FDA-Industry BsUFA Reauthorization Negotiation Meeting
March 31, 2016, 1:00pm-2:45pm
FDA White Oak Campus, Silver Spring, MD
Building 52/72, Room 3100

Purpose

To provide FDA and industry perspectives on the BsUFA II review model enhancements and plan for the discussions for future meetings.

Participants

FDA		Industry	
Michelle Adams	OC	David Ceryak	BIO (Eli Lilly)
Mark Ascione	CDER	Hillel Cohen	Biosimilars Forum (Sandoz)
Josh Barton	CDER	Andrew Emmett	PhRMA (Pfizer)
Sandra Benton	CDER	Jeffrey Francer	PhRMA
Leah Christl	CDER	David Gaugh	GPhA Biosimilars Council
Joseph Franklin	OC	Kim Greco	PhRMA (Amgen)
Patrick Frey	CDER	Sascha Haverfield	PhRMA
John Jenkins	CBER	Bruce Leicher	GPhA Biosimilars Council (Momenta)
Christopher Joneckis	CBER	Scott McGoohan	BIO
Andrew Kish	CDER	Jennifer Nowak	Biosimilars Forum (Holland & Knight)
Theresa Mullin	CDER	John Pakulski	GPhA Biosimilars Council (Mylan)
Vada Perkins	CBER	Juliana Reed	Biosimilars Forum (Coherus)
Amanda Roache	CDER	Michael Werner	Biosimilars Forum (Holland & Knight)
		Julie Zawisza	BIO (Baxalta)

The FDA and industry parties resumed discussion of the meeting management proposals that were initially discussed during the negotiation meeting on March 24. The industry parties explained that they were in the process of developing a consolidated view and would be prepared to discuss the proposals further at a later meeting.

FDA Perspectives on Enhancements to the Application Review Model

The FDA presented its views on the application review enhancements for BsUFA II. The FDA proposed establishing a review model similar to "the Program" initiated under the Prescription Drug User Fee Act (PDUFA) V. FDA considered that such a model in BsUFA II could promote the efficiency and effectiveness of the first cycle review process for biosimilars and minimize the number of review cycles necessary for approval. The major attributes of the Program were reviewed and include a mid-cycle communication, a late-cycle meeting, and a review clock that begins on the 60-day filing date.

The FDA provided an overview of an evaluation of the PDUFA V Review Program conducted by the Eastern Research Group (ERG) that provides an analysis of the Program review model in comparison to a baseline cohort of applications that were submitted under PDUFA IV. The FDA highlighted that the results of the report show an increase in the percent of applications approved in the first review cycle under the Program as compared to the baseline. ERG found that the Program created conditions that

enhanced the ability of FDA and applicants to work toward approval in the first review cycle where possible.

The FDA and industry parties discussed how the Program review model could be applied for BsUFA II. The Agency explained that the same Program under PDUFA would be applied to BsUFA II with all of the communication elements, goals of predictability, transparency, and extended review time to address issues. FDA stated that the current first cycle approval rate for biosimilar applications is low and noted that if additional review time had been available, issues encountered in some of these applications may have been addressed in the first review cycle, potentially resulting in a first cycle approval action instead of a complete response action.

The industry parties explained that the proposed approach would need to be shared with their members for further input and that additional input would be provided to FDA at a later meeting.

Plan for Future Meetings
The goal for the next BsUFA negotiation steering committee on April 7, 2016 would be to review the policy and guidance proposals in more detail.

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