

2: LEGAL CONDITIONS

AGDUFA imposes three legal conditions that must be satisfied in each fiscal year for FDA to collect and spend generic new animal drug user fees. A summary of how each of these legal conditions was satisfied in FY 2016 is shown below.

Legal Condition 1 – 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 2016, FDA's appropriation for salaries and expenses was \$2,719,308,000 excluding user fees. FDA's FY 2003 Salaries and Expenses Appropriation, excluding user fees, was \$1,799,035,086 after applying the adjustment factor. Therefore, the first legal condition was satisfied.

Legal Condition 2 – The amount of user fees collected for each fiscal year must be specified in that year's appropriation acts. The President signed the Consolidated Appropriations Act, 2016 (Public Law 114-113), on December 18, 2015. The Act specified that \$9,705,000 shall be derived from generic new animal drug user fees, and that generic new animal drug user fees collected in excess of this amount are also appropriated for FDA. Therefore, the second legal condition was satisfied.

Legal Condition 3 – User fees may be collected and used only in years when FDA spends a specified minimum amount of appropriated funds (exclusive of user fees) for the review of generic new animal drug applications. This specified minimum is the amount FDA spent on the review of generic new animal drug applications from appropriations (exclusive of user fees) in FY 2008, multiplied by an adjustment factor. The specified minimum level for FY 2016 is \$6,261,514. In FY 2016, FDA obligated \$6,300,520 from appropriations (exclusive of user fees) for the review of abbreviated applications for generic new animal drugs. Under AGDUFA, the condition is considered met if the total review expense funded by appropriations in any year is more than the amount that is 3 percent below the specified minimum. Because FDA spent more than the specified minimum amount from appropriations in FY 2016, the third legal condition was satisfied.

References

Detailed explanations and calculations of how each of these legal conditions was satisfied in FY 2016 are described in section 4.1 – Appendix A.