A. Step One—Secure a Payment Identification Number and Medical Device User Fee Cover Sheet From FDA Before Submitting Either the Application or the Payment. Note: FY 2004 Fee Rates Will be Available on the Cover Sheet Beginning on August 25, 2003.

Log onto the MDUFMA Web site at *http://www.fda.gov/oc/mdufma* and, under the forms heading, click on the link ''User Fee Cover Sheet.'' Complete the Medical Device User Fee Cover Sheet. Be sure you choose the correct application submission date range. (Two choices will be offered from August 25, 2003, until the middle of October 2003. One choice is for applications that will be received on or before September 30, 2003, which will be subject to FY 2003 fee rates. A second choice is for applications that will be received on or after October 1, 2003, which will be subject to FY 2004 fee rates.) After completing data entry, print a copy of the Medical Device User Fee Cover Sheet and note the unique Payment Identification Number located in the upper right-hand corner of the printed cover sheet.

B. Step Two—Electronically Transmit a Copy of the Printed Cover Sheet with the Payment Identification Number to FDA's Office of Financial Management

Once you are satisfied that the data on the cover sheet is accurate, electronically transmit that data to FDA according to the instructions on the screen. Since electronic transmission is possible beginning on August 25, 2003, it will no longer be necessary to fax a copy of the sheet to FDA. After August 25, 2003, applicants will be required to set up a user account and use passwords to assure data security in the creation and electronic submission of Cover Sheets.

C. Step Three—Mail Payment and a Copy of the Completed Medical Device User Fee Cover Sheet to the Saint Louis Address Specified Below

• Make the payment in U. S. currency by check, bank draft, or U.S. Postal money order payable to the Food and Drug Administration. (The tax identification number of the Food and Drug Administration is 53–0196965, should your accounting department need this information.)

• Please write your application's unique Payment Identification Number, from the upper right-hand corner of your completed Medical Device User Fee Cover Sheet, on your check, bank draft, or U.S. Postal money order.

• Mail the payment and a copy of the completed Medical Device User Fee Cover Sheet to: Food and Drug Administration, P.O. Box 956733, Saint Louis, MO, 63195–6733.

If you prefer to send a check by a courier such as FEDEX or UPS, the courier may deliver the checks to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, Missouri 63101.

(Note: This address is for courier delivery only. Contact the US Bank at 314–418–4821 if you have any questions concerning courier delivery.)

It is helpful if the fee arrives at the bank at least 1 day before the application arrives at FDA. FDA records the official application receipt date as the later of the following:

• The date the application was received by FDA.

• The date US Bank notifies FDA that payment has been received. US Bank is required to notify FDA within 1-working day, using the Payment Identification Number described previously.

D. Step Four—Submit your Application to FDA With a Copy of the Completed Medical Device User Fee Cover Sheet

Please submit your application and a copy of the completed Medical Device User Fee Cover Sheet to one of the following addresses:

• Medical device applications should be submitted to: Food and Drug Administration, Center for Devices and Radiological Health, Document Mail Center (HFZ–401), 9200 Corporate Blvd., Rockville, MD 20850.

• Biologic applications should be sent to: Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center (HFM–99), suite 200N, 1401 Rockville Pike, Rockville, MD 20852–1448.

Dated: July 29, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–19655 Filed 7–31–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Establishment of Prescription Drug User Fee Rates for Fiscal Year 2004

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) 2004. The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Prescription Drug User Fee Amendments of 2002 (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. Revenue amounts for application fees, establishment fees, and product fees for FY 2004 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 levels established in the statute, after those amounts have been first adjusted for inflation and workload. This notice establishes fee rates for FY 2004 for application fees ($573,500 for an application requiring clinical data, and $286,750 for an application not requiring clinical data or a supplement requiring clinical data), establishment fees ($226,800), and product fees ($36,080). These fees are effective on October 1, 2003, and will remain in effect through September 30, 2004. For applications and supplements that are submitted on or after October 1, 2003, the new fee schedule must be used. Invoices for establishment and product fees for FY 2004 will be issued in August 2003, using the new fee schedule.

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

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: (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 (see 21 U.S.C. 379h(a)). When certain conditions are met, FDA may waive or reduce fees (see 21 U.S.C. 379h(d)).

For FY 2003 through FY 2007 revenue amounts for application fees, establishment fees, and product fees are established by PDUFA III (the Prescription Drug User Fee Amendments of 2002, title 5 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002). 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 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 2004 for application, establishment, and product fees. These fees are effective on October 1, 2003, and will remain in effect through September 30, 2004.

II. Revenue Amount for FY 2004, and Adjustments for Inflation and Workload

A. Statutory Fee Revenue Amounts

PDUFA III specifies that the fee revenue amount for FY 2004 for each category of fees (application, product, and establishment) is $77,000,000, before any adjustments are made, for a total of $231,000,000 from all three categories of fees (see 21 U.S.C. 379h(b)).

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: (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 adjustment for FY 2004 is 4.27 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, 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). No compounding is applied to this amount because there was no inflation increase applied in FY 2003.

The inflation-adjusted revenue amount for each category of fees for FY 2004 is the statutory fee amount ($77,000,000) increased by 4.27 percent, the inflation adjuster for FY 2004. The FY 2004 inflation-adjusted revenue amount is $80,287,900 for each category of fee, for a total inflation-adjusted fee revenue amount of $240,863,700 in FY 2004.

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 PDUFA III, House of Representatives report number 107–481, provides additional instructions 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, 2003.

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 applying data generated in a 2002 KPMG study of FDA's drug review workload 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 change in workload of negative 1.4 percent for FY 2004.

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 % Change	Column 4 Weighting Factor	Column 5 Weighted % Change
New Drug Applications/Biological License Applications	119.8	116.6	-2.7%	45.0%	-1.2%
Commercial Investigational New Drug Exemptions	629.8	617.8	-1.9%	40.7%	-0.8%
Efficacy Supplements	159.2	164.8	3.5%	5.7%	0.2%
Manufacturing Supplements	2100.6	2193.0	4.4%	8.7%	0.4%
FY 2004 Workload Adjuster					-1.4%

PDUFA III specifies that the workload adjuster may not result in fees that are less than the inflation-adjusted revenue amount. For this reason, the workload adjustment will not be applied in FY 2004, and the inflation-adjusted revenue amount for each category of fees for FY 2004 ($80,287,900) becomes the revenue target for fees in FY 2004, for a total inflation-adjusted fee revenue target in FY 2004 of $240,863,700 for fees from all three categories.

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 (see 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 2004 is $80,287,900, as calculated in the previous section. 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 FAEs that FDA will receive in FY 2004, the 5-year rolling average for the most recent 5 years will be based on actual counts of fee-paying FAEs received for fiscal years 1999 through 2003. For FY 2003, 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 2003, 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, 2003. Column 4 estimates the 12-month total fee-paying FAEs for FY 2003 based on the applications received through June 30, 2003. 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 2003 FAEs RECEIVED THROUGH JUNE 30, 2003 AND PROJECTED THROUGH SEPTEMBER 30, 2003

Application or Action	Column 1 Total FAEs Received Through June 30, 2003	Column 2 Fee Exempt or Waived FAEs Through June 30, 2003	Column 3 Total Fee Paying FAEs Through June 30, 2003	Column 4 12-Month Projection for Fee Paying FAEs
Applications Requiring Clinical Data	65.0	17.0	48.0	64.0
Applications Not Requiring Clinical Data	6.5	0.5	6.0	8.0
Supplements Requiring Clinical Data	40.0	6.0	34.0	45.3
Withdrawn or Refused to File	0.0	0.0	0.0	0.0
Total	111.5	23.5	88.0	117.3

In the first 9 months of FY 2003 FDA received 111.5 FAEs, of which 88 were fee-paying. Based on data from the last 7 FYs, on average, 25 percent of the applications submitted each year come in the final 3 months. Dividing 88 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 2003 at 117.3.

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 2004 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 1999, FY 2000, FY 2001, and FY 2002 respectively were 5.3, 12.5, 19, and 4.5. Since fees on these supplements will be paid for pediatric applications submitted in FY 2004, the number of pediatric supplement FAEs exempted from fees each year from FY 1999 through 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 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 2003, is 140.0 FAEs. FDA will set fees for FY 2004 based on this estimate as the number of full application equivalents that will pay fees.

TABLE 3.—FAEs 5-YEAR AVERAGE

Year	1999	2000	2001	2002	2003	5-year Avg.
Fee-Paying FAEs	118.7	153.0	107.6	127.6	117.3	131.8
Exempt Pediatric Supplement FAEs	5.3	12.5	19.0	4.5	0.0	8.2
Total	158.3	165.9	126.6	132.1	117.3	140.0

The FY 2004 application fee is estimated by dividing the estimated number of full applications that will pay fees, 140, into the fee revenue amount to be derived from application fees in FY 2004, $80,287,900. The result, rounded to the nearest one hundred dollars, is a fee of $573,500 per full application requiring clinical data, and

$286,750 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 (see 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 fiscal year 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 2004 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 2003, the establishment fee was based on an estimate that 354 establishments would be subject to and would pay fees. By the end of FY 2003, FDA estimates that 379 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 2003, for a net of 354 fee-paying establishments. FDA will use this number, 354, for its FY 2004 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 ($80,287,900) by the estimated 354 establishments, for an establishment fee rate for FY 2004 of $226,800 (rounded to the nearest one hundred dollars).

B. Product Fees

At the beginning of FY 2003, the product fee was based on an estimate that 2,293 products would be subject to and pay product fees. By the end of FY 2003, FDA estimates that 2,260 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 35 waivers and reductions made, FDA estimates that 2,225 products will qualify for product fees in FY 2003, after allowing for waivers and reductions, and will use this number for its FY 2004 estimate. Accordingly, the FY 2004 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees ($80,287,900) by the estimated 2,225 products for a FY 2004 product fee of $36,080 (rounded to the nearest ten dollars).

VI. Fee Schedule for FY 2004

The fee rates for FY 2004 are set out in table 4 of this document:

TABLE 4.

FEE CATEGORY	FEE RATES FOR FY 2004
APPLICATIONS	
Requiring clinical data	$573,500
Not requiring clinical data	$286,750
Supplements requiring clinical data	$286,750
ESTABLISHMENTS	$226,800
PRODUCTS	$36,080

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 submitted after September 30, 2003. 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. Your check can be mailed to: Food and Drug Administration, P.O. Box 360909, Pittsburgh, PA 15251–6909

If checks are sent by a courier that requests a street address, 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 on the enclosed check. The tax ID number of the FDA is 530 19 6965.

B. Establishment and Product Fees

By August 31, 2003, FDA will issue invoices for establishment and product fees for FY 2004 under the new Fee Schedule. Payment will be due on October 1, 2003. FDA will issue invoices in October 2004 for any products and establishments subject to fees for FY 2004 that qualify for fees after the August 2003 billing.

Dated: July 29, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0325]

Guidance for Industry on 180-Day Exclusivity When Multiple Abbreviated New Drug Applications Are Submitted on the Same Day; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day.'' This guidance explains how FDA intends to determine eligibility for 180-day exclusivity when multiple substantially complete abbreviated new drug applications (ANDAs) that contain a paragraph IV certification to the same