

## 2: LEGAL CONDITIONS

PDUFA imposes three legal conditions that FDA must satisfy to collect and spend prescription drug user fees. A summary of how each of these legal conditions was satisfied in FY 2016 is below.

**Legal Condition 1** – FDA’s overall Salaries and Expenses Appropriation (excluding user fees and rental payments to the General Services Administration (GSA)) must meet or exceed FDA’s FY 1997 Salaries and Expenses Appropriation (excluding user fees and rental payments to GSA), adjusted for inflation (see Adjustment Factor in Appendix 4.1). In FY 2016, FDA’s appropriation for salaries and expenses was \$2,542,625,000, excluding user fees and rent payments to GSA. FDA’s FY 1997 Salaries and Expenses Appropriation excluding user fees and rent was \$1,229,868,763 after applying the FY 2016 adjustment factor. Therefore, the first legal condition was satisfied.

**Legal Condition 2** – The amount of user fees collected for each fiscal year must be provided in that year’s appropriation act. The President signed the Consolidated Appropriations Act, 2016 (Public Law 114-113), on December 18, 2015. It specified that \$851,481,000 shall be derived from prescription drug user fees, and that prescription drug user fees collected in excess of this amount, if any, are 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 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 (see Adjustment Factor in Appendix 4.1). The specified minimum level for FY 2016 is \$221,923,702. In FY 2016, FDA obligated \$320,942,599 from appropriations (exclusive of user fees) for the review of human drug applications. Because FDA spent more than the specified minimum amount 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.