

## **MEETING THE LEGAL CONDITIONS FOR USER FEES IN FY 2012**

ADUFA imposes three legal conditions that FDA must satisfy each fiscal year for the Agency to collect and spend animal drug user fees. A summary of how each of these legal conditions was satisfied in FY 2012 is shown below. Detailed explanations and calculations are described in Appendix A.

**The first legal condition:** FDA's overall Salaries and Expenses appropriation (excluding user fees) must meet or exceed FDA's FY 2003 Salaries and Expenses appropriation (excluding user fees), including an adjustment for inflation. In FY 2012, FDA's appropriation for salaries and expenses was \$2,497,021,000, excluding user fees. FDA's FY 2003 Salaries and Expenses appropriation, excluding user fees and then adjusted for inflation, was \$1,657,178,510. Therefore, the first legal condition was satisfied.

**The second legal condition:** The amount of user fees collected for each fiscal year must be specified in that year's Appropriation Acts. The President signed the Consolidated and Further Continuing Appropriations Act, 2012 (Public Law 112-55) on November 18, 2011. It specified that \$21,768,000 shall be derived from animal drug user fees. Therefore, the second legal condition was satisfied.

**The third legal condition:** User fees may be collected and used only in years when FDA spends a specified minimum amount of appropriated funds for the review of animal drug applications. This specified minimum is the amount FDA spent on the review of animal drug applications from appropriations (exclusive of user fees) in FY 2003, adjusted for inflation. The specified minimum level for FY 2012 is \$39,505,517. In FY 2012, FDA obligated \$49,019,929 from appropriations (exclusive of user fees) for the review of animal drug applications. Under ADUFA, this condition is considered met if the total review expense funded by appropriations in any year is no more than three percent below the specified minimum. Because FDA spent more than the specified minimum amount from appropriations in FY 2012, the third legal condition was satisfied.