4.2 – APPENDIX B: FEES, WAIVERS, AND REDUCTIONS

MDUFA Fee History

MDUFA III established fee rates for PMA and BLA fees and for annual establishment registration fees. The rates for all other fees are statutorily set as a percent of the full PMA fee. The premarket report fee and the efficacy supplement fee are equal to the PMA fee. The panel track supplement fee is 75 percent of the PMA fee. The 180-day supplement fee is 15 percent of the PMA fee. The real-time supplement fee is 7 percent of the PMA fee. The 30-day notice fee is 1.6 percent of the PMA fee. The premarket notification submission (510(k)) fee is 2 percent of the PMA fee. The request for classification information (513(g)) fee is 1.35 percent of the PMA fee, and the fee for periodic reporting concerning class III devices is 3.5 percent of the PMA fee. Qualified small businesses (an entity that reported $100,000,000 or less in gross receipts or sales in its most recent federal income tax return) pay 25 percent of the specified fee, except for 510(k)s, 30-day notices, and requests for classification for which they pay 50 percent of the specified rate. There is no small business rate for annual establishment registrations.[3]

[3] FDA published FY 2016 medical device user fee rates in the *Federal Register* on August 3, 2015 (80 FR 46033) https://www.gpo.gov/fdsys/pkg/FR-2015-08-03/pdf/2015-18907.pdf

Table 10 exhibits the rates for all fee types from FY 2006 through FY 2016.

TABLE 10: TRENDS IN MEDICAL DEVICE USER FEE RATES FOR STANDARD AND SMALL BUSINESS FEES FROM FISCAL YEARS 2006 TO 2016

	Full Fee Application	Panel Track Supplement	180-Day Supplement	Real-Time Supplement	510(k)	30-Day Notice	513(g) Request for Classification Information	Annual Fee for Class III Periodic Report	Annual Establishment Registration
FY 2006	$259,600	$259,600	$55,814	$18,691	$3,833	NA	NA	NA	NA
Small Business	*$98,648*	*$98,648*	*$21,209*	*$7,103*	*$3,066*	*NA*	*NA*	*NA*	*NA*
FY 2007	$281,600	$281,600	$60,544	$20,275	$4,158	NA	NA	NA	NA
Small Business	*$107,008*	*$107,008*	*$23,007*	*$7,705*	*$3,326*	*NA*	*NA*	*NA*	*NA*
FY 2008	$185,000	$138,750	$27,750	$12,950	$3,404	$2,960	$2,498	$6,475	$1,706
Small Business	*$46,250*	*$34,688*	*$6,938*	*$3,237*	*$1,702*	*$1,480*	*$1,249*	*$1,619*	*$1,706*
FY 2009	$200,725	$150,544	$30,109	$14,051	$3,693	$3,212	$2,710	$7,025	$1,851
Small Business	*$50,181*	*$37,636*	*$7,527*	*$3,513*	*$1,847*	*$1,606*	*$1,355*	*$1,756*	*$1,851*
FY 2010	$217,787	$163,340	$32,668	$15,245	$4,007	$3,485	$2,940	$7,623	$2,008
Small Business	*$54,447*	*$40,835*	*$8,167*	*$3,811*	*$2,004*	*$1,742*	*$1,470*	*$1,906*	*$2,008*
FY 2011	$236,298	$177,224	$35,445	$16,541	$4,348	$3,781	$3,190	$8,270	$2,179
Small Business	*$59,075*	*$44,306*	*$8,861*	*$4,135*	*$2,174*	*$1,890*	*$1,595*	*$2,068*	*$2,179*
FY 2012	$220,050	$165,038	$33,008	$15,404	$4,049	$3,521	$2,971	$7,702	$2,029
Small Business	*$55,013*	*$41,259*	*$8,252*	*$3,851*	*$2,024*	*$1,760*	*$1,485*	*$1,925*	*$2,029*
FY 2013	$248,000	$186,000	$37,200	$17,360	$4,960	$3,968	$3,348	$8,680	$2,575
Small Business	*$62,000*	*$46,500*	*$9,300*	*$4,340*	*$2,480*	*$1,984*	*$1,674*	*$2,170*	*$2,575*
FY 2014	$258,520	$193,890	$38,778	$18,096	$5,170	$4,136	$3,490	$9,048	$3,313
Small Business	*$64,630*	*$48,473*	*$9,695*	*$4,524*	*$2,585*	*$2,068*	*$1,745*	*$2,262*	*$3,313*
FY 2015	$250,895	$188,171	$37,634	$17,563	$5,018	$4,014	$3,387	$8,781	$3,646
Small Business	*$62,724*	*$47,043*	*$9,409*	*$4,391*	*$2,509*	*$2,007*	*$1,694*	*$2,195*	*$3,646*
FY 2016	$261,388	$196,041	$39,208	$18,297	$5,228	$4,182	$3,529	$9,149	$3,845
Small Business	*$65,347*	*$49,010*	*$9,802*	*$4,574*	*$2,614*	*$2,091*	*$1,765*	*$2,287*	*$3,845*

Table 11 summarizes the number of applications received by FDA, from FY 2014 through FY 2016, where fees were paid in full before September 30, 2016.

TABLE 11: TRENDS IN MEDICAL DEVICE APPLICATIONS ASSOCIATED WITH USER FEES COLLECTED FROM FY 2014 TO FY 2016

Application Type	FY 2014	FY 2015	FY 2016
Full Fee Applications	25	42	41
Small Business	*5*	*7*	*10*
Panel Track Supplement	12	22	18
Small Business	*3*	*3*	*1*
180-Day Supplements	122	143	139
Small Business	*24*	*15*	*18*
Real-Time Supplements	192	204	202
Small Business	*19*	*28*	*29*
510(k)s	3,034	2,768	2,784
Small Business	*1,037*	*1,037*	*1,046*
30-Day Notice	934	920	1,029
Small Business	*91*	*71*	*80*
513(g) Request for Classification Information	69	75	69
Small Business	*31*	*33*	*47*
Annual Fee for Periodic Reporting	668	554	399
Small Business	*74*	*73*	*53*
Establishment Registration	24,626	25,363	26,222

The quantity of application fees received by FDA should not be used as a surrogate for medical device review workload. Many applications submitted to FDA are not charged fees by FDA, and therefore are not counted in Table 11, for the following reasons:

- first applications (PMAs and BLAs) submitted by small businesses (defined for these purposes as an entity that reported $30,000,000 or less in gross receipts or sales in its most recent federal income tax return);
- applications bundled under one fee because of similar medical device review issues;

- applications solely for pediatric indications;
- applications for original investigational device exemptions (IDEs) and IDE supplements
- PMA supplements other than real-time and 180-day supplements;
- annual report submissions that must be examined;
- applications for HDEs submitted under section 520(m) of the FD&C Act;
- applications submitted under section 351 of the Public Health Service (PHS) Act for a product licensed for further manufacturing use only;
- applications submitted by a state or federal government entity for devices that are not intended for commercial distribution; and
- 510(k)s submitted to certified third-party reviewers, rather than to FDA.

MDUFA Waiver and Reduction History

MDUFA directs FDA to waive the first premarket application fee from a qualified small business and to reduce fees for subsequent applications from qualified small businesses in all categories except the annual establishment registration fee. In addition, MDUFA exempts applications submitted solely for pediatric indications from fees.

Table 12 summarizes the waivers and reductions granted by FDA for MDUFA fees payable in FY 2016, as well as the total value of each. Please note that the waivers and reductions listed below are for cohort year 2016 only.

TABLE 12: FY 2016 SMALL BUSINESS FEE WAIVERS AND REDUCTIONS GRANTED AS OF SEPTEMBER 30, 2016

Category	Number	Amount Reduced Per Fee	Total Value
Full Fees Waived	13	$261,388	$3,398,044
Full Fees Reduced	10	$196,041	$1,960,410
Panel Track Supplements Reduced	1	$147,031	$147,031
180-Day Supplements Reduced	18	$29,406	$529,308
Real-Time Supplements Reduced	29	$13,723	$397,886
510(k)s Fees Reduced	1,046	$2,614	$2,734,020
30-Day Notice Fees Reduced	80	$2,091	$167,337
513(g)s Fees Reduced	47	$1,764	$82,908
Annual Periodic Report Fees Reduced	53	$6,862	$366,554
Total	**1,297**		**$9,783,498**

Numbers have been rounded to the nearest dollar

In FY 2016, FDA waived 13 fees for first-time submissions of PMAs or BLAs, and waived or reduced 1,297 fees.

FDA collected $150,051,730 in fee revenue during FY 2016. Had there been no small-business waivers or reductions, FDA would have collected an additional $9,783,498 (i.e., an additional 6.5 percent of collections).

FDA received 2 HDE applications and 107 supplements in FY 2016 which include 70 30-day notices. None of these are subject to MDUFA fees. FDA does not know if any of these would have been submitted had they been subject to a fee, therefore the extent to which this exemption resulted in any loss of revenue is unknown.

CBER received 4 exemption requests in FY 2016 for applications submitted under section 351 of the PHS Act for a product licensed for further manufacturing use only.

FDA granted exemptions for state or federal government entities for products that were not intended for commercial distribution to 18 510(k)s and 1 30-Day Notice in FY 2016. The total value of these exemptions was $98,286.

FDA granted an exemption for pediatric indications in FY 2016 to 7 510(k)s, 1 30-Day Notice, 3 180-Day Supplements, 2 Real-Time Supplements, and 1 Panel Track Supplement. The total value of these exemptions was $391,037.

FDA received 80 510(k) submissions subject to third-party review in FY 2016 compared to 85 in FY 2015, 84 in FY 2014, 128 in FY 2013, and 175 in FY 2012. The decline in use of the third-party review program is mainly due to the decline in FDA review times. FDA exempted fees for these 80 submissions. The total value of these exemptions in FY 2016 was $418,240, assuming that 27 percent (the same percent of total FY 2016 510(k)s submitted that paid the small business rate) of the third-party submissions would have paid the reduced small business fee.

Table 13 summarizes total waivers, reductions, and exemptions granted from FY 2006 to FY 2016 and the corresponding dollar values.

TABLE 13: TRENDS IN SMALL BUSINESS FEE WAIVERS AND REDUCTIONS GRANTED AS OF SEPTEMBER 30, 2016

Waivers, Reductions, and Exemptions	Value of Each Type of Fee Waiver, Reduction, and Exemption				Total Value of All Fee Waivers, Reductions, and Exemptions
	Small Business	Govt. Sponsored Application Not for Commercial Distribution	Pediatric Indications	510(k)s Subject to Third-Party Review	
FY 2006	$4,274,178	$15,332	$405,254	$996,411	$5,691,175
FY 2007	$3,353,004	$12,474	$359,396	$948,010	$4,672,884
FY 2008	$5,755,408	$34,558	$305,028	$1,225,760	$7,320,754
FY 2009	$7,738,614	$0	$259,709	$963,894	$8,962,217
FY 2010	$8,370,548	$0	$505,002	$831,015	$9,706,565
FY 2011	$7,126,657	$0	$8,696	$691,767	$7,827,120
FY 2012	$8,519,907	$688,493	$248,045	$708,575	$10,165,020
FY 2013	$10,060,368	$54,560	$4,960	$548,080	$10,667,968
FY 2014	$7,351,997	$56,870	$5,170	$378,968	$7,793,005
FY 2015	$6,131,015	$1,896,764	$920,788	$426,530	$9,375,097
FY 2016	$9,783,498	$98,286	$391,037	$418,240	$10,691,061
Total	$83,573,421	$2,864,341	$3,807,724	$8,963,036	$99,208,522

Numbers have been rounded to the nearest dollar