FDA-Industry BsUFA Reauthorization Negotiation Meeting
Finance Sub-group
March 31, 2016, 3:00pm-4:45pm
FDA White Oak Campus, Silver Spring, MD
Building 52/72, Room 3100

Purpose

To provide FDA and industry perspectives on anticipated BsUFA II costs and plan for the discussions for future meetings.

Participants

FDA		Industry	
Mark Ascione	CDER	Hillel Cohen	Biosimilars Forum (Sandoz)
Josh Barton	CDER	David Gaugh	GPhA Biosimilars Council
Joseph Franklin	OC	Sascha Haverfield	PhRMA
Andrew Kish	CDER	Mark Hendrickson	GPhA Biosimilars Council
Robert Marcarelli	OC	Bruce Leicher	GPhA Biosimilars Council (Momenta)
Graham Thompson	CDER	Scott McGoohan	BIO
		John Pakulski	GPhA Biosimilars Council (Mylan)
		Juliana Reed	Biosimilars Forum (Coherus)
		Michael Werner	Biosimilars Forum (Holland & Knight)
		Stacy Holdsworth	PhRMA (Eli Lilly)

Overview of the BsUFA II Anticipated Costs

The FDA presented an overview of the anticipated program costs during BSUFA II resulting from estimated biosimilar development programs and submissions and corresponding workload discussed during the previous meeting. The Agency provided an overview of the methodology and data used to develop the anticipated costs. FDA and Industry discussed the anticipated workload, methodology, and estimated costs in BsUFA II.

FDA and Industry agreed on the importance of ensuring the Agency is sufficiently resourced during BsUFA II to enable FDA to manage workload and achieve performance goals.

Plan for Future Meetings

The goal for the BsUFA financial sub-group on April 7, 2016 will be to discuss proposals related to the user fee structure.

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