**ADDRESSES**) written or electronic comments on the draft guidance.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 The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.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Persons with access to the Internet may obtain the draft guidance at http://www.fda.gov/cder/guidance/index.htm, http://www.fda.gov/cber/guidelines.htm, or http://www.fda.gov/cvm/guidance/published.htm.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.*

[FR Doc. 03–4311 Filed 2–20–03; 8:45 am]

**BILLING CODE 4160–01–S**

## 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* 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 |

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[1] |

[1] 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.

**VII. When Do I Submit the Fee for Applications Submitted On or After the Date of Publication of This Notice?**

*A. Payment Options for Firms Submitting Medical Device Applications between Today and March 31, 2003.*

If you submit a medical device application subject to fees on or after the date of publication of this notice, and before April 1, 2003, you may either:

(1) Submit the application without first submitting payment, and pay the fee when an invoice is received; or

(2) Pay the fee at the time the application is submitted.

*B. Payment Requirement for Firms Submitting Medical Device Applications On or After April 1, 2003.*

If you submit a medical device application subject to fees on or after April 1, 2003, you must pay the fee for the application at or before the time the application is submitted. If you have not paid all fees owed, FDA will consider the application incomplete and will not accept it for filing (21 U.S.C. 379j(f)).

**VIII. What Are the Procedures for Paying Application Fees?**

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

*A. Step One—Secure a Payment Identification Number and Medical Device User Fee Cover Sheet From FDA Before Submitting Either the Application or the Payment.*

Log onto the MDUFMA Web site at http://www.fda.gov/oc/mdufma, and under the ''Forms'' heading, click on the link ''User Fee Cover Sheet.'' Complete the Medical Device User Fee Cover Sheet and print a copy. Note the unique Payment Identification Number located in the upper right-hand corner of the printed cover sheet.

*B. Step Two—Fax a Copy of the Printed Cover Sheet With the Payment Identification Number to FDA's Office of Financial Management.*

The FDA facsimile machine phone number to receive this completed Medical Device User Fee Cover Sheet is 301–827–9213. FDA will then enter the information into its accounting system, in order to associate payments with submitters. (Note: Later this year, after the Web site is upgraded, you will be able to transmit the completed form electronically and you will not need to fax a copy to FDA.)

*C. Step Three—Mail a Copy of the Completed Medical Device User Fee Cover Sheet and the Payment for Your Application to the St. Louis Address Specified in Item 3 as Follows:*

1. Make the payment in U.S. currency by check, bank draft, or U.S. postal money order payable to FDA. (The tax identification number of FDA is 53–0196965, should your accounting department need this information.)

2. Please note on your payment your application's unique Payment Identification Number from the upper right-hand corner of your printed Medical Device User Fee Cover Sheet.

3. Mail the payment and a copy of the completed Medical Device User Fee Cover Sheet to: Food and Drug Administration, P.O. Box 956733, St. Louis, MO 63195–6733.

If you prefer to send a check by a courier, the courier may deliver the checks to: US Bank, Attn: Government Lockbox, SL–MOC1GL, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314–418–4821 if you have any questions concerning courier delivery.)

It is helpful if the fee arrives at the bank at least 1 day before the application arrives at FDA. FDA records as the application receipt date the latter of the following:

a. The date the application was received by FDA; or

b. The date US Bank notifies FDA that payment has been received. US Bank is required to notify FDA within 1-working day, using the Payment Identification Number described in section VIII, C.2 of this document.

*D. Step Four—Submit Your Application to FDA With a Copy of the Completed Medical Device User Fee Cover Sheet.*

Please submit your application and a copy of the completed Medical Device User Fee Cover Sheet to one of the following addresses.

1. Medical device applications should be submitted to: Document Mail Center (HFZ–401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850.

2. Biologic applications should be sent to: Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1428.

Dated: February 13, 2003.

**William K. Hubbard,**

*Associate Commissioner for Policy and Planning.*

[FR Doc. 03–4490 Filed 2–21–03; 11:22 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. 03D–0060, 99D–1458, 00D–1538, 00D–1543, 00D–1542, and 00D–1539]**

### Draft Guidance for Industry on ''Part 11, Electronic Records, Electronic Signatures—Scope and Application;'' Availability of Draft Guidance and Withdrawal of Draft Part 11 Guidance Documents and a Compliance Policy Guide

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; availability; withdrawal.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Part 11, Electronic Records; Electronic Signatures—Scope and Application.'' This draft guidance explains FDA's current thinking regarding the requirements and application of part 11 (21 CFR part 11). As an outgrowth of its current good manufacturing practice (CGMP) initiative for human and animal drugs and biologics, FDA is embarking on a re-examination of part 11 as it applies to all FDA regulated products. We may revise provisions of part 11 as a result of that reexamination. The draft guidance explains that while this re-examination is under way, we intend to exercise enforcement discretion with respect to certain part 11 requirements. We are also announcing the withdrawal of Compliance Policy Guide (CPG) 7153.17 and previously published part 11 draft guidance documents on validation, glossary of terms, time stamps, and maintenance of electronic records.

**DATES:** Submit written or electronic comments on the draft guidance by April 28, 2003. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Division of Compliance Policy (HFC–230), Office