

3: FINANCIAL INFORMATION

3.1 – USER FEE COLLECTIONS

Introduction

ADUFA specifies that user fees shall be collected for certain animal drug applications and supplements upon their submission, and annual fees shall be collected for certain products, establishments, and sponsors. The statute also specifies the amount FDA is allowed to collect for each of these categories, and how the fee rates should be adjusted in each fiscal year for increases in workload. Per the statute, waivers may be granted under certain circumstances (see Appendix B). Under ADUFA, fees collected and appropriated, but not spent by the end of a fiscal year, continue to remain available for FDA to spend in future 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 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 updates prior year numbers annually.

The receivables for FY 2015 and FY 2016 are from uncollected product, establishment, and sponsor 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 by fee type collected during the past 2 fiscal years and reflects the amount of open receivables.

TABLE 1: ANIMAL DRUG USER FEE COHORT COLLECTIONS AND RECEIVABLES BY FEE SOURCE AS OF SEPTEMBER 30, 2016

Fees Collected	FY 2015	FY 2016	Notes
Application Fees	\$6,009,000	\$7,022,000	
Product Fees	\$7,146,338	\$6,006,090	
Establishment Fees	\$5,832,400	\$5,509,400	
Sponsor Fees	\$5,628,396	\$5,958,945	
Total Collections	\$24,616,134	\$24,496,435	A
Fees Receivable			
Product Fees	\$0	\$7,790	
Establishment Fees	\$0	\$105,950	
Sponsor Fees	\$1,103,794	\$1,414,000	
Total Receivables	\$1,103,794	\$1,527,740	

Numbers have been rounded to the nearest dollar

Notes

- A. In FY 2016, FDA received a net total of \$385,171 that was attributed to FY 2015 collections. Therefore, FDA increased its FY 2015 fee collections of \$24,230,963 (reported last year) to \$24,616,134 as of September 30, 2016.

References

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

A further breakdown of fees paid in FY 2016 is provided in section 4.2 Appendix B.