IMPORTANT INFORMATION ON THE MEDICAL DEVICE USER FEE RATES FOR FY 2009
August 2008

Dear Registered Establishment:

The United States Food and Drug Administration (US FDA) is publishing the fee rates and payment procedures for medical device user fees for fiscal year 2009 (October 1, 2008-September 30, 2009). 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. These fees apply to Premarket Approvals (PMAs), Product Development Protocols (PDPs), Premarket Reports (PMRs), Biologics Licensing Applications (BLAs for certain medical devices reviewed by FDA's Center for Biologics Evaluation and Research), some supplements, and Premarket Notifications [510(k)s]. In addition, the 2007 Amendments authorize FDA to collect fees for 30-day notices, requests for classification information (513g), and annual fees for periodic reporting on class III medical devices and for the registration of certain medical device establishments.

Payment for your submission must be received on or before the time you send your submission to FDA; the annual establishment registration fee must be paid between October 1, 2008 and December 31, 2008. If an applicant has not paid all fees owed, FDA will consider the application incomplete and will not accept it for filing or review. Small businesses may qualify for a waiver or a reduced fee on certain submissions to FDA.

Fees for Establishment Registration

There are no reduced fees for small business establishment registration; every establishment pays the same fee.

An owner or operator must register within 30 days after entering into an operation defined in 21 CFR 807.20. The 2007 Amendments changed section 510(p) of the act to require electronic submission of registration and listing information. This includes both the initial registration and annual registration. You will list your medical devices at the same time, but there is no fee for device listing. Please see enclosed letter that addresses who is subject to a fee for registration. For fiscal year 2009 (October 1, 2008 through September 30, 2009), the registration fee for each establishment that performs the types of activities which require payment is:

FY 2009 Establishment Registration Fee is $1,851 U.S. Dollars

Again, there are no reduced fees for small business establishment registration; every establishment pays the same fee.

Small Businesses; Fee Waiver and Fee Reduction regarding certain Medical Device Applications

In an effort to reduce the burden on small businesses, FDA provides a reduced rate for firms that meet the definition of a small business. The definition of a small business has not changed since 2006, i.e. $100 million or less in gross receipts or sales, including that of all affiliates. Small firms with gross receipts or sales of $30 million or less are eligible to have the fee on their first PMA waived. Firms based in the U.S. and firms based outside the U.S. may apply to FDA to qualify for a small business fee reduction.

Fees for Review of Premarket Notification [510(k)s] and Response to Request for Classification Information [513g]

For fiscal year 2009 (October 1, 2008 through September 30, 2009), the fee for 510(k) review and 513(g) response are the following.

FY 2009 Device Review User Fees (U.S. Dollars)		
Application	**Standard Fee**	**Small Business (≤$100 million in gross receipts or sales) Fee**
510(k)	$3,693	$1,847
513(g)	$2,710	$1,355

All types of 510(k)s — Traditional, Abbreviated, and Special — are subject to the fee, but there is no fee for a 510(k) initially reviewed by an FDA-accredited third-party.

The FY2009 fees apply to applications received on or after October 1, 2008. If *both* the application *and* payment are received prior to October 1, 2008, you should pay the FY 2008 fee.

(See Back Page)

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/devadvice/314a.html.

Fees for Review of Premarket Applications

For fiscal year 2009 (October 1, 2008 through September 30, 2009), the fees for these applications are:

FY 2009 Device Review User Fees (U.S. Dollars)		
Application	**Standard Fee**	**Small Business Fee**
Premarket Application (PMA, PDP, BLA, PMR)	$200,725	$50,181
First premarket application from firms with gross receipts or sales ≤ $30 million	Not Applicable	Fee is Waived
Panel-track Supplement	$150,544	$37,636
Efficacy Supplement (for BLA)	$200,725	$50,181
180-day Supplement	$30,109	$7,527
Real-time Supplement	$14,051	$3,513
30-day Notice	$3,212	$1,606
FY 2009 Annual Fee for Periodic Reporting on a Class III Device (U.S. Dollars)		
	Standard Fee	**Small Business Fee**
Annual fee for periodic reporting on a class III device	$7,025	$1,756

The FY2009 fees apply to applications received on or after October 1, 2008. If the application and payment are received prior to October 1, 2008, applicants should pay the FY 2008 fee.

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/devadvice/pma/userfees.html

Fees for FY 2010 and subsequent years will be published in the *Federal Register* 60 days before the start of each fiscal year.

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. 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

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

Sincerely yours,

John F. Stigi
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Center for Devices and Radiological Health
U.S. Food and Drug Administration