

3.5 – RESERVES AND BALANCE AVAILABLE FOR ALLOCATION

Introduction

AGDUFA’s carryover balance in FY 2016 is \$11,843,993. Anticipated claims on this balance are described below. After subtracting these claims, FDA’s total remaining carryover balance is \$4,327,319.

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

| Status of Carryover Funds | Amount | Notes |
|--------------------------------------------------------------------------|--------------------|-------|
| Total Carryover Balance | \$11,843,993 | |
| Reserve for Refunds | (\$100,000) | A |
| Reserve for Collections Deemed Unavailable due to Lack of Appropriations | (\$2,363,711) | B |
| Potential Offset in FY 2018 | (\$2,852,962) | |
| 3-Month Operating Reserve | (\$2,200,000) | C |
| Remaining Carryover Balance | \$4,327,319 | |

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 \$100,000 is being set aside.
- B. \$2,363,711 collected in excess of appropriations during AGDUFA I (\$268,071 in FY 2009 and \$2,095,640 in FY 2012) are deemed unavailable for obligation.
- C. AGDUFA II authorizes FDA to have up to 3 months of available carryover balance at the end of FY 2018 in order to sustain operations for the first 3 months of FY 2019. FDA will estimate the amount of carryover balance it expects to have available for obligation in August 2017, when fees are set for FY 2018. If carryover balances are less than the amount FDA needs to fund 3 months of operations in 2019, FDA may add up to the full shortfall amount to the fee revenues when fees for FY 2018 are set in August 2017. At the end of FY 2016 the amount of carryover needed to sustain operations for 3 months was \$2,200,000. This amount is currently covered by the balance available to FDA.