

### 3.5 – RESERVES AND BALANCE AVAILABLE FOR ALLOCATION

#### Introduction

MDUFA’s carryover balance in FY 2016 is \$103,152,912. There are anticipated claims on this balance that are described below. After subtracting these claims, FDA’s total remaining carryover balance is \$30,943,295.

#### Data

Table 5 provides a summary of carryover balances as of September 30, 2016, and anticipated claims on those balances.

**TABLE 5: SUMMARY STATEMENT OF MEDICAL DEVICE USER FEE CARRYOVER BALANCE AS OF SEPTEMBER 30, 2016**

Status of Carryover Funds	Amount	Notes
Total Carryover Balance	\$103,152,912	
Unearned Fee Revenue, FY 2008 through FY 2012	(\$8,423,817)	A
Unearned Fee Revenue, FY 2013 through FY 2016	(\$21,247,667)	A
Other Collections That Were Not Appropriated During the FY 2008 - FY 2011 Period	(\$9,348,152)	B
Offset When Fees Were Set for FY 2017	(\$14,678,151)	
1-Month Reserve for Next Fiscal Year	(\$9,000,000)	C
Collections That Have Been Offset but Not Appropriated During the FY 2008 - FY 2012 Period	(\$9,511,830)	D
<b>Remaining Carryover Balance</b>	<b>\$30,943,295</b>	

Numbers have been rounded to the nearest dollar

#### Notes

- A. FDA is unable to obligate or offset unearned revenue until applications are submitted to FDA pertaining to these funds. Total unearned revenue as of September 30, 2016, was \$8,423,817 from MDUFA II and \$21,247,667 from MDUFA III.
- B. The \$9,348,152 collected in excess of appropriations during the FY 2008 to FY 2011 period is deemed unavailable for obligation.
- C. MDUFA requires FDA to have at least 1 month of operating funds from fees (\$9,000,000) in reserve for the first month of the next fiscal year.
- D. Additionally, the \$9,511,830 in excess collections that was offset when setting fees for FY 2012 is deemed unavailable for obligation.