

### 3.6 – TOTAL GDUFA PROGRAM COSTS

#### Introduction

There are four organizations that support the GDUFA program: the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), the Office of Regulatory Affairs (ORA), and FDA Headquarters (HQ). The GDUFA program is supported by both user fees and non-user fee appropriations.

#### Data

Table 6 shows the full cost (non-user fee appropriations and user fees) for the GDUFA program during the past 4 fiscal years by FDA organizational components (CDER, CBER, ORA, and HQ). The percentages spent in the various FDA components have remained essentially stable over time, with CDER at approximately 81 percent, ORA at approximately 12 percent, and HQ at approximately 7 percent.

**TABLE 6: GDUFA PROGRAM – HISTORICAL TREND OF TOTAL COSTS BY ORGANIZATION AS OF SEPTEMBER 30 OF EACH FISCAL YEAR**

Fiscal Year	Total Spent	Spent by CDER	CDER %	Spent by CBER	CBER %	Spent by ORA	ORA %	Spent by HQ	HQ %
2013	\$266,884,096	\$215,983,391	81%	\$169,574	0%	\$33,801,677	13%	\$16,929,455	6%
2014	\$387,081,279	\$319,051,167	83%	\$737,326	0%	\$42,406,255	11%	\$24,886,531	6%
2015	\$452,705,318	\$367,926,837	81%	\$547,864	0%	\$57,572,841	13%	\$26,657,776	6%
2016	\$493,951,170	\$398,335,502	81%	\$619,055	0%	\$62,189,458	12%	\$32,807,154	7%

Numbers have been rounded to the nearest dollar

Table 7 provides the total amount spent on the GDUFA program for the last 4 fiscal years, and the dollar amount and percentage derived from fees and non-user fee appropriations. GDUFA fees have continued to increase as a percentage of total GDUFA program spending.

**TABLE 7: GDUFA PROGRAM - HISTORICAL TREND OF TOTAL COSTS BY FUNDING SOURCE AS OF SEPTEMBER 30 OF EACH FISCAL YEAR**

Fiscal Year	Total Spent	Spent from Appropriations	Appropriations Percent	Spent from GDUFA Fees	GDUFA Fee Percent
2013	\$266,884,096	\$145,603,996	55%	\$121,280,100	45%
2014	\$387,081,279	\$160,952,419	42%	\$226,128,860	58%
2015	\$452,705,318	\$120,624,899	27%	\$332,080,419	73%
2016	\$493,951,170	\$120,714,671	24%	\$373,236,499	76%

Numbers have been rounded to the nearest dollar

#### References

An expense category breakout of the FY 2015 and FY 2016 dollar amounts spent from GDUFA fees is provided in Table 2 in section 3.2 – User Fee Obligations.

The development of the costs associated with the GDUFA program is described in more detail in section 4.4 – Appendix D.