

3.4 – RESERVES AND BALANCE AVAILABLE FOR ALLOCATION

Introduction

BsUFA's carryover balance in FY 2016 is \$52,561,611. There are anticipated claims on this balance that are described below. After subtracting these claims, FDA's total remaining carryover balance is \$52,061,611.

Data

Table 4 provides a summary of carryover balances as of September 30, 2016, and anticipated claims on those balances.

TABLE 4: SUMMARY STATEMENT OF BIOSIMILAR BIOLOGICAL PRODUCT USER FEE CARRYOVER BALANCE AS OF SEPTEMBER 30, 2016

Status of Carryover Funds	Amount	Notes
Total Carryover Balance	\$52,561,611	
Reserve for Refunds	(\$500,000)	A
Remaining Carryover Balance	\$52,061,611	

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 \$500,000 is being set aside.