FDA-Industry BsUFA II Reauthorization Negotiation Meeting
Finance Sub-group
April 28, 2016, 3:00pm-4:15pm
FDA White Oak Campus, Silver Spring, MD
Building 52/72, Room 3100

Purpose

To continue discussing financial enhancements for BsUFA II including the user fee structure.

Participants

FDA		Industry	
Mark Ascione	CDER	Sascha Haverfield	PhRMA
Josh Barton	CDER	Mark Hendrickson	GPhA Biosimilars Council
Yanming Chae	CBER	Kay Holcombe	BIO
Joseph Franklin	OC	Stacy Holdsworth	PhRMA (Eli Lilly)
Azada Hafiz	CDER	Michael Levy	PhRMA
Andrew Kish	CDER	Scott McGoohan	BIO
Kirk Kerr	CDER	John Pakulski	GPhA Biosimilars Council (Mylan)
Robert Marcarelli	OC	Juliana Reed	Biosimilars Forum (Coherus)
Amanda Roache	CDER	Michael Werner	Biosimilars Forum (Holland & Knight)

BsUFA II User Fee Structure

In the previous meeting, industry requested FDA demonstrate the impact of the proposed annual adjustments to the target allocation on fees under certain fee paying submission scenarios. FDA shared the requested analysis. Industry expressed the desire to minimize variations in fee rates from year to year. FDA and industry agreed to continue discussing the user fee structure in a future meeting.

Plan for Future Meetings

The goal for the next meeting on May 12, 2016 will be to continue discussing financial enhancements for BsUFA II reauthorization and to discuss proposed changes to the fee structure and the commitment letter for financial enhancements.

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