

2: LEGAL CONDITIONS

BsUFA imposes two legal conditions that must be satisfied for FDA to collect and spend biosimilar biological product user fees. A summary of how each of these legal conditions was satisfied in FY 2016 is shown below.

Legal Condition 1 – The amount of user fees collected for each fiscal year must be specified in that year’s appropriation acts. 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 \$21,540,000 shall be derived from BsUFA fees, and that BsUFA fees collected in excess of this amount are also appropriated for FDA. Thus, in FY 2016, the first legal condition was satisfied.

Legal Condition 2 – FDA may not spend BsUFA fees in a fiscal year unless it allocates a minimum of \$20,000,000 in appropriated funds (excluding user fees), multiplied by the adjustment factor applicable to that fiscal year, for the BsUFA program. The specified minimum level for FY 2016 is \$21,167,560. In FY 2016, FDA allocated and obligated \$32,353,416 in appropriated funds (excluding user fees) for the BsUFA program, as defined in section 744G(13). Since FDA allocated and obligated more than the specified minimum amount in FY 2016, the second 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.