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FY 2016 Medical Device User Fees Announced

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On August 3, 2015, the FDA announced the medical device user fee rates and payment procedures for fiscal year ("FY") 2016, which applies from October 1, 2015 through September 30, 2016. The Agency will raise user fee rates by over 4%.

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Inside Medical Devices

Biotech, Food, Drug
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Under the ***Federal Food, Drug, and Cosmetic Act, as amended by the Medical Device User Fee Amendments of 2012 ("MDUFA III")***, FDA is authorized to collect user fees for certain medical device submissions as well as annual fees for periodic reports of class III devices and registration for certain establishments. A qualified applicant may pay a lower "small business" fee; however, there is no reduction in the establishment registration fee for small businesses. FDA's announcement and guidance, "FY 2016 Medical Device User Fee Small Business Qualification and Certification," also issued on August 3, contains information on how to qualify as a small business for the purposes of medical device user fees. Additionally, FDA's announcement includes information concerning the procedures for paying fees.

The fee rate for each submission type is based upon a specified percentage of the standard fee for a premarket application ("PMA"). The following are the FY 2016 standard user fees:

- PMA: $261,388
- Panel-track supplement: $196,041
- 180-day supplement: $39,208
- Real-time supplement: $18,297
- 510(k) premarket notification submission: $5,228
- 30-day notice: $4,182
- 513(g) request for classification information: $3,529
- Annual fee for periodic reporting on a class III device: $9,149
- Annual establishment registration fee: $3,845

According to the Agency's announcement, the fee you must pay is the fee that is in effect on the later of the date that your application is received by the Agency or the date your fee payment is recognized by the U.S. Treasury.

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