Important Information On The Medical Device User Fee Rates for FY 2013

U.S. Food & Drug Administration

Greetings Medical Device Stakeholder:

This letter provides the medical device user fee information, including fee rates and payment procedures, for Fiscal Year (FY) 2013 that runs from Oct. 1, 2012, through Sept. 30, 2013.

Federal law (The Food and Drug Administration Safety and Innovation Act - FDASIA) authorizes the FDA to collect user fees for certain medical device applications (see: http://www.gpo.gov/fdsys/pkg/BILLS-112s3187enr/ pdf/BILLS-112s3187enr.pdf [1]). These user fee requirements, which will be in effect for five years beginning on Oct. 1, 2012, are described in the Medical Device User Fee Amendments of 2012 (MDUFA III), which starts in Section 201 of FDASIA.

The FDA announced the FY 2013 user fees in a July 31 Federal Register notice, which can be found at: http://www.gpo.gov/fdsys/pkg/FR-2012-07-31/pdf/2012-18647.pdf [2].

According to law, the FDA requires u ser fees for the following types of medical device applications:

- premarket approvals applications (PMAs);
- product development protocols (PDPs);
- premarket reports (PMRs);
- original biologics license applications (BLAs for certain medical devices reviewed by FDA's Center for Biologics Evaluation and Research [CBER]);
- some PMA and PDP supplements (e.g., panel-track, 180-day, real-time, 30-day notice);
- BLA efficacy supplements;
- premarket notifications [510(k)s];
- 513(g)s (requests for device classification information); and,
- annual reports for PMAs, PDPs, and PMRs.

The FDA also requires user fees for the registration of all medical device establishments.

Below please find more information regarding the fees for establishment registration, small business waivers, and the user fees for applications for FY 2013.

FY 2013 Fees for Establishment Registration

The annual establishment registration fee must be paid between Oct. 1, 2012 and Dec. 31, 2012. For FY 2013, the registration fee for each establishment is **$2,575** US Dollars. There are no waivers or fee reductions for small businesses. Starting in FY 2013, **all** establishments must pay registration fees, regardless of establishment type or activities conducted.

Please refer to the following resources for information regarding registration:

- FDA letter to medical device establishments regarding registration changes for FY 2013 and summarizing the types of establishments required to register and list: Medical Device Establishment Registration and Listing - Notice of Changes for FY 2013 [3]
- FDA explanation of how to register and list: Device Advice: Device Registration and Listing [4]

FY 2013 Small Businesses; Fee Waiver and Fee Reduction for Certain Medical Device Applications

In an effort to reduce the burden on small businesses, the FDA provides a reduced rate for those businesses that meet the definition of a “small business.” As defined in the FDA Guidance on FY 2013 User Fees (see below), a business qualifies as a small business if it reports gross receipts or sales of no more than $100 million, including receipts and sales from its affiliates.

- For FDA medical device application user fees, small businesses with gross receipts or sales of $30 million or less are eligible for a fee waiver for their **first** PMA, PDP, PMR or BLA. Any business, regardless of location, may apply to the FDA for a small business determination (SBD).

More information on the SBD Program is described in the FDA Guidance “FY 2013 Medical Device User Fee Small Business Qualification and Certification [5].”

FY 2013 User Fees for Applications

The following table identifies the FY 2013 User Fees for Applications.

FY 2013 User Fees (in U.S. Dollars)

application type	standard fee	small business fee (≤ $100 million in gross receipts or sales)
510(k)†	$4,960	$2,480
513(g)	$3,348	$1,674
PMA, PDP, PMR, BLA	$248,000	$62,000
panel-track supplement	$186,000	$46,500
180-day supplement	$37,200	$9,300

real-time supplement	$17,360	$4,340
BLA efficacy supplement	$248,000	$62,000
annual report	$8,680	$2,170
30-day notice	$3,968	$1,984

† Note that all types of 510(k)s (Traditional, Abbreviated, and Special) are subject to the user fee. However, there is no user fee for 510(k)s submitted to the FDA on behalf of an FDA-accredited third-party reviewer.

As noted above, small businesses with gross receipts or sales of $30 million or less are eligible to have the fee waived on their **first** PMA, PDP, PMR or BLA.

The FY 2013 user fees apply to applications received by the FDA on or after Oct.1, 2012. If both your application *and* your payment are received prior to Oct. 1, 2012, you should pay the FY 2012 user fee. When you submit an application, do NOT send payment to the FDA with your application.

If you plan to send an application to the FDA, payment must be received *on or before* the date you send it. If the FDA receives an application without payment previously made in full, it will consider the application incomplete and will not begin its review. As further discussed below, small businesses may qualify for a waiver or reduced fee on certain applications to the FDA.

For More Information

If you have questions regarding user fees, regulatory requirements or other related information, we encourage you to contact the Division of Small Manufacturers, International, and Consumer Assistance (DSMICA) for assistance. DSMICA can be reached by phone at (800) 638-2041 or 301-796-7100 or by e-mail at dsmica@fda.hhs.gov [6].

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 e-mail at industry.biologics@fda.gov [7].

Further information regarding medical device user fees and the implementation of MDUFA III is available at: www.fda.gov/mdufa [8]. On this page, you can also sign up to receive updates each time the FDA updates MDUFA III information. Note that fees for FY 2014 will be published in the Federal Register 60 days before the start of the fiscal year.

Sincerely yours,

Elias Mallis
Director

Division of Small Manufacturers Assistance, International and Consumer Assistance (DSMICA)
Office of Communication, Education and Radiation Programs
Center for Devices and Radiological Health
U.S. Food and Drug Administration

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