

*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. Note: FY 2004 Fee Rates Will be Available on the Cover Sheet Beginning on August 25, 2003.*

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. Be sure you choose the correct application submission date range. (Two choices will be offered from August 25, 2003, until the middle of October 2003. One choice is for applications that will be received on or before September 30, 2003, which will be subject to FY 2003 fee rates. A second choice is for applications that will be received on or after October 1, 2003, which will be subject to FY 2004 fee rates.) After completing data entry, print a copy of the Medical Device User Fee Cover Sheet and note the unique Payment Identification Number located in the upper right-hand corner of the printed cover sheet.

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

Once you are satisfied that the data on the cover sheet is accurate, electronically transmit that data to FDA according to the instructions on the screen. Since electronic transmission is possible beginning on August 25, 2003, it will no longer be necessary to fax a copy of the sheet to FDA. After August 25, 2003, applicants will be required to set up a user account and use passwords to assure data security in the creation and electronic submission of Cover Sheets.

*C. Step Three—Mail Payment and a Copy of the Completed Medical Device User Fee Cover Sheet to the Saint Louis Address Specified Below*

- Make the payment in U. S. currency by check, bank draft, or U.S. Postal money order payable to the Food and Drug Administration. (The tax identification number of the Food and Drug Administration is 53-0196965, should your accounting department need this information.)

- Please write your application's unique Payment Identification Number, from the upper right-hand corner of your completed Medical Device User Fee Cover Sheet, on your check, bank draft, or U.S. Postal money order.

- Mail the payment and a copy of the completed Medical Device User Fee

Cover Sheet to: Food and Drug Administration, P.O. Box 956733, Saint Louis, MO, 63195-6733.

If you prefer to send a check by a courier such as FEDEX or UPS, the courier may deliver the checks to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, Missouri 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 the official application receipt date as the later of the following:

- The date the application was received by FDA.
- 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 previously.

*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:

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

- Biologic applications should be sent to: Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center (HFM-99), suite 200N, 1401 Rockville Pike, Rockville, MD 20852-1448.

Dated: July 29, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 03-19655 Filed 7-31-03; 8:45 am]

**BILLING CODE 4160-01-S**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

#### **Establishment of Prescription Drug User Fee Rates for Fiscal Year 2004**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the rates for prescription drug user fees for fiscal year (FY) 2004. The Federal Food,

and Cosmetic Act (the act), as amended by the Prescription Drug User Fee Amendments of 2002 (PDUFA III), authorizes FDA to collect user fees for certain applications for approval of drug and biological products, on establishments where the products are made, and on such products. Revenue amounts for application fees, establishment fees, and product fees for FY 2004 were established by PDUFA III. Fees for applications, establishments, and products are to be established each year by FDA so that revenues from each category will approximate the levels established in the statute, after those amounts have been first adjusted for inflation and workload. This notice establishes fee rates for FY 2004 for application fees (\$573,500 for an application requiring clinical data, and \$286,750 for an application not requiring clinical data or a supplement requiring clinical data), establishment fees (\$226,800), and product fees (\$36,080). These fees are effective on October 1, 2003, and will remain in effect through September 30, 2004. For applications and supplements that are submitted on or after October 1, 2003, the new fee schedule must be used. Invoices for establishment and product fees for FY 2004 will be issued in August 2003, using the new fee schedule.

#### **FOR FURTHER INFORMATION CONTACT:**

Frank Claunts, Office of Management and Systems (HFA-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4427.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Sections 735 and 736 of the act (21 U.S.C. 379g and h), establish three different kinds of user fees. Fees are assessed on: (1) Certain types of applications and supplements for approval of drug and biological products, (2) certain establishments where such products are made, and (3) certain products (see 21 U.S.C. 379h(a)). When certain conditions are met, FDA may waive or reduce fees (see 21 U.S.C. 379h(d)).

For FY 2003 through FY 2007 revenue amounts for application fees, establishment fees, and product fees are established by PDUFA III (the Prescription Drug User Fee Amendments of 2002, title 5 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002). Revenue amounts established for years after FY 2003 are subject to adjustment for inflation and workload. Fees for applications, establishments, and products are to be established each