

## USER FEE OBLIGATIONS

User fees are expended only for costs necessary to support the process for the review of abbreviated applications for generic new animal drugs, as defined in AGDUFA. Allowable and excludable costs for the process for the review of abbreviated applications for generic new animal drugs are described in Appendix D.

In FY 2012, FDA obligated \$4,366,351 from generic new animal drug user fees. Table 2 provides a breakout of user fee obligations by expense categories during the past two fiscal years.

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

EXPENSE CATEGORY	FY 2011	FY 2012
Personnel Compensation and Benefits	\$3,042,223	\$2,909,505
Travel and Transportation	\$108,677	\$57,218
Rent	\$17,900	\$98,908
Communications	\$23,232	\$3,419
Contract Services	\$1,272,376	\$1,083,689
Equipment and Supplies	\$203,568	\$211,802
Other <sup>1</sup>	\$17,824	\$1,810
<b>TOTAL OBLIGATIONS</b>	<b>\$4,685,800</b>	<b>\$4,366,351</b>

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

FDA dedicated 26 Full-Time Equivalent (FTE) to the process for the review of generic new animal drug applications in FY 2008, before AGDUFA was enacted. In FY 2012, AGDUFA fees and appropriations paid for a total of 57 FTE, 32 more FTEs than were used in FY 2008 for the review process. Employee salary and benefits paid from user fees in FY 2012 totaled approximately 67 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 generic new animal drugs.

See the section on total cost of the process for the review of abbreviated applications for generic new animal drugs, on page 10, for more discussion on the total process costs for the review of abbreviated applications for generic new animal drugs.