

3: FINANCIAL INFORMATION

3.1 – USER FEE COLLECTIONS

Introduction

GDUFA specifies that user fees shall be collected for certain pending applications in the backlog as of October 1, 2012 (assessed in FY 2013 only), ANDAs, PASs, DMFs, and FDF and API facilities. The statute also specifies the amount FDA is allowed to collect each fiscal year and how the fee rates should be adjusted in subsequent fiscal 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 the fee 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.

The receivables for FY 2015 and FY 2016 are from uncollected backlog, DMF, application filing, and facility 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 turns 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: HUMAN GENERIC DRUG USER FEE COLLECTIONS AND RECEIVABLES BY FEE SOURCE AS OF SEPTEMBER 30, 2016

Fees Collected	FY 2015	FY 2016	Notes
DMF Fees	\$19,778,180	\$22,297,172	
Application Filing Fees	\$38,442,924	\$74,206,567	
Facility Fees	\$224,788,772	\$219,621,327	
Total Collections	\$283,009,876	\$316,125,066	A
Fees Receivable	FY 2015	FY 2016	Notes
DMF Fees	\$26,720	\$48	
Application Filing Fees	\$58,730	\$442,738	
Facility Fees	\$3,215,269	\$3,322,048	
Total Receivables	\$3,300,719	\$3,764,834	

Numbers have been rounded to the nearest dollar

Notes

- A. FY 2016 total fee collections increased by \$33,115,190 over the previous fiscal year, primarily due to an 87-percent increase in application filing fee collections.

References

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

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