

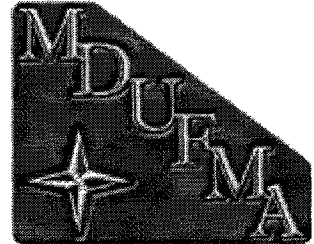
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Medical Device User Fees Have Been Reauthorized for Fiscal Years 2008 - 2012



(September 28, 2007)

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation — the Medical Device User Fee Amendments of 2007 — is part of a larger bill — the Food and Drug Administration Amendments Act of 2007 (H.R. 3850) — that affects many other FDA programs.

FDA will provide additional information concerning the 2007 Amendments during the coming weeks. Please check this site periodically to learn more. Here are some of the key changes you should be aware of —

- The 2007 Amendments substantially reduce all existing application fees, while providing for new types of medical device user fees.
- The new user fees are for:
 - Submission of a 30-day notice.
 - Submission of a 513(g) request for classification information.
 - An annual fee for periodic reporting on a class III device.
 - An annual fee for the registration of a medical device establishment that is a manufacturer, a single-use device reprocessor, or a specification developer.
- All medical device establishments must now register and list by electronic means (through the Internet). Your annual registration and listing will now take place from October 1 through December 31 of each year.

All Existing Fees are Reduced for FY 2008

All existing application fees will be substantially reduced for FY 2008, and small business discounts are even more generous:

How Will the 2007 Amendments Affect Existing Fees?			
	Existing Fees for FY 2007	New Fees for FY 2008	Percentage Reduction from FY 2007 to FY 2008

Application Type	Standard Fee	Small Business	Standard Fee	Small Business	Standard Fee	Small Business
Premarket Application (PMA, PDP, PMR, BLA)	\$ 281,600	\$ 107,008	\$ 185,000	\$ 46,250	-34%	-57%
Panel-track PMA Supplement	\$ 281,600	\$ 107,008	\$ 138,750	\$ 34,688	-51%	-68%
BLA Efficacy Supplement	\$ 281,600	\$ 107,008	\$ 185,000	\$ 46,250	-34%	-57%
180-day PMA Supplement	\$ 60,544	\$ 23,007	\$ 27,750	\$ 6,938	-54%	-70%
Real-time PMA Supplement	\$ 20,275	\$ 7,705	\$ 12,950	\$ 3,237	-36%	-58%
510(k) Premarket Notification	\$ 4,158	\$ 3,326	\$ 3,404	\$ 1,702	-18%	-49%

New Fees for FY 2008

In conjunction with substantially reducing existing application fees, the 2007 Amendments provide for new types of medical device user fees —

- A fee for each 30-day notice submitted to FDA. A 30-day notice is a notice under section 515(d)(6) of the FD&C Act that is limited to a request to make modifications to manufacturing procedures or methods of manufacture affecting the safety and effectiveness of a device.
- A fee for each 513(g) request for classification information submitted to FDA. This is a request made under section 513(g) of the FD&C Act for information respecting the class in which a device has been classified or the requirements applicable to a device.
- An annual fee for periodic reporting made under a condition of approval of a class III device. This is an annual fee associated with periodic reports required by a premarket application approval order.
- An annual fee for the registration of each medical device establishment. An establishment that is required to register under section 510 of the FD&C Act must pay this annual fee if it is one of the following —
 - A manufacturer. — An establishment that makes by any means any article that is a device, including an establishment that sterilizes or otherwise makes such article for or on behalf of a specification developer or any other person.
 - A single-use device reprocessor. — An establishment that performs manufacturing operations on a single-use device that has previously been used on a patient.
 - A specification developer. — An establishment that develops specifications for a device that is distributed under the establishment’s name but which performs no manufacturing, including an establishment that, in addition to developing specifications, also arranges for the manufacturing of devices labeled with another establishment’s name by a contract manufacturer.

There is no discounted small business fee; every establishment that is required to pay the annual registration fee will pay the same fee.

The new fees for FY 2008 are summarized in the following table:

New Types of Fees
FY 2008

Application Type	Standard Fee	Small Business
30-day Notice	\$ 2,960	\$ 1,480
513(g) Request	\$ 2,498	\$ 1,249
Periodic Reporting on a Class III Device	\$ 6,475	\$ 1,619
Establishment Registration	\$1,706	

Guidance on How to Qualify as a “Small Business” for FY 2008 Will Be Available As Soon as Possible

As soon as possible, FDA intends to provide updated guidance on how your business can qualify as a “small business” for FY 2008. The new guidance will be announced on this web page as soon as it is available. If you qualify as a small business for FY 2008, you will be able to pay any FY 2008 fee as the discounted small business rate. You may also be able to receive a waiver of the fee for your first (ever) premarket application (premarket approval application, biologics license application, product development protocol, or premarket report).

Foreign Businesses Can Now Qualify as a “Small Business”

The 2007 Amendments provide a means for a foreign business to qualify as a “small business,” even if it cannot provide a Federal (U.S.) income tax return. The foreign business will have to provide certain information to FDA, including a “National Taxing Authority Certification” from the local equivalent of the U.S. Internal Revenue Service. As soon as possible, FDA intends to provide updated guidance on how your business can qualify as a “small business” for FY 2008. The new guidance will be announced on this web page as soon as it is available.

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Application Type	Standard Fee	Small Business Fee
30-day Notice	\$ 2,980	\$ 1,480
213(g) Request	\$ 2,488	\$ 1,248
Periodic Reporting on Class II Devices	\$ 8,418	\$ 4,818
Establishment Registration	\$ 1,705	

Guidance on How to Qualify as a "Small Business" for FY 2008 Will Be Available As Soon as Possible

As soon as possible, FDA intends to provide updated guidance on how your business can qualify as a "small business" for FY 2008. The new guidance will be discussed on this web page as soon as it is available. If you qualify as a small business for FY 2008, you will be able to pay any FY 2008 fee as the equivalent small business rate. You may also be able to receive a waiver of the fee for your first (and) subsequent application (premarket approval) application. Clinical data, application, product development protocol, or premarket report.

Foreign Businesses Can Now Qualify as a "Small Business"

The 2007 Amendments provide a means for a foreign business to qualify as a "small business" even if it cannot provide a Federal (U.S.) income tax return. The foreign business will have to provide certain information to FDA, including a "National Taxing Authority" notification from the local equivalent of the U.S. Internal Revenue Service. As soon as possible, FDA intends to provide updated guidance on how your business can qualify as a "small business" for FY 2008. The new guidance will be discussed on this web page as soon as it is available.

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Division of Regulatory Affairs, Center for Devices and Radiological Controls
U.S. Food and Drug Administration, 1085 Lincoln Blvd., Silver Spring, MD 20910
Phone: (301) 796-8400, Fax: (301) 796-8401, Email: oc@fda.gov