

amount (\$27,255,000) increased by 4.27 percent, the inflation adjuster for FY 2004. The FY 2004 inflation-adjusted revenue amount is \$28,418,789.

C. Workload Adjustment to Inflation Adjusted Fee Revenue Amount

For each FY beginning in FY 2004, MDUFMA provides that fee revenue amounts, after they have been adjusted for inflation, shall be further adjusted to reflect increases in workload for the process for the review of medical device applications (see 21 U.S.C. 379j(c)(2)). FDA's current assessment reflects that the change in total review workload as defined in MDUFMA has changed by less than 1 percent. Based on this assessment, FDA is not applying a workload adjustment to the FY 2004 inflation-adjusted revenue amount of \$28,418,789. The need for workload adjustment will be assessed anew next year when FY 2005 fees are established.

D. Compensating Adjustment to Fee Revenue Amount Once Adjustments for Inflation and Workload Have Been Made

For each FY beginning in FY 2004, MDUFMA provides that fee revenue amounts, after they have been adjusted

for inflation and workload, shall be further adjusted, if necessary, to compensate for the cumulative shortfall in fee revenue from previous years (see 21 U.S.C. 379j(c)(3)). In FY 2003, FDA had expected to collect a total of \$25,125,000 in MDUFMA fees, the fee revenue amount stated in the statute (see 21 U.S.C. 379j(b)). As of June 30, 2003, for 9 months of the fiscal year, total fee collections were \$14,360,304. If fee collections in the last 3 months are proportional to collections in the first 9 months, FDA will collect another \$4,786,768 million—for a total of about \$19,147,000 million for the year. In addition FDA expects to collect about \$500,000 of outstanding accounts receivable, for a FY 2003 estimated total fee collection of \$19,647,000. This is \$5,478,000 million less than the statutory revenue amount for FY 2003.

In implementing the compensating adjustment provision, FDA will increase the FY 2004 revenue amount by the amount of the revenue shortfall in FY 2003, \$5,478,000. Accordingly, adding \$5,478,000 to the inflation-adjusted revenue amount of \$28,418,789 derived above (see section II.B of this document), provides a final adjusted

revenue amount for FY 2004 of \$33,896,789. Fees for FY 2004 are being set to generate this amount of revenue.

III. Fee Calculations for FY 2004

A. Estimating Numbers of Applications That Will Pay Fees

Under MDUFMA, the amount of fee revenue collected is a function of two factors—the fee rate for the application and the number of applications that will pay each type of fee.

To set fees for FY 2004, FDA must first estimate the number of applications that will pay each type of fee. For FY 2003, before MDUFMA was enacted, FDA estimated the number of applications that would pay each type of fee. That estimate was based on the average number of each category of applications over the 5-year period before MDUFMA was enacted, FY 1997 through FY 2001. These estimates took into account FDA's estimates of the number of applications that would qualify for a small business reduction or exemption. (It should be noted that the two-tier fee structure for 510(k)'s is to begin in FY 2004.) The original FY 2003 estimates are shown in Table 1 of this document.

TABLE 1.—ORIGINAL ESTIMATES OF NUMBERS OF FEE-PAYING APPLICATIONS

Type of Fee-Paying Application	Full Year Numbers Based on Original Estimates		
	Full Fee	Reduced Fee	Waived
Original Premarket Applications (PMAs)/Product Development Protocols (PDPs)/Premarket Reports (PMRs)/Biologics License Applications (BLAs) and Full Fee Supplements	58	10	10
180-Day PMA/PDP Supplements to PMAs	171	24	
Real Time Supplements to PMAs	86	14	
Premarket Notifications (510(k)s)	880	3,120	

The reason that MDUFMA fee revenues are projected to fall approximately \$5,478,000 short of the revenue target in FY 2003 is that FDA collected fewer full fees than projected for Original PMAs and BLAs and their full-fee supplements, and fewer fees for 180-day supplements. The major reasons for this are twofold. A number of the applications were "bundled," using guidance developed after MDUFMA was enacted, and did not have to pay separate fees. In addition, the agency received fewer full PMAs, BLAs and 180-day supplements in the first 9 months of FY 2003 than the 5-year averages estimated. Because of this, FDA considered basing fees for FY 2004 on lower estimates of the number of full PMA/BLA fees and 180-day supplement

fees. This would have resulted in even higher fees for FY 2004.

The agency decided against revising estimated numbers of fee-paying applications in setting the FY 2004 fees, however, because such a revision would have been based on data from too brief a period—the 3 months from April 1 through June 30, 2003, during which applications were not accepted for filing unless the fee was paid. Instead, the agency will continue to use its original estimate of the numbers of fee-paying applications (see Table 1 of this document) again in setting fees for FY 2004.

FDA will reassess whether or not it needs to adjust its original estimates of the number of each type of fee-paying application a year from now when it sets fees for FY 2005. At that time the

agency will have 15 months of data to use to determine whether its original estimates for annual numbers of applications were too high.

B. Determining The Fee Rates

Under MDUFMA, all fees are set as a percent of the full fee for a PMA (see 21 U.S.C. 379j(a)(1)(A)). In order to generate \$33,896,789 in FY 2004, using the above estimates of the numbers of each type of application that will pay a fee at each rate (see Table 1 of this document), the rate for a full PMA will be \$206,811 for FY 2004. For all applications other than premarket notification submissions, the small business rate is 38 percent of the full fee rate (see 21 U.S.C. 379j(d)(2)(C)). For premarket notification submissions (510(k)'s), the small business rate is 80