

ADDRESSES) written or electronic comments on the draft guidance. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.fda.gov/cvm/guidance/published.htm>.

Dated: February 19, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drugs Administration

Medical Device User Fee Payment Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the payment procedures for medical device user fees for fiscal year (FY) 2003. The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), authorizes FDA to collect user fees for certain medical device applications. The FY 2003 fee rates were published in the **Federal Register** of November 21, 2002 (67 FR 70228 at 70229, as amended by the **Federal Registers** of January 10, 2003, and January 22, 2003 (68 FR 1469 and 68 FR 3033)); however, FDA could not begin to collect these fees until enabling appropriations were enacted. Those enabling appropriations were enacted on February 20, 2003, so FDA is now able to collect Medical Device User Fees for FY 2003. Accordingly, FDA will issue invoices for all fees payable for applications submitted between October 1, 2002, and March 31, 2003. Those invoices will be due and payable within 30 days of issuance. For all applications submitted on or after April 1, 2003, fees must be paid at the time that applications are submitted to FDA. This notice provides payment procedures for those submitting medical device applications that may be subject to user fees.

FOR FURTHER INFORMATION CONTACT: For further information on MDUFMA visit the FDA Web site <http://www.fda.gov/>

[oc/mdufma](http://www.fda.gov/) or contact James G. Norman, Office of Systems and Management (HFZ-2), Food and Drug Administration, Center for Devices and Radiological Health (CDRH), 9200 Corporate Blvd., Rockville, MD 20850, 301-827-6829.

SUPPLEMENTARY INFORMATION:

I. Background

Sections 737 and 738 of the act (21 U.S.C. 379i and j) establish fees for certain medical device applications and supplements. When certain conditions are met, FDA may waive or reduce fees (21 U.S.C. 379j(d) and (e)).

MDUFMA establishes aggregate revenue amounts for application fee revenues each year for FY 2003 through FY 2007. Revenue amounts established for years after FY 2003 are subject to adjustment for inflation, workload, and revenue shortfalls from previous years. FDA will set and publish fees each year so that total revenues will approximate the levels established in the statute, after those amounts have been adjusted for inflation, workload, and, if required, revenue shortfalls from previous years.

II. What Are the Fees for Applications Submitted in FY 2003?

Table 1 of this document provides fee rates for applications submitted on October 1, 2002, and remaining in effect through September 30, 2003, as previously published (67 FR 70228 at 70229, as amended by 68 FR 1469 and 68 FR 3033).

TABLE 1—FEE TYPES, PERCENT OF PMA FEE, AND FY 2003 FEE RATES

Application Fee Type	Full Fee Amount as a Percent of PMA Fee	FY 2003 Full Fee	FY 2003 Small Business Fee
Premarket Approval (PMA), Product Development Protocol (PDP), Biologic License Application (BLA) (submitted under section 515(c) or (f) of the act (21 U.S.C. 360e(c) or (f)) or section 351 of the Public Health Service Act (the PHS Act) , respectively)	100	\$154,000	\$58,520
Premarket Report (PMR)(submitted under section 515(c)(2) of the act)	100	\$154,000	\$58,520
Panel Track Supplement (submitted under section 515 of the act to an approved PMA, PDP, or PMR that requests a significant change in design or performance of the device, or a new indication for use of the device, and for which clinical data are generally necessary to provide reasonable assurance of safety and effectiveness)	100	\$154,000	\$58,520
Efficacy Supplement (submitted under section 351 of the PHS Act to an approved BLA)	100	\$154,000	\$58,520
180-Day Supplement (submitted under section 515 of the act to an approved PMA, PDP or PMR that is not a panel track supplement and requests a significant change in components, materials, design, specification, software, color additives, or labeling)	21.5	\$33,110	\$12,582