3: FINANCIAL INFORMATION

3.1 – USER FEE COLLECTIONS

Introduction

PDUFA specifies that user fees shall be collected for prescription drug applications and annual fees shall be collected for establishments and products. The statute further specifies how the fees must be calculated each fiscal year, including annual adjustments that must be made for inflation and changes in workload.

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, but 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 years' numbers.

Under PDUFA, 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. However, an offset provision requires that if the sum of PDUFA fees collected for the first three fiscal years and estimated to be collected for the fourth fiscal year exceed the cumulative amount appropriated for the first four fiscal years, the excess must be offset in the fifth fiscal year (i.e., the excess must be subtracted from the amount of fees that FDA would otherwise be authorized to collect for FY 2017). An offset of $124,065,726 was taken when PDUFA fees were set for FY 2017.[1]

FDA issues invoices for product and establishment fees twice a year: in August for fees due on October 1, and in November after the close of the fiscal year for new product and establishment fees not previously assessed.

The receivables for FY 2015 and FY 2016 are from uncollected product and establishment 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 outstanding debt, PSC turns the debt over to the United States Treasury for further collection efforts.

[1] FDA published FY 2017 prescription drug user fee rates in the *Federal Register* on July 28, 2016 (81 FR 49674), https://www.gpo.gov/fdsys/pkg/FR-2016-07-28/pdf/2016-17870.pdf

Data

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

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

Fees Collected	FY 2015	FY 2016	Notes
Application Fees	$297,964,800	$317,846,025	
Establishment Fees	$271,675,336	$273,657,122	
Product Fees	$279,464,685	$265,644,258	
Total Collections	**$849,104,821**	**$857,147,405**	A
Fees Receivable	**FY 2015**	**FY 2016**	**Notes**
Establishment Fees	$758,744	$1,862,916	
Product Fees	$548,475	$1,939,907	
Total Receivables	**$1,307,219**	**$3,802,824**	

Numbers have been rounded to the nearest dollar

Notes

A. In FY 2016, FDA received a net total of $27,177,400 that was attributed to FY 2015 collections. As a result, FDA increased its FY 2015 fee collections from $821,927,421 reported last year to $849,104,821 as of September 30, 2016. The increase in FY 2015 fee revenue was due to the collection of fees associated with the annual “clean up” billing issued after the close of the fiscal year for new product and establishment fees not assessed in August.

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.