

percent of the full rate for premarket notification submissions (see 21 U.S.C. 379j(e)(2)(C)(i)). The FY 2004 fee rates for all application categories are set out in Table 2 of this document.

TABLE 2.—FEE TYPES, PERCENT OF PMA FEE, AND FY 2004 FEE RATES

Application Fee Type	Full Fee Amount as a Percent of PMA Fee	FY 2004 Full Fee	FY 2004 Small Business Fee
PMA (submitted under section 515(c)(1) or 515(f) of the act or section 351 of the Public Health Service (PHS Act))		\$206,811	\$78,588
PMR (submitted under section 515(c)(2) of the act)	100%	\$206,811	\$78,588
Panel Track Supplement (to an approved PMA 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%	\$206,811	\$78,588
Efficacy Supplement (to an approved premarket application under section 351 of the PHS Act)	100%	\$206,811	\$78,588
180-Day Supplement (to an approved PMA 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%	\$44,464	\$16,896
Real Time Supplement (to an approved PMA or PMR that is not a panel track supplement and requests a minor change to the device, such as a minor change to the design of the device, software, manufacturing, sterilization, or labeling, and for which the applicant has requested and the agency has granted a meeting or similar forum to jointly review and determine the status of the supplement)	7.2%	\$14,890	\$5,658
Premarket Notification (submitted under section 510(k) of the act)	1.42% in aggregate	\$3,480	\$2,784

IV. Adjustment for Excess Collections in Previous Years

Under the provisions of MDUFMA, if the agency collects more fees than were provided for in appropriations in any year, FDA is required to reduce its anticipated fee collections in a subsequent year by that amount (21 U.S.C. 379j(h)(4)). No adjustments under this provision are required for fees assessed in FY 2004. If fees assessed in FY 2004 should inadvertently result in excess collections in FY 2004, then when fees are set for FY 2005 a reduction in fee rates for FY 2005 will be made for any excess collections that may have occurred in FY 2004.

V. Small Business Qualification for Purposes of MDUFMA Fees

Firms with annual gross sales and revenues of \$30 million or less, including gross sales and revenues of all affiliates, partners, and parent firms, may qualify for a fee waiver for their first PMA, and for lower rates for subsequent PMA's, premarket reports, supplements, and premarket notification submissions.

Even if a firm qualified under MDUFMA as a small business in FY 2003, it must obtain a new small business certification and decision number for FY 2004 and for each

subsequent fiscal year. This can be initiated any time after the publication of this notice. For FY 2004, firms that have not received a FY 2004 small business qualification decision number from FDA will not be permitted to submit the reduced small business fees. FDA urges firms to apply for this qualification 60 days before they intend to submit their application and fee.

To qualify, you are required to submit the following:

- Certified copies of your Federal Income Tax Return for the most recent taxable year (2002 or later), including certified copies of the income tax returns of your affiliates, partners, and parent firms.
- A certified list of all parents, partners, and affiliate firms since October 1, 2002.

You can find information for determining if an applicant qualifies for a small business first-time PMA waiver and lower rates for subsequent applications on the FDA Web site at <http://www.fda.gov/oc/mdufma>. At that Web site, under the heading "Guidance Documents," click on the link "Qualifying as a Small Business." This Web site provides detailed instructions and the address for mailing documentation to support qualification as a small business under MDUFMA.

VI. Procedures for Paying Application Fees

Any application or supplement subject to fees under MDUFMA that is received on or after October 1, 2003, through September 30, 2004, is subject to the FY 2004 fee rate. It is the date that the application is received in the reviewing center's document room that determines whether the fee rates for FY 2003 or FY 2004 apply—not the date that FDA receives the payment. FDA must receive the correct fee at the time that an application is submitted, or the application will not be accepted for filing or review.

FDA requests that you follow the steps below before submitting a medical device application subject to a fee. Please pay close attention to these procedures to ensure that FDA links the fee with the correct application. (Note: In no case should the check for the fee be submitted to FDA with the application.)