

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 An application that is withdrawn or refused for filing counts as one-fourth of an FAE if it initially paid a full application fee, or one-eighth of an FAE if it initially paid one-half of the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 Re- ceived Through June 30, 2003	Column 2 Fee Exempt or Waived FAEs Through June 30, 2003	Column 3 Total Fee Pay- ing FAEs Through June 30, 2003	Column 4 12-Month Pro- jection 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