DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

IMPORTANT INFORMATION ON THE MEDICAL DEVICE USER FEE RATES FOR 2005

AUGUST 2004

Dear Registered Establishment:

On October 26, 2002 the Medical Device User Fee and Modernization Act (MDUFMA) of 2002 became law. It authorizes the Food and Drug Administration (FDA) to charge a fee for certain medical device product reviews. 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].

The fee must be paid for the above listed applications, unless the applicant is eligible for a waiver or exemption. Small businesses may qualify for a waiver or a reduced fee. Payment must be received on or before the time the application is submitted. If the applicant has not paid all fees owed, FDA will consider the application incomplete and will not accept it for filing

Fees for Premarket Notification (510(k)s)

For fiscal year 2005 (October 1, 2004 through September 30, 2005), the fee for 510(k) review is the following.

FY 2005 Device Review User Fees (U.S. Dollars)		
Application	**Standard Fee**	**Small Business Fee**
510(k)	$3,502	$2,802

The FY2005 fees apply to applications received on or after October 1, 2004. If the application and payment are received prior to October 1, 2004, applicants should pay the FY 04 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/314a.html

This application fee applies to all 510(k)'s including Traditional, Abbreviated, and Special 510(k)s.

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Fees for Premarket Approvals

For fiscal year 2005 (October 1, 2004 through September 30, 2005), the fees for these applications are:

FY 2005 Device Review User Fees (U.S. Dollars)		
Application	**Standard Fee**	**Small Business Fee**
Premarket Application (PMA, PDP, BLA)	$239,237	$90,910
Premarket Report (premarket approval application for a reprocessed device)	$239,237	$90,910
First premarket application *by a small business*	Not applicable	Fee is waived
Panel-track Supplement	$239,237	$90,910
Efficacy Supplement (for BLA)	$239,237	$90,910
180-day Supplement	$51,436	$19,546
Real-time Supplement	$17,225	$6,546

The FY2005 fees apply to applications received on or after October 1, 2004. If the application and payment are received prior to October 1, 2004, applicants should pay the FY 04 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 2006 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 301-443-6597 or by email at DSMICA@CDRH.FDA.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 FY05 User Fees is available at: http://www.fda.gov/OHRMS/DOCKETS/98fr/04-17440.htm, while additional information about the Medical Device User Fee and Modernization Act is available at: http://www.fda.gov/cdrh/mdufma/index.html.

Sincerely yours,

John F. Stigi

John F. Stigi
Director
Division of Small Manufacturers, International and Consumer Assistance
Office of Communication, Education and Radiation Programs
Center for Devices and Radiological Health