

MEETING THE LEGAL CONDITIONS FOR USER FEES IN FY 2011

PDUFA imposes three legal conditions that FDA must satisfy before the Agency can collect and spend prescription drug user fees. A summary of how each of these legal conditions was satisfied in FY 2011 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 1997 Salaries and Expenses appropriation (excluding user fees), including an adjustment for inflation. In FY 2011, FDA's appropriation for salaries and expenses was \$2,301,163,000, excluding user fees and rent payments to GSA. FDA's FY 1997 Salaries and Expenses appropriation excluding user fees and rent, and then adjusted for inflation was \$1,119,766,000. 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 FY 2011 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act (Public Law 112-10) on April 15, 2011. It specified that \$667,057,000 shall be derived from prescription 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 human drug applications. This specified minimum is the amount FDA spent on the review of human drug applications from appropriations (exclusive of user fees) in FY 1997, adjusted for inflation. The specified minimum level for FY 2011 is \$202,056,000. In FY 2011, FDA obligated \$397,795,306 from appropriations (exclusive of user fees) for the review of human drug applications. Because FDA spent more than the specified minimum amount from appropriations in FY 2011, the third legal condition was satisfied.