

## For Industry

### MDUFMA User Fees Cover Sheet

The Medical Device User Fee Cover Sheet is required for your Medical Device Application Submission. After completing the cover sheet, you will be assigned a unique user fee payment identification number that distinguishes and tracks your fee payment and submission.

#### How to Fill Out the MDUFMA User Fee Cover Sheet On-line:

FDA offers your organization the ability to complete a Medical Device User Fee Cover Sheet online and submit it electronically. To fill out the form online, you need Microsoft Internet Explorer 5.5 or higher or Netscape Navigator 4.7 or higher.

Read the instructions below and then go to [Create MDUFMA User Fee Cover Sheet](#) to fill out the form.

**1. You will register on-line** by providing the following information:

- One of the following: Employer Identification Number (EIN), Dun & Bradstreet Number (DUNS), or Organization Number
- Contact Name
- Company Name
- Address
- City
- State
- Zip Code
- Country
- Telephone
- Fax
- E-mail

EIN numbers are required for U.S. firms, and DUNS numbers are recommended (but optional) for foreign firms. If you have previously registered with the FDA User Fee System for an ADUFA or PDUFA cover sheet, you will have been issued an Organization ID number (Org ID). The Org ID uniquely identifies your organization to the FDA. You will need one of these three numbers to proceed with registration.

**2. Fill out the Medical Device User Fee Cover Sheet.** Please answer a series of questions regarding the type of application being submitted for FDA's review. You

will have the opportunity to view the cover sheet in draft form before submitting it to FDA.

**3. When you are done, click the **SUBMIT** button** to complete the cover sheet submission process. A form will appear with an electronically generated user fee payment identification number that is located in the upper right-hand corner, beginning with the letters MD. This number will assist FDA in tracking your payment and submission for the review process.

## **Submitting Payment**

Please send a printed copy of the completed Cover sheet along with a check, bank draft, or U.S. Postal money order made payable to the Food and Drug Administration for the fee amount due. Remember to include the Payment Identification Number, beginning with 'MD', and the FDA P.O. Box on the enclosed check.

### **Mail payment and cover sheet to:**

US Bank Lock Box  
P.O. Box 956733  
St. Louis, MO 63195-6733

*Note: In no case should payment be submitted with the application.*

### **If checks are to be sent by a courier that requires a street address, the courier can deliver the checks to:**

US Bank  
ATTN: Government Lockbox 956733  
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.*

### **If using a wire transfer, you may send your payment using the following information.**

You are responsible to pay any administrative costs associated with the processing of a wire transfer. Contact your bank or financial institution regarding additional fees. Please note that the review of your applications can not begin until full payment is received.

US Department of Treasury  
TREAS NYC  
33 Liberty Street

New York, NY 10045

FDA Deposit Account Number: 75060099

US Department of Treasury routing/transit number: 021030004

SWIFT Number: FRNYUS33

Please include the user fee payment identification number, beginning with "MD" and ensure that the fee that your bank will charge for the wire transfer is added to your fee payment.

## **Mailing the Application**

Mail application and include a *copy* of the completed Cover sheet as the first page of your application and each copy to:

U.S. Food and Drug Administration  
Center for Devices and Radiological Health  
Document Mail Center – WO66-G609  
10903 New Hampshire Avenue  
Silver Spring, MD 20993-0002

*or*

Food and Drug Administration  
Center for Biologics Evaluation and Research  
1401 Rockville Pike, Suite 200 N  
HFM-99 (Document Control Room)  
Rockville, MD 20852-1448

## **If You Have Problems:**

**If you already submitted an application and/or payment and forgot your user fee payment identification number or are unable to use the online system:**

Contact the FDA User Fees Financial Support Team at 301-796-7200 or via email at [userfees@fda.gov](mailto:userfees@fda.gov).

**If you are unsure whether or not you need to file an application with FDA or are unsure what type of application to file**

Contact: Division of Small Manufacturers, International, and Consumer Assistance (DSMICA)  
FDA Center for Devices and Radiological Health  
1-800-638-2041 or 301-796-7100

Contact: Office of Communication, Training and Manufacturers Assistance FDA

Center for Biologic Evaluation and Research 301-827-2000

- [Create MDUFMA User Fee Cover Sheet](#)

OMB No. 0910-0511  
Form FDA 3601 (01/07)