

3.4 – COLLECTIONS REALIZED

Introduction

The following information depicts collections realized by cohort year (the same as Total Collections in Table 1 section 3.1 – User Fee Collections), collection amounts specified in the appropriation acts, and the offset amount taken when fees were set for FY 2017.

Under MDUFA, if cumulative collections for FY 2013 through FY 2015, plus an estimate of collections for FY 2016, exceed the fee revenues specified in appropriation acts during that period, FDA will lower the fee rates to reduce fee revenues for FY 2017 by the cumulative amount that fees exceeded the amounts specified in appropriation acts during that period. An offset of \$14,678,151 was taken when fees were set for FY 2017.²

Data

Previous cohort year collections realized in FY 2016 have been updated from last year's report. The update reflects net collections for each cohort year through September 30, 2016. Cohort year fees collected after September 30, 2016, will be reported in the FY 2017 Financial Report. Other variances between Table 3 and Table 4 are a result of unapplied collections at the end of the fiscal year. These collections will either be applied or refunded during FY 2017.

² FDA published FY 2017 medical device user fee rates in the *Federal Register* on July 29, 2016 (81 FR 49987) <https://www.gpo.gov/fdsys/pkg/FR-2016-07-29/pdf/2016-17903.pdf>

TABLE 4: MEDICAL DEVICE USER FEES COLLECTED, COLLECTION AMOUNTS SPECIFIED IN APPROPRIATION ACTS, AND EXCESS AMOUNTS AS OF SEPTEMBER 30, 2016

Fiscal Year	Collection Amount Specified in Appropriation Acts	Collections Realized	Amount in Excess of Collection Amount Specified in Appropriation Acts
2003	\$25,125,000	\$21,620,549	\$0
2004	\$31,654,000	\$26,281,779	\$0
2005	\$33,938,000	\$31,814,416	\$0
2006	\$40,300,000	\$35,047,878	\$0
2007	\$43,726,000	\$28,715,714	\$0
Total MDUFA I			\$0
2008	\$48,431,000	\$48,770,867	\$339,867
2009	\$52,547,000	\$58,665,328	\$6,118,328
2010	\$57,014,000	\$65,624,239	\$8,610,239
2011	\$61,860,000	\$71,446,026	\$9,586,026
2012	\$57,605,000	\$67,118,096	\$9,513,096
Total MDUFA II			\$34,167,556
2013	\$97,722,000	\$103,990,982	\$6,268,982
2014	\$114,833,000	\$124,306,525	\$9,473,525
2015	\$128,282,000	\$139,308,453	\$11,026,453
2016	\$137,677,000	\$152,612,309	\$14,935,309
Total MDUFA III			\$41,704,270

Numbers have been rounded to the nearest dollar

References

For more detail on collection amounts specified in appropriation acts, refer to section 2 – Legal Conditions.