

\$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