

### 3.6 – TOTAL PDUFA PROGRAM COSTS

#### Introduction

There are four organizations that support the PDUFA 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 PDUFA program is supported by user fee and non-user fee appropriations.

#### Data

Table 7 shows the costs (non-user fee appropriations and user fees) for the PDUFA program during the past 10 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 69 percent, CBER at approximately 20 percent, ORA at approximately 3 percent, and HQ at approximately 8 percent.

**TABLE 7: PDUFA 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 %
2007	\$575,005,992	\$385,939,977	67%	\$122,871,873	21%	\$25,860,072	5%	\$40,334,070	7%
2008	\$713,900,390	\$493,748,819	69%	\$145,080,623	20%	\$27,811,039	4%	\$47,259,909	7%
2009	\$855,426,294	\$585,414,578	68%	\$170,363,705	20%	\$36,509,080	4%	\$63,138,931	8%
2010	\$931,845,581	\$640,509,784	69%	\$176,353,112	19%	\$34,968,204	4%	\$80,014,481	8%
2011	\$1,025,621,707	\$719,677,685	70%	\$199,895,537	20%	\$37,783,238	4%	\$68,265,247	6%
2012	\$1,032,419,218	\$714,461,517	69%	\$201,589,189	20%	\$37,186,485	4%	\$79,182,027	7%
2013	\$966,169,007	\$661,662,397	68%	\$191,204,309	20%	\$31,508,236	3%	\$81,794,065	9%
2014	\$1,077,263,695	\$732,426,835	68%	\$225,907,603	21%	\$34,166,935	3%	\$84,762,322	8%
2015	\$1,127,664,528	\$779,711,530	69%	\$235,182,801	21%	\$30,716,326	3%	\$82,053,871	7%
2016	\$1,157,817,695	\$801,353,416	69%	\$228,314,238	20%	\$40,513,807	3%	\$87,636,234	8%

Numbers have been rounded to the nearest dollar

Table 8 provides the total amount spent on the PDUFA program for the last 10 years, and the dollar amount and percentages derived from user fee and non-user fee appropriations. The percentage attributable to PDUFA fees has increased over time, but has been essentially stable in recent years.

**TABLE 8: PDUFA 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 PDUFA Fees	PDUFA Fee Percent
2007	\$575,005,992	\$254,576,372	44%	\$320,429,620	56%
2008	\$713,900,390	\$263,113,555	37%	\$450,786,835	63%
2009	\$855,426,294	\$343,374,894	40%	\$512,051,400	60%
2010	\$931,845,581	\$358,587,181	38%	\$573,258,400	62%
2011	\$1,025,621,707	\$397,795,307	39%	\$627,826,400	61%
2012	\$1,032,419,218	\$395,490,417	38%	\$636,928,801	62%
2013	\$966,169,007	\$299,267,407	31%	\$666,901,600	69%
2014	\$1,077,263,695	\$343,539,748	32%	\$733,723,947	68%
2015	\$1,127,664,528	\$331,598,549	29%	\$796,065,980	71%
2016	\$1,157,817,695	\$320,942,599	28%	\$836,875,096	72%

Numbers have been rounded to the nearest dollar

## References

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

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