FDA Publishes Medical Device User Fees for 2016

On Aug 13, 2015, the FDA issued a new Guidance for Industry, FDA Staff and Foreign Governments listing FY 2016 Medical Device User Fees for Small Business Qualification and Certification. As you will notice in the table below, there is a substantial reduction of user fees for small businesses. The guidance provides instructions for applying for a fee reduction.

Under the user fee system medical device companies must pay fees to the FDA when they register their establishments and list their devices with the agency, before they can market a new medical device in the U.S. These fees help the FDA increase the efficiency of regulatory processes with a goal of reducing the time it takes to bring safe and effective medical devices to the U.S. market.

Table 1 – Medical Device User Fees for FY 2016

Application Type	Standard	Small Business
Premarket Application (PMA, BLA, PDP)	261,388	65,347
Premarket Report (for a reprocessed single-use device)	261,388	65,347
Panel-Track PMA supplement	196,041	49,010
BLA Efficacy Supplement	261,388	65,347
180-Day PMA Supplement	39,208	9,802
Real-Time PMA Supplement	18,297	4,574
Premarket Notification (510(k))	5,228	2,614
30-day notice	4,182	2,091
513(g) request for classification information	3,529	1,765
Annual fee for periodic reporting on a class III device	9,149	2,287
Establishment Registration Fee - There is no reduced fee for a small business. If this is the only fee you expect to pay during FY 2016, do not submit an FY 2016 Small Business Qualification and Certification request.		
Type of Fee	**Annual Fee**	
Establishment registration fee	3,845	