

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

Application Fee Type	Full Fee Amount as a Percent of PMA Fee	FY 2003 Full Fee	FY 2003 Small Business Fee
Real Time Supplement (submitted under section 515 of the act 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 device design, 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 or an approved PDP)	7.2	\$11,088	\$4,213
Premarket Notification (submitted under section 510(k) of the act)	1.42	\$2,187	\$2,187 <sup>1</sup>

<sup>1</sup> A small business will pay the full (standard) fee of \$2,187 for a premarket notification submitted to FDA during FY 2003. A small business fee, set at 80 percent of the standard 510K fee, will be available beginning FY 2004.

### III. Are All Device Applications and Submissions Subject to Fees?

Premarket applications and submissions not listed in table I are not subject to a MDUFMA user fee. The following are examples of submissions that do not require a MDUFMA fee:

- Any type of investigational device exemption submission made under section 520(g) of the act (21 U.S.C. 360j(g)).
- A request made under section 513(f)(2) of the act (21 U.S.C. 360c(f)(2)) for an evaluation of automatic class III designation (also known as a de novo or risk-based classification).
- A modification to the manufacturing procedures or method of manufacturing submitted as a 30-day notice or as a 135-day supplement if notified by FDA that such a supplement is needed.
- An “express PMA supplement” for a manufacturing facility site change.
- Annual (or other periodic) reports required for an approved PMA.

In addition to the types of submissions described above that are not subject to MDUFMA fees, certain applications are exempt from fees. Exempted applications include:

- Applications submitted under section 520(m) of the act that qualify for a humanitarian device exemption (21 U.S.C. 379j(a)(1)(B)(i)).
- Applications submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only (21 U.S.C. 379j(a)(1)(B)(ii)).
- Applications submitted by a State or U.S. Federal Government entity for a device that is not to be distributed commercially (21 U.S.C. 379j(a)(1)(B)(iii)).
- Premarket notification submissions reviewed by an accredited third party (21 U.S.C. 379j(a)(1)(B)(iv)).
- Applications or supplements whose sole purpose is to support conditions of use in a pediatric population (21 U.S.C. 379j(a)(1)(B)(v)).

• First time PMA/PDP/BLA submissions from small businesses as discussed in section V of this document.

If you are unsure of whether a planned submission will be subject to a MDUFMA user fee, please contact CDRH’s Division of Small Manufacturers, International and Consumer Assistance, on 1–800–638–2041 or 301–443–6597, for assistance.

### IV. Where May I Find Guidance on the Type of Fees Applicable to My Application?

For guidance on which type of fee applies to your application, please see the document entitled “Assessing User Fees: PMA Supplement Definitions, Modular PMA Fees, BLA and Efficacy Supplement Definitions, Bundling Multiple Devices in a Single Application, and Fees for Combination Products: Guidance for Industry and FDA.” You may find a link to this document on FDA’s Web site at: <http://www.fda.gov/oc/mdufma>. At that Web site, under the heading “Guidance Documents” click on the link “Assessing User Fees—PMA Supplements, Modular PMAs, BLAs and Efficacy Supplements, Bundling, and Combination Products.” This guidance will help you determine fees for PMA supplements (panel-track, 180-day, and real-time), modular PMAs, as well as combination products. It also provides information on when bundling multiple devices in a single application would be appropriate.

### V. How Does a Firm Qualify as a Small Business 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 PMAs, premarket reports, and supplements. Such firms may also qualify for lower rates for premarket

notification submissions in FY 2004 and subsequent years.

To qualify, you are required to submit the following:

(1) Certified copies of your Federal Income Tax Return for the most recent taxable year, including certified copies of the income tax returns of your affiliates, partners, and parent firms.

(2) 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. When Do I Submit a Fee for an Application Submitted On or After October 1, 2002, and On or Before the Date of Publication of This Notice?

You must pay a fee for any medical device application subject to a fee that you submitted on or after October 1, 2002 (21 U.S.C. 379j(a)(1)(A)). (Section III of this document addresses applications exempted from fees and procedures related to them.) FDA will issue invoices to all applicants who submitted medical device applications on or after October 1, 2002, and through the date of this notice. FDA will issue those invoices during March and April 2003, and payment will be due within 30 days of issuance date. FDA will include detailed payment instructions with the invoices. Please include the invoice numbers on all payments submitted in response to these invoices.