

USER FEE OBLIGATIONS

User fees are expended only for costs necessary to support the process for the review of animal drug applications, as defined in ADUFA. Allowable and excludable costs for the process for the review of animal drug applications are described in Appendix D.

In FY 2012, FDA obligated \$16,137,101 from animal drug user fees. Table 2 provides a breakout of user fee obligations by expense category during the past two fiscal years.

**TABLE 2
ANIMAL DRUG USER FEE OBLIGATIONS BY EXPENSE CATEGORY
AS OF SEPTEMBER 30, 2011 AND SEPTEMBER 30, 2012**

| EXPENSE CATEGORY | FY 2011 | FY 2012 |
|-------------------------------------|---------------------|---------------------|
| Personnel Compensation and Benefits | \$9,890,135 | \$9,133,701 |
| Travel and Transportation | \$403,782 | \$341,478 |
| Rent | \$671,800 | \$558,930 |
| Communications | \$37,297 | \$11,503 |
| Contract Services | \$4,638,973 | \$4,903,151 |
| Equipment and Supplies | \$924,531 | \$1,184,934 |
| Other ¹ | \$66,282 | \$3,404 |
| TOTAL OBLIGATIONS | \$16,632,800 | \$16,137,101 |

¹Other includes expenses from categories such as rent payments to others, printing & reproduction, and other miscellaneous expenses.

FDA dedicated 197 FTEs to the process for the review of animal drug applications in FY 2003, before ADUFA was enacted. In FY 2012, ADUFA fees and appropriations paid for a total of 303 FTEs, 106 more FTEs than were used in FY 2003 for the review process. Employee salary and benefits paid from user fees in FY 2012 totaled approximately 57 percent of the obligations from user fees. FDA is working to strengthen and expand its capacities to conduct efficient and timely reviews, and to ensure the safety and effectiveness of new animal drugs.

More discussion of the total process costs for the review of applications for new animal drugs appears on page 10.