

FDA-Industry BsUFA II Reauthorization Negotiation Meeting
Finance Sub-group
May 12, 2016, 3:00pm-4:00pm
FDA White Oak Campus, Silver Spring, MD
Building 52/72, Room 3100

Purpose

To continue to discuss financial enhancements for BsUFA II including the user fee structure and to discuss proposed commitment letter language.

Participants

FDA

Mark Ascione CDER
Josh Barton CDER
Yanming Chae CBER
Azada Hafiz CDER
Andrew Kish CDER
Kirk Kerr CDER
Robert Marcarelli OC
Amanda Roache CDER

Industry

Sascha Haverfield PhRMA
Mark Hendrickson GPhA Biosimilars Council
Kay Holcombe BIO
Stacy Holdsworth PhRMA (Eli Lilly)
Bruce Leicher GPhA Biosimilar Council (Momenta)
Michael Levy PhRMA
Scott McGoohan BIO
John Pakulski GPhA Biosimilars Council (Mylan)
Juliana Reed Biosimilars Forum (Coherus)
Michael Werner Biosimilars Forum (Holland & Knight)

BsUFA II User Fee Structure

FDA and industry continued discussing the user fee structure. FDA and industry discussed potential enhancements to the user fee structure that could mitigate volatility in FDA funding levels and sponsor fee amounts caused by fluctuations in fee-paying submissions from year-to-year during BsUFA II. FDA and industry discussed applying restrictions to how much the fee amounts can increase and providing the Agency the flexibility to modify the proportion of revenue generated from each fee type for each fiscal year to alleviate the increases in fee amounts. FDA and industry agreed to continue discussing components of the user fee structure in a future meeting.

Commitment Letter

FDA and industry discussed potential financial commitments for the Biosimilar Biological Product Reauthorization Performance Goals and Procedures, also known as the commitment letter, and proposed statutory changes to the fee provisions in the FD&C Act. FDA and industry agreed to review proposed commitment letter language and proposed statutory changes in a future meeting.

Plan for Future Meetings

The goal for the next meeting on May 18, 2016 will be to continue discussing financial enhancements for BsUFA II reauthorization, and continue discussing changes to the commitment letter and proposed statutory language for financial enhancements.

There were no other substantive proposals, significant controversies, or differences of opinion discussed at this meeting.