

Appropriation Language Analysis

Language Provision	Explanation
Reauthorization of FY 2008 Current Law User Fees – Animal Drug User Fee Act (ADUFA)	The FY 2008 enacted appropriations language for the ADUFA user fee programs is struck because collecting these fees is subject to re-authorization in FY 2009. The Administration will propose legislation to reauthorize the collection and spending of fees, subject to appropriation.
Animal Generic Drug User Fee	The Administration will propose legislation to allow FDA to collect fees to support animal generic drug review. The additional resources, estimated at \$4,831,000 in 2009, will enable FDA to reduce review times and create a sustainable performance driven program that maintains high standards for product safety and efficacy.
Generic Drug Review User Fee	The Administration will propose legislation to allow FDA to collect fees to support generic drug review. The additional resources, estimated at \$16,628,000 in 2009, will enable FDA to reduce review times and respond to the growing number of generic drug applications.
Animal Drug User Fee – Reauthorization	The authority to collect fees under ADUFA expires on September 30, 2008. The terms of legislation to reauthorize ADUFA are currently under discussion. Contingent on reauthorization by FY 2009, the budget requests \$13,698,000 in spending authority from PDUFA user fees. This amount is subject to change depending on the reauthorization statute.