Published on *The National Law Review* https://natlawreview.com

FDA FY 2017 Medical Device User Fees Announced

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On July 29, 2016, the ***FDA*** announced the medical device user fee rates and payment procedures for fiscal year ("FY") 2017, which applies from October 1, 2016 through September 30, 2017. The FY 2017 user fees declined from the previous year's rates.

Under the ***Federal Food, Drug, and Cosmetic Act ("FDCA")***, 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.

FDA's announcement describes the procedures to qualify as a small business. If a business has gross receipts or sales of no more than $100 million for the most recent tax year, the business *may* qualify for reduced "small business" fees. However, there is no "small business" reduction in the establishment registration fee. FDA's announcement also includes information concerning the procedures for paying fees.

The fee rate for each submission type and for periodic reporting is based upon a specified percentage of the standard fee for a premarket application ("PMA"). The following are the FY 2017 standard user fees:

- PMA: $234,495
- Panel-track supplement: $175,871
- 180-day supplement: $35,174
- Real-time supplement: $16,415
- 510(k) premarket notification submission: $4,690
- 30-day notice: $3,752
- 513(g) request for classification information: $3,166
- Annual fee for periodic reporting on a class III device: $8,207

- Annual establishment registration fee: $3,382

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.

National Law Review, Volume VI, Number 217