004, PDUFA III 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)).

The conference report accompanying the Prescription Drug User Fee Amendments of 2002, 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 each of the four types of applications specified in the workload adjustment provision (human drug applications, commercial investigational new drug 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, 2005.

The results of these calculations are presented in the first 2 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, reflecting 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. This weighting factor was developed by averaging data generated in a 2002 KPMG study of FDA's drug review workload and data from FDA's time reporting systems to submission data for the most recent 5-year period. Column 5 of table 1 of this document is the weighted percent change in each category of workload, and 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 1.43 percent for FY 2006 when compared to the base years.

TABLE 1.—WORKLOAD ADJUSTER CALCULATION

Application Type	Summary of Workload Adjustment Calculations				
	Column 1 5-Year Avg. Base Years	Column 2 Latest 5-Year Avg.	Column 3 Percent Change	Column 4 Weighting Factor	Column 5 Weighted % Change
NDA's/BLA's	119.6	116.2	-2.8%	41.9%	-1.19%
Commercial IND's	629.8	641.6	1.9%	41.8%	0.78%
Efficacy Supps.	159.2	166.0	4.3%	6.0%	0.26%
Manufacturing Supps.	2,100.6	2,422.8	15.3%	10.3%	1.58%
FY 2006 Workload Adjuster					1.43%

Increasing the inflation-adjusted revenue amount for application fees of $97,601,273 by the FY 2005 workload adjuster (1.43 percent) results in an increase of $1,395,698, for a total inflation and workload adjusted application fee revenue amount of $98,996,971. Increasing the inflation-adjusted revenue amount for establishment and product fees, each of which is $97,600,144, by the FY 2005 workload adjuster (1.43 percent) results in an increase of $1,395,682, for a total inflation and workload adjusted application fee revenue amount of $98,995,826 for each category. The total FY 2006 inflation and workload adjusted fee revenue target for all three fee categories combined is $296,988,623.

III. Application Fee Calculations

PDUFA III provides that the rates for application, product, and establishment fees be established 60 days before the beginning of each FY (21 U.S.C. 379h(c)(4)). The fees are to 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 III established for FY 2006 is $98,996,971, as calculated in section II.C of this document. Application fees will be set to generate this amount.

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

For FY 2003 through FY 2007, 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 five most recent fiscal years. This use of the rolling average of the five most recent fiscal years is the same method that was applied in making the workload adjustment.

In estimating the number of fee-paying FAE's that FDA will receive in FY 2006, the 5-year rolling average for the most recent 5 years will be based on actual counts of fee-paying FAEs received for FY 2001 through 2005. For FY 2005, 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.

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 2005, 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, 2005. Column 4 estimates the 12-month total fee-paying FAEs for FY 2005 based on the applications received through June 30, 2005. All of the counts are in FAEs. A full application requiring clinical data counts as one FAE. An application not requiring clinical data counts 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 it initially paid a full application fee, or one-eighth of an FAE if it initially paid one-half of the full application fee amount.

TABLE 2.—FY 2005 FULL APPLICATION EQUIVALENTS RECEIVED THROUGH JUNE 30, 2005, AND PROJECTED THROUGH SEPTEMBER 30, 2005

Application or Action	Column 1 Total Received Through 6/30/2005	Column 2 Fee Exempt or Waived Through 6/30/2005	Column 3 Total Fee Paying Through 6/30/2005	Column 4 12-Month Projection
Applications Requiring Clinical Data	70.0	23.0	47.0	62.7
Applications Not Requiring Clinical Data	4	0.0	4	5.3

TABLE 2.—FY 2005 FULL APPLICATION EQUIVALENTS RECEIVED THROUGH JUNE 30, 2005, AND PROJECTED THROUGH SEPTEMBER 30, 2005—Continued

Application or Action	Column 1 Total Received Through 6/30/2005	Column 2 Fee Exempt or Waived Through 6/30/2005	Column 3 Total Fee Paying Through 6/30/2005	Column 4 12-Month Projection
Supplements Requiring Clinical Data	45	5.0	40	53.3
Withdrawn or Refused to File	0.25	0.0	0.25	0.3
Total	119.25	28.0	91.25	121.6

In the first 9 months of FY 2005 FDA received 119.25 FAE's, of which 91.25 were fee-paying. Based on data from the last 7 fiscal years, on average, 25 percent of the applications submitted each year come in the final 3 months. Dividing 91.25 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 2005 at 121.6.

All pediatric supplements, which had been exempt from fees prior to January 4, 2002, were required to pay fees effective January 4, 2002. This is the result of section 5 of the Best Pharmaceuticals for Children Act that repealed the fee exemption for pediatric supplements effective January 4, 2002. Thus, in estimating FY 2006 fee-paying receipts we must add all the pediatric supplements that were previously exempt from fees prior to January 4, 2002. The exempted number of FAEs for pediatric supplements for FY 2001 and FY 2002 respectively were 19 and 4.5. Since fees on these supplements are paid for pediatric applications submitted in FY 2003 and beyond, the number of pediatric supplement FAEs exempted from fees each in both FY 2001 and FY 2002 (the years in the table when fees were exempted) are added to the total of fee-paying FAEs received each year.

As table 3 of this document shows, the average number of fee-paying FAEs received annually in the most recent 5-year period, assuming all pediatric supplements had paid fees, and including our estimate for FY 2005, is 129 FAEs. FDA will set fees for FY 2006 based on this estimate as the number of full application equivalents that will pay fees.

TABLE 3.—FEE-PAYING FULL APPLICATION EQUIVALENT—FIVE YEAR AVERAGE

Year	2001	2002	2003	2004	2005	5-Year Avg.
Fee-Paying FAEs	107.6	127.6	119.5	145.1	121.6	124.3
Exempt Pediatric Supplement FAEs	19.0	4.5	0.0	0.0	0.0	4.7
Total	126.6	132.1	119.5	145.1	121.6	129.0

The FY 2006 application fee is estimated by dividing the average number of full applications that paid fees over the latest 5 years, 129, into the fee revenue amount to be derived from application fees in FY 2006, $98,996,971. The result, rounded to the nearest one hundred dollars, is a fee of $767,400 per full application requiring clinical data, and $383,700 per application not requiring clinical data or per supplement requiring clinical data.

IV. Adjustment for Excess Collections in Previous Years

Under the provisions of PDUFA, as amended, if the agency collects more fees than were provided for in appropriations in any year after 1997, FDA is required to reduce its anticipated fee collections in a subsequent year by that amount (21 U.S.C. 379h(g)(4)).

In FY 1998, Congress appropriated a total of $117,122,000 to FDA in PDUFA fee revenue. To date, collections for FY 1998 total $117,737,470—a total of $615,470 in excess of the appropriation limit. This is the only FY since 1997 in which FDA has collected more in PDUFA fees than Congress appropriated.

FDA also has some requests for waivers or reductions of FY 1998 fees that have been decided but that are pending appeals. For this reason, FDA is not reducing its FY 2006 fees to offset excess collections at this time. An offset will be considered in a future year, if FDA still has collections in excess of appropriations for FY 1998 after the pending appeals for FY 1998 waivers and reductions have been resolved.

V. Fee Calculations for Establishment and Product Fees

A. Establishment Fees

At the beginning of FY 2005, the establishment fee was based on an estimate that 354 establishments would be subject to and would pay fees. By the end of FY 2005, FDA estimates that 400 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 25 establishment fee waivers or reductions will be made for FY 2005, for a net of 375 fee-paying establishments. FDA will use this same number again, 375, for its FY 2006 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 ($98,995,826) by the estimated 375 establishments, for an establishment fee rate for FY 2006 of $264,000 (rounded to the nearest $100).

B. Product Fees

At the beginning of FY 2005, the product fee was based on an estimate that 2,225 products would be subject to and pay product fees. By the end of FY 2005, FDA estimates that 2,390 products will have been billed for product fees, before all decisions on requests for waivers or reductions are made. Assuming that there will be about 40 waivers and reductions granted, FDA estimates that 2,350 products will qualify for product fees in FY 2005, after allowing for waivers and reductions, and will use this number for its FY 2006

estimate. Accordingly, the FY 2006 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees ($98,995,826) by the estimated 2,350 products for a FY 2006 product fee of $42,130 (rounded to the nearest $10).

VI. Fee Schedule for FY 2006

The fee rates for FY 2006 are set out in table 4 of this document.

TABLE 4.—FY 2006 FEE RATES

FEE CATEGORY	FEE RATES FOR FY 2006
Applications	
Requiring clinical data	$767,400
Not requiring clinical data	$383,700
Supplements requiring clinical data	$383,700
Establishments	$264,000
Products	$42,130

VII. 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, 2005. 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 360909, Mellon Client Service Center—rm. 670, 500 Ross St., Pittsburgh, PA 15251–6909.

If checks are to be sent by a courier, the courier can deliver the checks to: Food and Drug Administration (360909), Mellon Client Service Center—rm. 670, 500 Ross St., Pittsburgh, PA 15262–0001. (Note: This Mellon Bank address is for courier delivery only.)

Please make sure that the FDA post office box number (P.O. Box 360909) is written on the check. The tax identification number of the Food and Drug Administration is 530 19 6965.

B. Establishment and Product Fees

By August 31, 2005, FDA will issue invoices for establishment and product fees for FY 2006 under the new Fee Schedule. Payment will be due on October 1, 2005. FDA will issue invoices in October 2006 for any products and establishments subject to fees for FY 2006 that qualify for fees after the August 2005 billing.

Dated: July 26, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4975–N–22]

Notice of Proposed Information Collection: Comment Request; Mortgagee Request for Extension of Time Requirements

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* September 30, 2005.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Wayne Eddins, Reports Management Officer, Department of Housing and Urban Development, 451 7th Street, SW., L'Enfant Plaza Building, Room 8001, Washington, DC 20410 or *Wayne_Eddins@hud.gov*.

FOR FURTHER INFORMATION CONTACT: JeniRuth Nix, Program Analyst, Office of Single Family Housing, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, telephone (202) 708–1672 (this is not a toll free number) for copies of the proposed forms and other available information.

SUPPLEMENTARY INFORMATION: The Department is submitting the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Mortgagee's Request for Extension of Time Requirements.

OMB Control Number, if applicable: 2502–0436.

Description of the need for the information and proposed use: In the event of default, foreclosure, and conveyance requirements of an insured mortgage, the mortgagee is entitled to receive insurance benefits from the date of default to the date of insurance benefits. In the event of preservation and protection (P&P) requirements of the fiscal integrity of a conveyed property, the mortgagee is entitled to receive insurance benefits for the preservation of the property. HUD regulations require that the mortgagee take certain actions within specific time limitations. Failure to meet such limitations may result in curtailment of interest payments. Information collected here allows the Department to evaluate requests for extension of the regulatory time limits within which specific foreclosure processing and P&P steps must be taken.

Agency form numbers, if applicable: HUD–50012.

Estimation of the total numbers of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: An estimation of the total numbers of hours needed to prepare the information collection is 4,504, number of respondents is 146, frequency of response is on occasion, the total number of responses is 28,150, and the estimated response time is 10 minutes.

Status of the proposed information collection: This is a revision of a currently approved collection.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C., Chapter 35, as amended.

Dated: July 22, 2005.

Brian D. Montgomery,

Assistant Secretary for Housing-Federal Housing Commissioner.

[FR Doc. E5–4079 Filed 7–29–05; 8:45 am]

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