

3.4 – COLLECTIONS REALIZED

Introduction

Under GDUFA, the total amount of user fees collected for a cohort year must be provided in appropriation acts. In FY 2016, the appropriations language enacted in Public Law 114-113 specified that \$318,363,000 shall be derived from human generic drug user fees, and that human generic drug user fees collected in excess of this amount are also appropriated for FDA. The total amount of GDUFA fees collected for FY 2016 is available for allocation for the GDUFA program.

Data

Table 4 depicts fee collections realized during GDUFA by cohort year (the same as Total Collections in Table 1 section 3.1 – User Fee Collections), collection amounts specified in the appropriations acts, and any amounts in excess of the collection amount specified in the appropriations acts. Other variances between Table 3 and Table 4 are a result of unapplied collections at the end of the fiscal year. These collections will either be applied or refunded during FY 2017. For each of the last 2 years, collections realized were less than the amounts specified in the appropriations act.

TABLE 4: HUMAN GENERIC DRUG USER FEES COLLECTED, COLLECTION AMOUNTS SPECIFIED IN APPROPRIATIONS ACTS, AND EXCESS AMOUNTS AS OF SEPTEMBER 30, 2016

| Fiscal Year | Collections Realized | Collection Amount Specified in Appropriations Act | Amount in Excess of Collection Specified in Appropriations Act |
|-------------|----------------------|---|--|
| 2013 | \$301,571,553 | \$299,000,000 | \$2,571,553 |
| 2014 | \$321,803,006 | \$305,996,000 | \$15,807,006 |
| 2015 | \$283,009,876 | \$312,116,000 | - |
| 2016 | \$316,125,066 | \$318,363,000 | - |

Numbers have been rounded to the nearest dollar