Important Information on the Medical Device User Fee Rates for FY2012 (Updated)

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[1]**(October 1, 2011 through September 30, 2012)**

Greetings Registered Establishment:

This letter is to notify you of the fiscal year 2012, (October 1, 2011-September 30, 2012), fee rates and payment procedures for medical device user fees payable to the United States Food and Drug Administration, (US FDA). This information was also announced in the Federal Register notice published on August 1, 2011 and is available at: http://www.gpo.gov/fdsys/pkg/FR-2011-08-01/html/2011-19335.htm [2].

The Federal Food, Drug, and Cosmetic Act, (FD&C Act), as amended by the Medical Device User Fee Amendments of 2007, ("the 2007 Amendments"), authorizes the FDA to collect user fees for certain medical device applications. 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 [CBER]); some PMA, PDP and BLA supplements; and Premarket Notifications, [510(k)s]. Additionally, the 2007 Amendments authorize the FDA to collect fees for 30-day notices; requests for information regarding classification [513(g)s]; and annual fees for periodic reporting on class III medical devices and for the registration of certain medical device establishments. The information regarding who must register, list and pay the fee is available at: Device Advice - Who Must Register, List and Pay the Fee [3].

If you plan to send a submission to the FDA, payment must be received *on or before* the date you send it. 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.

FY 2012 Fees for Establishment Registration

The annual establishment registration fee must be paid between October 1, 2011 and December 31, 2011. For fiscal year 2012, the registration fee for each

establishment is $2,029 US Dollars. There are no waivers or fee reductions for small business establishment registration. Every establishment pays the same fee. Note the exception for CBER licensed biologic devices, in which invoices are sent by FDA after December 31 of each year per CBER's standard operating procedure (SOPP 8704: Managing MDUFA User Fee Payments and Billing Activities [4]).

The 2007 Amendments changed section 510(p) of the act to require electronic [5] 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. For assistance with registration and listing, please go to the CDRH website on Device Registration and Listing [6].

FY 2012 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 or BLA waived. Both U.S. firms and firms based outside the U.S. may apply to FDA to qualify for a small business fee reduction.

For further information about qualifying as a small business, please go the CDRH Website on Medical Device User Fee and Modernization Act [7]. From the user fee page, please select "FY 2012 Medical Device Small Business Qualification and Certification" for instructions.

FY 2012 Application Fees

The FY2012 fees apply to applications received on or after October 1, 2011. If *both* the application *and* payment are received prior to October 1, 2011, you should pay the FY 2011 fee. When submitting an application, do NOT send payment to FDA with your application. Instructions regarding how and where to send payment and how to qualify as a small business, are available on "MDUFMA Fee Page [8]."

FY 2012 Fees for Review of Premarket Notification Submissions [510(k)s] and Requests for Information Regarding Classification [513(g)s]

FY 2012 Device Review User Fees (U.S. Dollars)		
Submission	Standard Fee	Small Business (≤$100 million in gross receipts or sales) Fee
510(k)	$4,049	$2,024
513(g)	$2,971	$1,485

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

FY 2012 Fees for Review of Premarket Applications

FY 2012 Device Review User Fees (U.S. Dollars)		
Submission	Standard Fee	Small Business Fee
Premarket Application (PMA, PDP, BLA, PMR)	$220,050	$55,013
First premarket application from firms with gross receipts or sales ≤ $30 million	Not Applicable	Fee is Waived
Panel-track Supplement	$165,038	$41,259
Efficacy Supplement (for BLA)	$220,050	$55,013
180-day Supplement	$33,008	$8,252
Real-time Supplement	$15,404	$3,851
Annual Report	$7,702	$1,925
30-day Notice	$3,521	$1,760

Fees for FY 2013 will be published in the *Federal Register* 60 days before the start of the fiscal year.

The Division of Small Manufacturers, International, and Consumer Assistance (DSMICA) [9] can answer questions about user fees, regulatory requirements, and help you find guidance documents. DSMICA can be contacted by phone at 800-638-2041 or 301-796-7100 or by email at DSMICA@FDA.HHS.GOV [10]. Questions regarding products regulated by the Center for Biologics Evaluation and Research (CBER) should be directed to the Office of Communication, Outreach and Development (OCOD), Manufacturers Assistance and Technical Training (MATT) Branch. CBER MATT can be contacted by phone at (800) 835-4709 or (301) 827-1800 or by email at industry.biologics@fda.gov

Further information regarding medical device user fees is available at the CDRH MDUFMA web page [7].

Sincerely yours,

Elias Mallis
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Office of Communication, Education and Radiation Programs
Center for Devices and Radiological Health

U.S. Food and Drug Administration

SOURCE [11]

SOURCE [12]

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http://www.mdtmag.com/news/2011/08/important-information-medical-device-user-fee-rates-fy2012-updated

Links:
[1] http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/UCM266889.pdf
[2] http://www.gpo.gov/fdsys/pkg/FR-2011-08-01/html/2011-19335.htm
[3] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm
[4] http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm073018.htm
[5] http://www.ecnmag.com/News/Feeds/2011/08/applications-medical-electronics-important-information-on-the-medical-device-user-f/searchkeyword.aspx?q=electronic&ao=0
[6] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm
[7] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
[8] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109177.htm
[9] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm
[10] mailto://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/DSMICA@FDA.HHS.GOV
[11] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm266885.htm
[12] http://www.ecnmag.com/News/Feeds/2011/08/applications-medical-electronics-important-information-on-the-medical-device-user-f/