

### 3.3 – CARRYOVER BALANCES

#### Introduction

PDUFA fees collected, appropriated, and not obligated at the end of the fiscal year remain available to FDA in future fiscal years. These funds are referred to as “carryover balances.”

Table 4 reflects the amount of fees collected net of any refunds or other adjustments that occurred during each fiscal year, for all cohort years combined, and the amount obligated during the fiscal year. The numbers do not include any accounts receivable. Therefore, the numbers for FY 2015 and FY 2016 are different from the numbers in Table 1 in section 3.1 – User Fee Collections, which reflect the total net collections for the cohort years only.

Obligations in Table 4 include any recoveries and deobligations from prior years, which may cause differences from Tables 2 and 8. In FY 2016, FDA recovered \$619,652 in PDUFA deobligations.

#### Data

Table 4 captures FDA’s carryover balances since the enactment of PDUFA in FY 1993.

The operations in FY 2016 resulted in a net increase of the carryover balance of \$47,427,122 (from \$362,345,905 at the end of FY 2015 to \$409,773,027 at the end of FY 2016). The increase in carryover is due to higher-than-expected fee-paying applications received in FY 2016 and collections from the FY 2015 product and establishment clean-up billing.

**TABLE 4: PRESCRIPTION DRUG USER FEE COLLECTIONS, OBLIGATIONS, AND CARRYOVER BALANCES BY FISCAL YEAR**

Program	Fiscal Years	Beginning Carryover	Net Collection	Obligations	Year-End Carryover
PDUFA	1993-1997	\$0	\$328,768,265	\$292,306,111	\$36,462,154
PDUFA II	1998-2002	\$36,462,154	\$680,152,170	\$693,931,100	\$22,683,224
PDUFA III	2003-2007	\$22,683,224	\$1,435,876,426	\$1,327,743,557	\$130,816,093
PDUFA IV	2008-2012	\$130,816,093	\$2,848,504,459	\$2,800,851,845	\$178,468,707
PDUFA V	2013	\$178,468,707	\$728,595,772	\$666,901,600	\$240,162,879
	2014	\$240,162,879	\$796,660,672	\$733,723,947	\$303,099,604
	2015	\$303,099,604	\$855,312,281	\$796,065,980	\$362,345,905
	2016	\$362,345,905	\$883,682,566	\$836,255,444	\$409,773,027

Numbers have been rounded to the nearest dollar