

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Establishment of Prescription Drug User Fee Rates for Fiscal Year 2003

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) 2003. The Federal Food, Drug, and Cosmetic Act (the act), as amended most recently 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. This notice establishes fee rates by PDUFA for FY 2003 for application fees (\$533,400 for an application requiring clinical data, and \$266,700 for an application not requiring clinical data or a supplement requiring clinical data), establishment fees (\$209,900), and product fees (\$32,400). These fees are effective on October 1, 2002, and will remain in effect through September 30, 2003. For applications and supplements that are submitted on or after October 1, 2002, the new fee schedule must be used. Invoices for establishment and product fees for FY 2003 will be issued in August 2002 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 379h), 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 (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 revenue amounts for application fees, establishment fees, and product fees are established by PDUFA III. 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 2003 for application, establishment, and product fees. These fees are effective on October 1, 2002, and will remain in effect through September 30, 2003.

II. Inflation and Workload Adjustment Process

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 2003 (see 21 U.S.C. 379h(c)(1)). No inflation adjustment is to be made with respect to fee revenue amounts established in the statute for FY 2003.

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)). No workload adjustment is to be made with respect to fee revenue amounts established in the statute for FY 2003.

Since neither inflation nor workload adjustments apply to the revenue amounts established in PDUFA III for FY 2003, the levels specified in the statute are the amounts that fees set by FDA for FY 2003 should generate. Those statutory revenue amounts are \$74,300,000 from application fees, \$74,300,000 from establishment fees, and \$74,300,000 from product fees.

III. Fee Calculations

PDUFA III provides that the fee 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

Application fees are assessed at different rates for qualifying applications depending on whether the applications require clinical data for safety or effectiveness (other than bioavailability or bioequivalence studies) (21 U.S.C. 379h(a)(1)(A)). Applications that require clinical data are subject to the full application fee. Applications that do not require clinical data and supplements that require clinical data are assessed one-half the fee of applications that require clinical data. If FDA refuses to file an application or supplement, 75 percent of the application fee is refunded to the applicant (21 U.S.C. 379h(a)(1)(D)).

The application fee revenue amount that PDUFA III established for FY 2003 is \$74,300,000 (21 U.S.C. 379h(b)). For FY 2003 no adjustment is to be made for either inflation or workload changes (21 U.S.C. 379h(c)). Application fees for FY 2003 will be set to generate \$74,300,000.

B. Estimate of Numbers 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 each year by averaging the number of fee-paying FAEs received in each of the five most recent FYs. This use of the rolling average of the five most recent FYs is the same method that will also be applied in future years in making the workload adjustment.

In estimating the number of fee-paying FAEs that FDA will receive in FY 2003, the 5-year rolling average for the most recent 5 years will be based on actual counts of fee-paying FAEs received for FYs 1998 through 2001. For FY 2002, 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 1, under column 2 of this document, shows the total number of each type of FAE received in the first 9 months of FY 2002; whether fees were paid or not. Column 3 shows the number of FAEs for which fees were waived or exempted during this period, and column 4 shows the number of fee-paying FAEs received through June 30, 2002. The last column estimates the 12-month total fee-paying FAEs for FY 2003 based on the applications received through June 30, 2002. 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 1.—FY 2002 FULL APPLICATION EQUIVALENTS (FAEs) RECEIVED THROUGH JUNE 30, 2002, AND PROJECTION

Application or Action	Total FAEs Received Through June 30, 2002	Fee Exempt or Waived FAEs Through June 30, 2002	Total Fee Paying FAEs Through June 30, 2002	12-Month Projection for Fee-Paying FAEs
Applications requiring clinical data	65.00	18.00	47.00	62.667
Applications not requiring clinical data	9.00	3.00	6.00	8.00
Supplements requiring clinical data	43.50	11.00	32.50	43.333
Withdrawn or refused to file	0.75	0.25	0.50	0.667
Total	118.25	32.25	86.00	114.67

In the first 9 months of FY 2002, FDA received 118.25 FAEs, of which 86 were fee-paying. Based on data from the last 5 FYs, on average, 25 percent of the applications submitted each year come in the final 3 months. Thus, dividing 86 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 2002 at 114.7.

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 2003 fee-paying receipts we must assume all the pediatric supplements that were previously exempt from fees will be subject to fees in FY 2003. In FY 1998, 8 full fees were exempted for pediatric supplements; the exempted number of FAEs for pediatric supplements for FY 1999, FY 2000, FY 2001, and FY 2002, respectively, were 5.25, 12.5, 19, and 4.5. Since fees on these supplements will be paid for pediatric applications submitted in FY 2003, the number of pediatric supplement FAEs exempted from fees each year from FY 1998 through FY 2002 (the only years when fees were exempted) are added to the total of fee-paying FAEs received each year.

As table 2 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 2002, is 139.3 FAEs. FDA will set fees for FY 2003 based on this estimate as the number of full application equivalents that will pay fees.

TABLE 2.

Type of FAE	1998	1999	2000	2001	2002	5-Year Average
Fee-paying FAEs	118.7	153.0	153.4	107.6	114.7	129.5
Exempt pediatric supplement FAEs	8.0	5.3	12.5	19.0	4.5	9.9
Total	126.7	158.3	165.9	126.6	119.2	139.3

The FY 2003 application fee is estimated by dividing the estimated number of full applications that will pay fees, 139.3, into the statutorily set amount to be derived from application fees in FY 2003, \$74,300,000. The result, rounded to the nearest one hundred dollars, is a fee of \$533,400 per

full application requiring clinical data, and \$266,700 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 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 2003 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 2002, the establishment fee was based on an estimate that 354 establishments would be subject to and would pay fees. By the end of FY 2002, 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 2002, for a net of 354 fee-paying establishments. FDA will use this number, 354, for its FY 2003 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 (\$74,300,000), by the estimated 354 establishments, for an establishment fee rate for FY 2003 of \$209,900 (rounded to the nearest one hundred dollars).

B. Product Fees

At the beginning of FY 2002, 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 2002, FDA estimates that 2,348 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 55 waivers and reductions made, FDA estimates that 2,293 products will qualify for product fees in FY 2002, after allowing for waivers and reductions, and will use this number for its FY 2003 estimate. Accordingly, the FY 2003 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees (\$74,300,000) by the estimated 2,293 products for a product fee rate of \$32,400 (rounded to the nearest ten dollars).

VI. Fee Schedule for FY 2003

The fee rates for FY 2003 are set out in table 3 of this document:

TABLE 3.

Fee Category	Fee Rates for FY 2003
Applications	
Requiring clinical data	\$533,400
Not requiring clinical data	\$266,700
Supplements requiring clinical data	\$266,700
Establishments	\$209,900
Products	\$32,400

VII. Implementation of Adjusted Fee Schedule

A. Application Fees

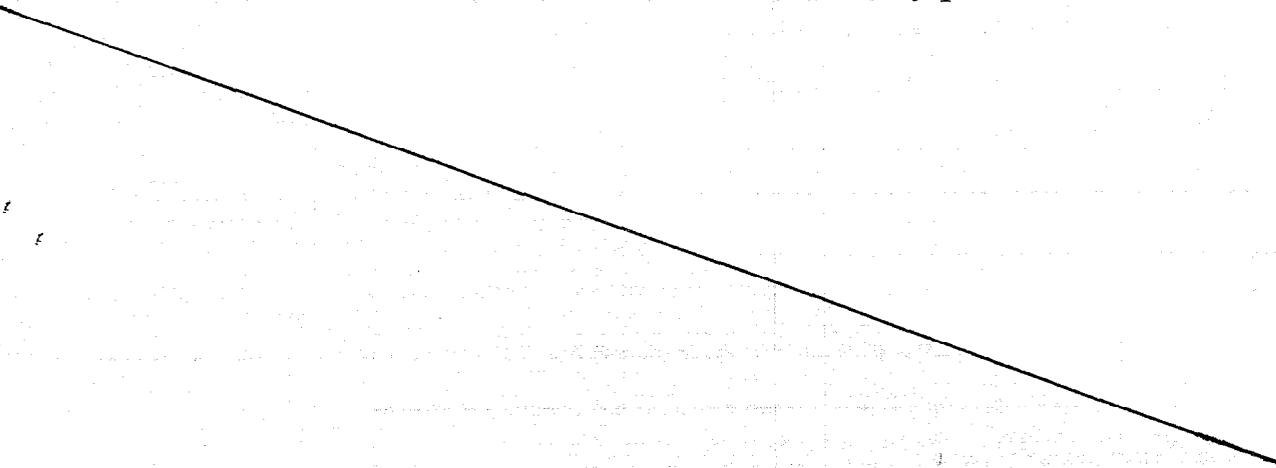
Any application or supplement subject to fees under PDUFA that is submitted after September 30, 2002, must be accompanied by the appropriate application fee established in the new fee schedule. Payment must be made in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the U.S. Food and Drug Administration. Please include the user fee ID number on your check. Your check can be mailed to: U.S. Food and Drug Administration, P.O. Box 360909, Pittsburgh, PA 15251-6909.

If checks are to be sent by a courier that requests a street address, the courier can deliver the checks to: U.S. 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 P.O. Box number (P.O. Box 360909) is on the enclosed check. The tax identification number of the U.S. Food and Drug Administration is 530 19 6965.

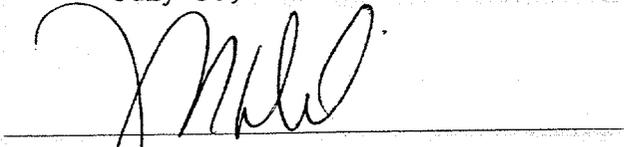
B. Establishment and Product Fees

By August 31, 2002, FDA will issue invoices for establishment and product fees for FY 2003 under the new fee schedule. Payment will be due on October 1, 2002. FDA will issue invoices in October 2003 for any products and



establishments subject to fees for FY 2003 that qualify for fees after the August 2002 billing.

Dated: 7/30/02
July 30, 2002.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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