

### 3.6 – TOTAL MDUFA PROGRAM COSTS

#### Introduction

There are four organizational components that support the MDUFA program: the Center for Devices and Radiological Health (CDRH), the Center for Biologics Evaluation and Research (CBER), the Office of Regulatory Affairs (ORA), and FDA Headquarters (HQ). The MDUFA 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) of the MDUFA program during the past 10 fiscal years by FDA organizational components (CDRH, CBER, ORA, and HQ). The percentages spent in the various FDA components have remained essentially stable over time.

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

Fiscal Year	Total Spent	Spent by CDRH	CDRH %	Spent by CBER	CBER %	Spent by ORA	ORA %	Spent by HQ	HQ %
2007	\$208,333,497	\$159,387,019	77%	\$22,889,470	11%	\$11,511,598	6%	\$14,545,410	7%
2008	\$235,199,599	\$179,941,933	77%	\$26,815,222	11%	\$11,835,564	5%	\$16,606,880	7%
2009	\$270,848,437	\$212,217,413	78%	\$29,121,473	11%	\$10,747,226	4%	\$18,762,325	7%
2010	\$292,707,540	\$224,106,088	77%	\$30,132,907	10%	\$13,893,434	5%	\$24,575,111	8%
2011	\$299,864,531	\$231,004,393	77%	\$33,715,375	11%	\$14,464,887	5%	\$20,679,876	7%
2012	\$320,136,649	\$244,845,422	76%	\$33,818,790	11%	\$15,550,580	5%	\$25,921,857	8%
2013	\$324,367,624	\$249,456,182	77%	\$32,558,370	10%	\$12,891,793	4%	\$29,461,279	9%
2014	\$360,203,389	\$277,908,584	77%	\$37,020,557	10%	\$14,339,241	4%	\$30,935,007	9%
2015	\$377,839,866	\$295,387,061	78%	\$39,812,108	11%	\$13,312,237	4%	\$29,328,460	8%
2016	\$382,410,783	\$301,765,033	79%	\$35,685,878	9%	\$13,640,088	4%	\$31,319,784	8%

Numbers have been rounded to the nearest dollar

Table 7 provides the total amount spent on the MDUFA program for the last 10 years, and the dollar amount and percentages derived from fees and non-user fee appropriations.

**TABLE 7: MDUFA 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 MDUFA Fees	MDUFA Fee Percent
2007	\$208,333,497	\$173,130,797	83%	\$35,202,700	17%
2008	\$235,199,599	\$198,776,699	85%	\$36,422,900	15%
2009	\$270,848,437	\$223,545,693	83%	\$47,302,744	17%
2010	\$292,707,540	\$235,520,440	80%	\$57,187,100	20%
2011	\$299,864,531	\$240,608,031	80%	\$59,256,500	20%
2012	\$320,136,649	\$249,808,499	78%	\$70,328,150	22%
2013	\$324,367,624	\$232,638,224	72%	\$91,729,400	28%
2014	\$360,203,389	\$253,261,667	70%	\$106,941,722	30%
2015	\$377,839,866	\$247,322,622	65%	\$130,517,244	35%
2016	\$382,410,783	\$242,831,997	64%	\$139,578,785	36%

Numbers have been rounded to the nearest dollar.

## References

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

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