

## 2: LEGAL CONDITIONS

GDUFA imposes three legal conditions that must be satisfied for FDA to collect and spend human generic 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 total appropriations for salaries and expenses (excluding user fees) must be equal to or greater than FDA’s FY 2009 appropriations for salaries and expenses (excluding user fees) multiplied by the adjustment factor. FDA’s FY 2016 total appropriation for salaries and expenses (excluding user fees) was \$2,719,308,000 whereas the FY 2009 salaries and expenses appropriation (excluding user fees) was \$2,138,129,014 after applying the FY 2016 adjustment factor. Thus, the first legal condition was satisfied.

**Legal Condition 2** – Fees authorized under GDUFA shall be collected and available in each fiscal year in an amount not to exceed that specified in appropriation acts for such fiscal year. The Consolidated Appropriations Act, 2016 (Public Law 114-113) which the President signed on December 18, 2015, made appropriations through September 30, 2016, for the salaries and expenses account of FDA. It specified that \$318,363,000 shall be derived from human generic drug user fees, and that human generic drug user fees collected in excess of this amount, if any, are appropriated for FDA. Thus, the second legal condition was satisfied.

**Legal Condition 3** – FDA must allocate a minimum of \$97,000,000 of appropriations (excluding user fees) multiplied by the adjustment factor, and these funds shall be available to defray the costs of the GDUFA program. The specified minimum level for FY 2016 is \$101,717,595. In FY 2016, FDA obligated \$120,714,671, exclusive of user fees, for the GDUFA program. As 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.