



**IMPORTANT INFORMATION ON MEDICAL DEVICE USER FEES FOR FY 2008**

**Dear Registered Establishment and Other Stakeholders:**

The United States Food and Drug Administration (U.S. FDA) is announcing the medical device user fee rates and payment procedures for fiscal year (FY) 2008 (October 1, 2007 - September 30, 2008). The Federal Food, Drug, and Cosmetic Act (FD&C), as amended by the Medical Device User Fee Amendments of 2007 ("the 2007 Amendments"), authorizes FDA to collect user fees for certain medical device applications and submissions, for periodic reporting on class III devices, and for the registration of certain establishments.

To avoid any delay in the review of an application or submission, your payment must be received by FDA on or before the time the submission is received by FDA. If you have not paid all fees owed, FDA will consider your submission incomplete and will not accept it for review. If you are a small business, you may qualify for reduced fees, and you may also qualify for a waiver of the fee for your first Premarket Application.

**New — Annual Fee for Establishment Registration**

The 2007 Amendments require certain medical device establishments to pay an annual registration fee. (See **Enclosed Letter - Establishment Registration Fees and Electronic Registration and Listing for Medical Device Establishments**). For fiscal year 2008 (October 1, 2007 - September 30, 2008), the fee for registration of any establishment is:

**FY 2008 Establishment Registration Fee is \$1,706 (U.S.) for each establishment.**

There are no small business fee waivers or reduced fees for establishment registration. If you do not pay a required establishment registration fee, your registration will be considered incomplete and your establishment is deemed to have failed to register in accordance with section 510.

**New — Additional Types of Submissions are Subject to a Fee**

The 2007 Amendments make two additional types of submissions subject to user fees: a **30-day Notice** and a **Request for Classification Information [513(g) Request]**. If you make one of these submissions on or after October 1, 2007, you must pay a fee, as shown in the table on the back of this page.

**New — Annual Fee for Periodic Reporting on a Class III Device**

If you market a class III device that is subject to periodic reporting (e.g., you are required to submit an annual report concerning the device), you must pay an annual fee, as shown in the table on the back of this page.

**All Existing Fees are Reduced beginning FY 2008**

The standard and small business fees that apply in FY 2007 will be significantly reduced beginning October 1, 2007. The new fees are shown in the table on the back of this page.

**The FY 2008 fee rates apply to submissions made on or after October 1, 2007.** If FDA receives *both* your submission *and* your payment before October 1, 2007, you will pay the fee in effect for FY 2007. If FDA receives *either* your application *or* your payment after September 30, 2008, you will have to pay the fee for an FY 2009 submission (fees for FY 2009 will be published in the Federal Register in early August 2008).

If you want to pay the small business fee rate for an application or submission, or you want to receive a waiver of the fee for your first premarket application, you must qualify as a small business *before* you send your submission to FDA. Your gross receipts or sales, including the gross receipts or sales of all of your affiliates, must not exceed \$100 million (and must not exceed \$30 million to qualify for a waiver of the fee for your first Premarket Application). To learn how to qualify as a small business, see FDA's guidance document, FY 2008 Medical Device Small Business Qualification and Certification, available at <http://www.fda.gov/cdrh/mdufma>.

**(See Back)**

## New — Foreign Businesses Can Now Qualify for Small Business Fees

The 2007 Amendments permit a foreign business to qualify as a small business and pay the small business fee without submitting a Federal (U.S.) income tax return. You will have to submit information to FDA, including a Certification from your National Taxing Authority showing that your gross receipts or sales, including the gross receipts or sales of all of your affiliates, do not exceed \$100 million when expressed in U.S. dollars. To learn how a foreign business can qualify as a small business, see FDA's guidance document, FY 2008 Medical Device Small Business Qualification and Certification, available at <http://www.fda.gov/cdrh/mdufma>.

### Fees for Medical Device Application, Submissions, and Periodic Reporting

The 2007 Amendments reduce the standard and small business fees for all applications and submissions that were subject to a fee in FY 2007. For fiscal year 2008 (October 1, 2007 - September 30, 2008), the fees for medical device applications, submissions, and periodic reported are:

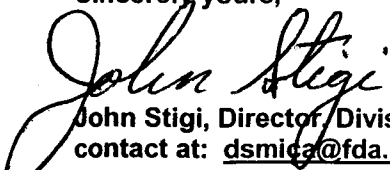
FY 2008 Fees for Medical Device Applications, Submissions, and Periodic Reporting (U.S. Dollars)		
Application	Standard Fee	Small Business Fee
Premarket Application (PMA, PDP, BLA, PMR)	\$185,000	\$46,250
<b>First</b> premarket application from a small business with gross receipts or sales of no more than \$30 million	—	Fee is waived
Panel-track PMA Supplement	\$138,750	\$34,688
BLA Efficacy Supplement	\$185,000	\$46,250
180-day PMA Supplement	\$27,750	\$6,938
Real-time PMA Supplement	\$12,950	\$3,238
Annual Fee for Periodic Reporting on a Class III Device	\$6,475	\$1,619
30-day Notice	\$2,960	\$1,480
510(k) Premarket Notification The 510(k) fee applies to all types of 510(k)s — Traditional, Abbreviated, and Special.	\$3,404	\$1,702
513(g) Request for Classification Information	\$2,498	\$1,249

**Do NOT send payment to FDA with your application.** Additional information, including instructions on how and where to send payment and how to qualify as a small business, is available at: <http://www.fda.gov/cdrh/mdufma>.

The Division of Small Manufacturers, International and Consumer Assistance (DSMICA) can answer questions concerning the new law and help you find guidance documents and other reference materials. DSMICA can be contacted by phone at 800-638-2041 or 240-276-3150 or by email at [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov). Questions regarding products regulated by the Center for Biologics Evaluation and Research should be directed to the Office of Communication, Training and Manufacturers Assistance (OCTMA). OCTMA can be contacted by phone at (301) 827-2000 or (800) 835-4709 or by email at [matt@cber.fda.gov](mailto:matt@cber.fda.gov)

Additional information regarding medical device user fees is available at: <http://www.fda.gov/cdrh/mdufma>.

Sincerely yours,



John Stigi, Director, Division of Small Manufacturers, International and Consumer Assistance, please contact at: [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov).



## **Establishment Registration Fees and Electronic Registration and Listing for Medical Device Establishments**

**To: Official Correspondents of medical device establishments**

**Effective October 1, 2007, FDA will require:**

- **A user fee to be paid for certain types of establishment registrations and**
- **Electronic registration of medical device establishments and the listings produced or processed by these establishments.**

The following questions and answers provide additional information about electronic registration and listing and other changes to the program

### **1. What are the changes in the annual registration process?**

1. All establishments must register and list electronically.
2. The period for annual registration will be from October 1<sup>st</sup> to December 31<sup>st</sup> of each year. Establishments will list at the same time they complete their annual registration requirements.
3. There is now a fee for annual registration for certain types of establishments. See the section, "Who is required to pay the establishment fee?" Your registration is not complete until we notify you that all requirements have been met.

### **2. Who must complete a 2008 annual registration?**

All firms that are currently registered must complete an annual registration. In addition, all contract manufacturers and contract sterilizers (establishments that sterilize or otherwise make a device for a specification developer or any other person) must also now register each year.

### **3. When do I complete the 2008 annual registration?**

All 2008 annual registrations must be completed electronically between October 1, 2007 and December 31, 2007.

### **4. Who is required to pay the establishment registration fee?**

The following types of establishments are required to pay the establishment registration fee:

- Device manufacturers
- Contract sterilizers (establishments that sterilize a device for a specification developer or any other person)

- Contract manufacturers (establishments that make a device for a specification developer or any other person)
- Single-use device reproducers
- Specification developers

## **5. What is the establishment registration fee for fiscal year 2008?**

The establishment registration fee for fiscal year 2008 is \$1,706.

## **6. How do I submit my registration for 2008 electronically?**

There are five basic steps for submitting your 2008 registration electronically:

1. You will be sent an account ID and password/PIN via email.
2. Use the account ID and password to log on to our site at:  
<https://www.access.fda.gov/oa/>
3. Review the registration information for your establishment and make any updates.
4. Review your listing information (if you are required to list your devices) and make updates. See “How do I submit my Listing information?”
5. Submit payment if you are required to do so.

Online help will be available for each of the steps listed above.

## **7. How do I submit payment for the annual establishment registration fee?**

Follow the instructions on the screen to make your payment. Be sure to allow for enough time for your payment to be received and recorded. This process can take up to two weeks. Your registration is not complete until FDA notifies you that all requirements have been met. That notification will be sent to you via email.

## **8. When is my registration for 2008 completed?**

Your registration is complete when you have entered the information electronically at our site, have paid the establishment registration fee (if you are required to do so), and have received notification from us that all requirements have been met. That notification will be sent to you via email.

## **9. Will my current registration and listing data be moved to the new electronic system?**

Yes. All of the registration and listing information that we have on file for your establishment and your products will be moved to the new system. You may, however, be required to update certain product information when you first log into the electronic system.

## **10. Who is required to list their devices?**

All firms, with one exception, that are currently required to register must also list their devices at the time of the annual registration. Initial Importers are required to register annually, but are not required to list. In addition, contract manufacturers and contract sterilizers (establishments that sterilize or otherwise make a device for a specification developer or any other person) must also now list at the time of their annual registration.

## **11. How do I submit my Listing information?**

Listing information is submitted at the same time as your annual registration information.

1. Complete the electronic annual establishment registration.
2. Review the listings currently on record for your establishment.
3. Make updates as needed.
4. You may include multiple proprietary names for a given listing if applicable.
5. For each listing, you will need to identify whether your product requires premarket notification/approval or is exempt.

If your product requires premarket notification/approval you will:

- a. Enter the premarket submission number
- b. Enter the proprietary names
- c. Identify the activities that you perform on or to the products

If your product is exempt you will:

- a. Identify the product code(s)
- b. Enter the proprietary names
- c. Identify the activities that you perform on or to the products

## **12. When will I be able to update my listing information?**

You will be able to update your listings using the electronic system at any time, including when a new device is being produced or if there is a change to a device already listed.

## **13. Are there any reductions in fees for small businesses or other groups?**

No, all establishments who are required to pay have the same establishment registration user fee.

**14. I do not have access to the Internet. How can I submit my annual registration and listing?**

The law requires that all registration and listings be submitted electronically unless FDA grants you a waiver “because electronic registration and listing is not reasonable for the person requesting such waiver”. To apply for a waiver, please submit your request with a complete explanation of why you cannot submit your registration through the Internet to:

Food and Drug Administration  
Center for Devices and Radiological Health, HFZ-308  
9200 Corporate Boulevard  
Rockville, MD 20850-4015

**15. Where can I get assistance if I have any questions?**

For assistance you may contact us at:

Email: [device.reg@fda.hhs.gov](mailto:device.reg@fda.hhs.gov)  
Phone: 240-276-0110

Or

You may also contact the Division of Small Manufacturers, International and Consumer Assistance at:

Email: [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov)  
Phone: 240-276-3150 or 800-638-2041