FDA-Industry BsUFA II Reauthorization Negotiation Meeting
Finance Sub-group
May 19, 2016, 2:00pm-3:00pm
FDA White Oak Campus, Silver Spring, MD
Building 52/72, Room 2100

Purpose

The purpose of the meeting was to continue to discuss financial enhancements for BsUFA II and proposed changes to the commitment letter and statutory language for financial enhancements.

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	Bruce Leicher	GPhA Biosimilar Council (Momenta)
Andrew Kish	CDER	Michael Levy	PhRMA
Kirk Kerr	CDER	Scott McGoohan	BIO
Robert Marcarelli	OC	John Pakulski	GPhA Biosimilars Council (Mylan)
Amanda Roache	CDER	Juliana Reed	Biosimilars Forum (Coherus)
		Michael Werner	Biosimilars Forum (Holland & Knight)

BsUFA II Commitment Letter

FDA and industry continued to discuss enhancements to the user fee structure. FDA and industry continued discussion of additional edits to the financial components of the BsUFA II commitment letter. Contingent on these further edits, FDA and industry agreed the draft document reflects the proposed BsUFA II changes to the current fee structure to enhance financial predictability, transparency, and stability was ready for review by the Steering Committee.

BsUFA II Statutory Language

FDA and industry discussed potential revisions to propose for the fee provisions in the Federal Food, Drug, and Cosmetic Act (FD&C Act) to achieve modifications to the current fee structure. FDA and industry agreed to continue discussing proposed revisions to the statutory fee provisions at future meetings.

Plan for Future Meetings

The goal for the next meeting on May 26, 2016 will be to continue discussing proposed changes to the statutory fee provisions of the FD&C Act.

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