

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 Fac- tor	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