3.5 - RESERVES AND BALANCE AVAILABLE FOR ALLOCATION

Introduction

GDUFA's carryover balance in FY 2016 is \$173,675,175. There are anticipated claims on this balance that are described below. After subtracting these claims, FDA's total remaining carryover balance is \$168,675,175.

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 HUMAN GENERIC DRUG USER FEE CARRYOVER BALANCE
AS OF SEPTEMBER 30, 2016

Status of Carryover Funds	Amount	Notes
Total Carryover Balance	\$173,675,175	
Reserve for Refunds	(\$5,000,000)	Α
Remaining Carryover Balance	\$168,675,175	

Numbers have been rounded to the nearest dollar

Notes

A. Prudent operations require that a reserve be kept aside for potential refunds. For that purpose a total of \$5,000,000 is being set aside.