

3.2 – USER FEE OBLIGATIONS

Introduction

GDUFA fees may be expended only for costs necessary to support “human generic drug activities” as defined in GDUFA. For ease of reference, “human generic drug activities” are referred to as “the GDUFA program” in this report. For more information on the allowable and excluded costs, see section 4.3 – Appendix C.

Fluctuations in object class obligations are due to variations in programmatic operations from year to year. As a result, increases or decreases in specific categories do not necessarily indicate growth or reductions in the overall GDUFA program.

Data

Table 2 provides a breakout of user fee obligations by expense category during the past 2 fiscal years. Employee salaries and benefits accounted for over 48 percent of FY 2016 human generic drug user fee obligations, which was an increase of approximately 7 percent from FY 2015. This is a direct result of significant hiring that occurred to meet GDUFA goals (obligations for personal compensation increased 31 percent between FY 2015 and FY 2016).

**TABLE 2: HUMAN GENERIC DRUG USER FEE OBLIGATIONS BY OBJECT CLASS EXPENSE CATEGORY
BREAKDOWN AS OF SEPTEMBER 30, 2015 AND 2016**

Object Class Expense Category	FY 2015	FY 2016
Personnel Compensation Benefits		
Full-time permanent	\$79,172,563	\$101,240,741
Other than full-time permanent	\$11,862,625	\$17,516,502
Other personnel compensation	\$4,628,937	\$6,533,811
Military personnel	\$8,861,503	\$10,966,490
Special personnel services payments	\$6,087	\$4,274
Civilian personnel benefits	\$28,725,500	\$38,845,274
Military personnel benefits	\$4,399,124	\$5,530,017
Benefits former personnel	\$0	\$15,262
Total Personnel Compensation and Benefits	\$137,656,339	\$180,652,370
Non-Pay Costs		
Travel & transportation of persons	\$4,269,094	\$5,307,079
Transportation of things	\$288,254	\$314,794
Rent payments to GSA	\$13,178,668	\$14,705,000
Rent payments to others	\$18,845	\$341,211

Object Class Expense Category	FY 2015	FY 2016
Communications, utilities & miscellaneous	\$2,678	\$1,243,708
Printing & reproduction	\$31,494	\$16,152
Other contractual services:		
Consulting services	\$7,243,975	\$12,144,689
Other services	\$87,945,159	\$75,495,754
Purchases of goods & services from government accounts	\$30,700,488	\$30,312,030
Operations & maintenance of facilities	\$3,303,486	\$3,514,243
Research & development contracts	\$3,841,489	\$6,319,658
Operations & maintenance of equipment	\$3,528,396	\$6,348,624
Subsistence and support of persons	\$0	\$0
Supplies & materials	\$3,351,137	\$3,971,226
Equipment	\$4,902,847	\$10,692,213
Land & structure	\$0	\$0
Grants, subsidies, & contributions	\$31,818,069	\$21,609,659
Insurance claims & indemnities	\$0	\$0
Interest account	\$0	\$0
Receivables – collected	\$0	\$248,090
Total Non-Pay Costs	\$194,424,080	\$192,584,129
Total Obligations	\$332,080,419	\$373,236,499

Numbers have been rounded to the nearest dollar

References

Additional information on GDUFA program costs can be found in section 3.6 – Total GDUFA Program Costs.