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FDA Announces New Device User Fees with Significant Increases for Some Submissions

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On August 29, 2017, FDA published a *Federal Register* notice with the device user fees for the Agency's Fiscal Year (FY) 2018, which begins on October 1, 2017.[1] Due to statutory increases, inflation adjustments and target revenue adjustments, many of the new user fees are notably higher than in the 2017 FY. In addition, among the user fees announced for the coming year are significant new user fees for de novo requests, which have historically not had associated user fees. At the same time, the percentage discount received by small businesses (i.e., those with less than $100 million in annual revenue) has increased for 510(k) premarket notifications and is now applicable to the newly initiated de novo request fees, leading to a greater benefit for small business designation than in years past. Companies considering submissions over the next year will want to time them carefully and consider applying for small business designation as soon as possible, if applicable.

FDARA Updates to User Fees

The FY 2018 device user fees and small business designation documents were issued following the enactment of the FDA Reauthorization Act (FDARA), which President Trump signed into law August 18, 2017.[2] FDA's first authorization for collection of device user fees came from the Medical Device User Fee Amendments (MDUFA).[3] Every five years, the collection of device user fees are reauthorized and updated. FDARA serves as the fourth iteration of MDUFA. FDARA made several other adjustments to how user fees are calculated, resulting in notably larger fees for the coming year. These modifications include: (1) FDARA required FDA to apply an inflation adjustment calculation of the user fees for every year, including the year immediately following passage of the reauthorization, and (2) FDARA authorized an additional discretionary target revenue adjustment. When combined with a base fee increase (explained immediately below), the result is a 32.5% increase across the board for all application types compared to FY 2017, except for the standard 510(k) fee, which was increased by 125%.[4]

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[1] See "Medical Device User Fee Rates for Fiscal Year 2018" *available at* https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-18378.pdf. The Notice is scheduled to be published in the *Federal Register* on August 29, 2017.

[2] Pub.L. 115-52, see https://www.govtrack.us/congress/bills/115/hr2430/text.

[3] MDUFA was contained in the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).

[4] Note, the small business user fee for 510(k)s increased only 12.6% compared to FY 2017 due to an additional amendment by FDARA. This is discussed in more detail below.

Application Type	Percent of Base Fee
510(k)	3.4%
513(g)	1.35%
De Novo	30%
PMA	100%
Panel Track Supplement	75%
Real-Time Supplement	7%
BLA Efficacy Supplement	100%
PMA Annual Report	3.5%
30-day Notice	1.6%

Per FDARA, the new unadjusted, base user fee amount for FY 2018-2022 will be as follows:

	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Premarket Application	$294,000	$300,000	$310,000	$328,000	$329,000

FY 2018 Medical Device User Fees

While the base fee was set by FDARA, FDA is required to adjust that fee using specific inflation metrics. In addition, FDARA grants FDA a new power to adjust the base fee in order to meet revenue targets set by the FDARA. On August 29, 2017, FDA issued a Federal Register Notice announcing the final user fees determined according to these adjustments. It is worth noting that historically FDA did not generally adjust fees for the year immediately following a reauthorization. Thus, some of the increased fees may come as somewhat of a surprise to some in industry.

The table below, reproduced in part from FDA's Federal Register Notice, provides the 2018 statutory fee (second column), the fees as adjusted based on inflation and revenue targets (fourth column showing final fee) and a comparison to the 2017 fee (final column).

Application Type	FY 2018 Statutory Fee (Base Fees)	FY 2018 Inflation Adjusted Statutory Base Fees	Adjusted FY 2018 Fees to Meet Revenue Targets (Standard Fees)	*FY 2017 Fees*
Full Fee Application	$294,000	$310,058	$310,764	*$234,495*
Small Business	$73,500	$77,514	$77,691	*$58,624*
Panel-Track Supplement	$220,500	$232,543	$233,073	*$175,871*
Small Business	$55,125	$58,136	$58,268	*$43,968*
De Novo Classification Request	$88,200	$93,017	$93,229	*N/A*
Small Business	$22,050	$23,254	$23,307	*N/A*
180-Day Supplements	$44,100	$46,509	$46,615	*$35,174*
Small Business	$11,025	$11,627	$11,654	*$8,794*
Real-Time Supplements	$20,580	$21,704	$21,753	*$16,415*
Small Business	$5,145	$5,426	$5,438	*$4,104*
510(k)s	$9,996	$10,542	$10,566	*$4,690*
Small Business	$2,499	$2,635	$2,642	*$2,345*

Application Type	FY 2018 Statutory Fee (Base Fees)	FY 2018 Inflation Adjusted Statutory Base Fees	Adjusted FY 2018 Fees to Meet Revenue Targets (Standard Fees)	*FY 2017 Fees*
30-Day Notice	$4,704	$4,961	$4,972	*$3,752*
Small Business	$2,352	$2,480	$2,486	*$1,876*
513(g) Request for Classification Information	$3,969	$4,186	$4,195	*$3,166*
Small Business	$1,985	$2,093	$2,098	*$1,583*
Annual Fee for Periodic Reporting	$10,290	$10,852	$10,877	*$8,207*
Small Business	$2,573	$2,713	$2,719	*$2,052*
Establishment Registration	$4,375	$4,614	$4,624	*$3,382*
Total				*N/A*

*Note, FDA issued an email on August 28, 2017, entitled "Important Information on Medical Device User Fees for Fiscal Year 2018 (October 1, 2017 through September 30, 2018)", which listed different standard and small business user fees than what appeared in the Federal Register. We have confirmed that the Federal Register numbers are correct.

New De Novo Request User Fee

One of the key issues discussed as part of the MDUFA IV negotiations was the addition for user fees for de novo requests. The de novo process allows FDA to create a new classification for low to moderate risk devices and simultaneously clear a specific product. Originally, de novo requests could only be filed after a company had pursued the 510(k) pathway and FDA had determined that the product was not substantially equivalent. As a result, there was no separate user fee. However, in 2012, Congress changed the law to allow companies to go directly to the de novo pathway. Since that time, most de novos have been filed without first going through the 510(k) process. Consequently, they have been filed without any user fee. Because there is no user fee, there is also no user fee goal towards which FDA commits to work. In exchange for the newly required de novo fees, FDA has committed to ramp up its de novo review performance over the next five years. Specifically, FDA made the following review commitments:

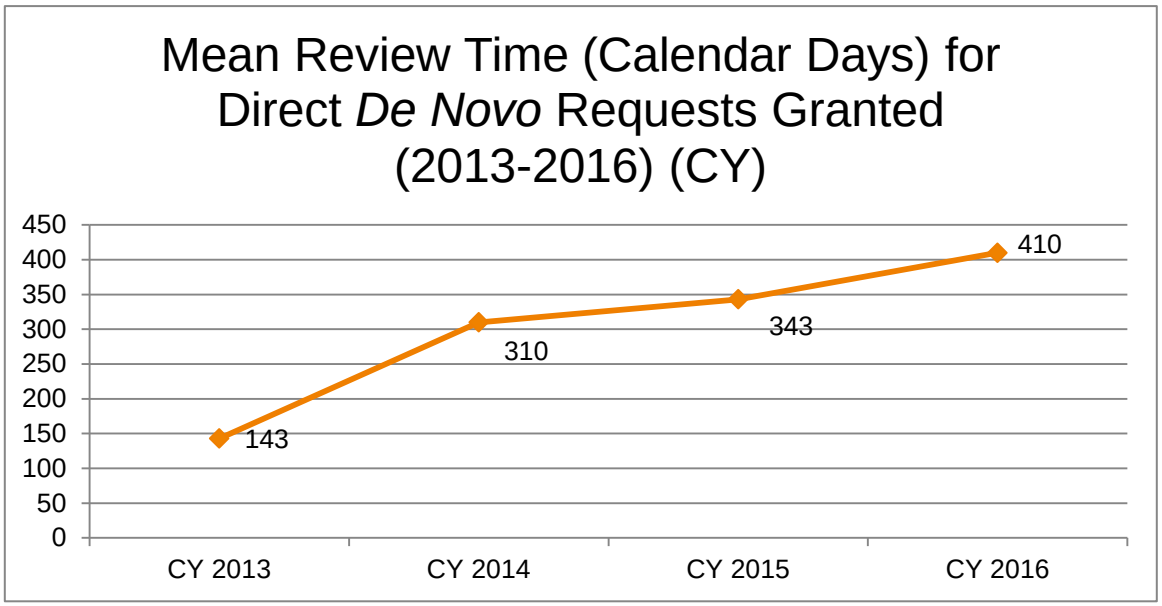
Percent of De Novo Requests to be Issued a MDUFA Decision within 150 FDA Days of Receipt of Submission				
FY2018	FY2019	FY2020	FY2021	FY2022
50%	55%	60%	65%	70%

FDA's goal is to provide a final decision within 150 FDA days for 70% of de novo requests submitted in FY 2022. The compromise acknowledges the burden placed on FDA by the de novo pathway, as well as FDA's inability to meet the statutorily defined review period of 120 days for such submissions.[5]

Although review data is readily available for other types of marketing applications, FDA's reporting requirement for de novo requests under MDUFA III has been inconsistently followed. Per the

[5] FDC Act § 513(f)(2)(A)(iii).

Agency's 2012 Commitment Letter for MDUFA Performance Goals and Procedures,[6] FDA was only required to annually report the number of de novo submissions received and the average number of calendar days to a decision; however the Agency only reported the first of these metrics. Regardless, the average review time for granted de novo requests, derived from the Agency's de novo database, is illustrative. As shown in the table below, the average number of calendar days to a decision date has been steadily increasing.



In addition to setting specific review goals, FDA also agreed to more robust de novo reporting requirements in order to assess the above performance goals.

Small Business Designation

As noted above, FDA has also now released the small business designation request materials for FY2018.[7] Small businesses (i.e., those having gross receipts or sales of no more than $100 million for the most recent tax year) are able to apply for a small business designation and pay only a portion of the assigned user fee. The forms needed to apply for this designation are typically available at least 60 days before the start of the FY because that is the length of time FDA has to issue a decision once the request is received. Since the forms required to be submitted just became available on August 28, 2017, companies are only just now able to start the process for a small business designation. As shown in the table above, the savings associated with small business designation can be quite significant. Note that FDA does not allow companies who receive a small

[6] See https://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf.

[7] See FDA guidance document "FY 2018 Medical Device User Fee Small Business Qualification and Certification" (Aug. 29, 2017) *available at* https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM573375.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery.

business designation after filing a premarket submission to retroactively apply the lower user fee to the already filed submission.

Conclusion

The reauthorization of user fees avoids disruption to FDA's review of premarket submissions. However, industry members may experience some sticker shock given the increase in user fees compared to FY 2017. In light of these increases, companies considering submission in the next few months may ramp up efforts to submit prior to October 1, 2017, when the new fees go into effect. Meanwhile, small businesses who intend to file a submission in beginning of FY 2018 should proceed to apply for their small business designation immediately to avoid any unnecessary delays.

In addition, the new de novo request user fee may be met with mixed support within industry. There has been some discussion that the new fee is too high, especially for smaller companies, and could stifle innovation of low to moderate risk innovative technology. In addition, while the applicant of the de novo request needs to pay the associated fee, all other future devices of the same type will be able to use the de novo device as a predicate and thus, will be eligible for the 510(k) pathway with the associated lower fee. At the same time, the inclusion of a user fee for de novos and the associated review goals may ultimately result in improving the review process for de novo submissions. Given the highly variable review times for this submission type, improvement would be welcome.

Lastly, while this update focuses on the medical device user fee provisions in FDARA, the legislation also includes other topics. Other device related topics covered by FDARA include electronic filings, improvements to the inspection process for device establishments, fostering innovation in medical imaging, and risk-based classification of accessories, as well as various other related topics, several of which will be covered by future updates.

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