

3.4 – COLLECTIONS REALIZED

Introduction

The following information depicts collections realized by cohort year (the same as Total Collections in Table 1, section 3.1 – User Fee Collections), collection amounts specified in the appropriation acts, and offset amounts made when fees for FY 2007 and FY 2012 were set. An offset of \$124,065,726 was taken when fees were set for FY 2017.

Data

Previous cohort-year collections realized in FY 2016 have been updated from last year’s report. The update reflects net collections for each cohort year through September 30, 2016. Cohort year fees collected after September 30, 2016, will be reported in the FY 2017 Financial Report. Other variances between Table 4 and Table 5 are a result of unapplied collections at the end of the fiscal year. These collections will either be applied or refunded during FY 2017.

TABLE 5: PRESCRIPTION DRUG USER FEES COLLECTED, COLLECTION AMOUNTS SPECIFIED IN APPROPRIATION ACTS, AND EXCESS AMOUNTS AS OF SEPTEMBER 30, 2016

Fiscal Year	Collections Realized	Collection Amount Specified in Appropriation Acts	Amount in Excess of Collection Amount Specified in Appropriation Acts	Notes
1998	\$117,849,016	\$117,122,000	\$727,016	
1999	\$125,729,367	\$132,273,000	-	
2000	\$141,134,682	\$145,434,000	-	
2001	\$138,421,429	\$149,273,000	-	
2002	\$141,408,975	\$161,716,000	-	
Total PDUFA II			\$727,016	
2003	\$218,302,684	\$222,900,000	-	
2004	\$258,560,500	\$249,825,000	\$8,735,500	
2005	\$287,178,231	\$284,394,000	\$2,784,231	
2006	\$313,541,278	\$305,332,000	\$8,209,278	
2007	\$370,610,684	\$352,200,000	\$18,410,684	
Total PDUFA III			\$38,139,693	A
2008	\$478,184,756	\$459,412,000	\$18,772,756	
2009	\$531,876,530	\$510,665,000	\$21,211,530	
2010	\$555,748,523	\$578,162,000	(\$22,413,477)	
2011	\$593,024,940	\$667,057,000	(\$74,032,060)	
2012	\$707,406,592	\$702,172,000	\$5,234,592	
Total PDUFA IV			(\$51,226,659)	A,B

Fiscal Year	Collections Realized	Collection Amount Specified in Appropriation Acts	Amount in Excess of Collection Amount Specified in Appropriation Acts	Notes
2013	\$721,225,394	\$718,669,000	\$2,556,394	
2014	\$805,649,146	\$760,000,000	\$45,649,146	
2015	\$849,104,821	\$798,000,000	\$51,104,821	
2016	\$857,147,405	\$851,481,000	\$5,666,405	
Total PDUFA V			\$104,976,766	
Offset When Fees Were Set for FY 2017			\$124,065,726	C

Numbers have been rounded to the nearest dollar

Notes

- A. Collections exceeding amounts specified in appropriations acts through FY 2007 totaled \$38,866,709. Excess collections offset under section 736(g)(4) of the FD&C Act when fees were set for FY 2007 totaled \$7,957,922. Excess collections offset under section 736(g)(4) of the FD&C Act when fees were set for FY 2012 totaled \$30,974,959.
- B. FDA had excess collections in PDUFA IV in FY 2008 and FY 2009 totaling \$39,984,286. However, overall FDA under-collected by \$51,226,659 in FY 2008 – FY 2012.
- C. Under PDUFA, if cumulative collections through FY 2015—including an estimate for FY 2016—exceed the fee revenues specified in appropriation acts during that period, FDA will lower the fee rates for FY 2017 by the cumulative amount that fees exceeded the amounts specified in appropriation acts during that period. An offset of \$124,065,726 was taken when fees were set for FY 2017; this offset amount included an estimate for the FY 2016 clean-up billing, which is why the FY 2016 contribution to the offset calculation is larger than the value that appears in Table 5 under “amount collected in excess of the amount specified in appropriations acts,” which reflects actual collections as of September 30, 2016.