

3: FINANCIAL INFORMATION

3.1 – USER FEE COLLECTIONS

Introduction

MDUFA specifies that user fees shall be collected for medical device application submissions and annual user fees shall be collected for establishment registration and periodic reporting. The statute also directs FDA to set the fee rate for each application type and for periodic reports as a percentage of the standard fee for a PMA. Under MDUFA, fees collected and appropriated, but not spent by the end of a fiscal year, continue to remain available for FDA to spend in future years.

User fee collections are reported in the year the fee was originally due – referred to as the cohort year. For example, a fee originally due in FY 2015, even if it is received in FY 2016, is attributed to FY 2015 collections. Totals reported for each fiscal year are net of any refunds for the cohort year. To ensure the quality of the information provided in this financial report, FDA annually updates prior year numbers.

Unearned Fees¹ are fees received for applications that had not been submitted to FDA as of September 30, 2016, or for FY 2016 establishment fees received without identification of the remitter.

The receivables for FY 2015 and FY 2016 are from uncollected establishment and periodic reporting fees. After 90 days of attempting to collect the delinquent debt, FDA turns these receivables over to the Program Support Center (PSC), Department of Health and Human Services, for further attempts at collection. After 120 days of the debt being outstanding, PSC will turn the debt over to the United States Treasury for further collection efforts.

Data

Table 1 provides totals of user fees collected during the past 2 fiscal years and reflects the amount of open receivables.

**TABLE 1: MEDICAL DEVICE USER FEE COLLECTIONS AND RECEIVABLES BY FEE SOURCE
AS OF SEPTEMBER 30, 2016**

Fees Collected	FY 2015	FY 2016	Notes
Application Fees	\$47,397,431	\$51,734,600	
Registration Fees	\$91,911,022	\$100,877,708	
Total Collections	\$139,308,453	\$152,612,309	A
Unearned Fees	FY 2015	FY 2016	Notes
Application Fees	\$4,048,001	\$6,881,052	
Registration Fees	\$893,238	\$1,564,829	
Total Unearned	\$4,941,239	\$8,445,881	

¹ “Unearned Fees” are fees received for applications that had not been submitted to FDA as of September 30, 2016, or for FY 2016 establishment fees received without identification of the remitter. The unearned fees are included above in the “Total Fees Collected” amounts.

Fees Receivable	FY 2015	FY 2016	Notes
Application Fees	\$955,047	\$2,667,241	
Registration Fees	\$0	\$0	
Total Receivables	\$955,047	\$2,667,241	

Numbers have been rounded to the nearest dollar

Notes

- A. Because of refunds and transfers, the total fee collections for cohort year 2015 decreased by \$2,333,189 compared to the collections reported in the FY 2015 financial report. Additionally, all but \$4,941,239 of the unearned fee revenue reported in FY 2015 has now been either refunded or credited to the cohort year in which the application was actually received.

References

The balances carried over from year to year are described in section 3.3 - Carryover Balances.

Trending of historical fees paid and rates are provided in section 4.2 - Appendix B.