FDA-Industry BsUFA Reauthorization Steering Committee Meeting
April 28, 2016, 1:00pm-2:45pm
FDA White Oak Campus, Silver Spring, MD
Building 52/72, Room 3100

Purpose

The purpose of the meeting was to obtain perspective from industry on a biosimilar Program review model and to discuss industry's feedback on draft commitment language for other proposals.

Participants

FDA		Industry	
Mark Ascione	CDER	Andrew Emmett	PhRMA (Pfizer)
Josh Barton	CDER	Jeffrey Francer	PhRMA
Joseph Franklin	OC	Kim Greco	PhRMA (Amgen)
Patrick Frey	CDER	Sascha Haverfield	PhRMA
John Jenkins	CDER	Mark Hendrickson	GPhA Biosimilars Council
Chris Joneckis	CBER	Kay Holcombe	BIO
Andrew Kish	CDER	Michael Levy	PhRMA
Theresa Mullin	CDER	Scott McGoohan	BIO
Neel Patel	CDER	Jennifer Nowak	Biosimilars Forum (Holland & Knight)
Vada Perkins	CBER	John Pakulski	GPhA Biosimilars Council (Mylan)
Amanda Roache	CDER	Juliana Reed	Biosimilars Forum (Coherus)
Graham Thompson	CDER	Michael Werner	Biosimilars Forum (Holland & Knight)
		Julie Zawisza	BIO (Baxalta)

Industry Perspective on a Biosimilar Program Review Model

Industry began by providing feedback on FDA's proposal to establish a biosimilar review model similar to "the Program" initiated for new drugs under the Prescription Drug User Fee Act. Industry tentatively agreed to support FDA's proposal, conditional upon revisions to the draft commitment language provided by FDA. Industry then provided an overview of its suggested edits to the draft commitment letter language including an interim evaluation to assess the program's performance. FDA and industry discussed the need to optimize the timing of this evaluation to ensure that a sufficient amount of data would be available and to have the report findings available in time for the negotiation of BsUFA III.

Industry and FDA Perspective on Other Proposals

FDA and industry discussed draft commitment letter language related to meeting management, dedicated biosimilar staff capacity, and other proposals. FDA provided feedback to industry on edits suggested to the draft commitment letter on meeting management. FDA and industry agreed that the FDA should maintain the ability to deny a Type II meeting in particular circumstances. Industry responded that it will consider some of the feedback received from FDA and provide additional edits to the commitment letter language for meeting management for discussion at a later meeting.

FDA answered several questions from industry related to the dedicated biosimilar unit. FDA explained that the unit will enhance FDA's capability to conduct 351(k) reviews and address policy issues. FDA anticipated that the new unit would not result in duplication of work but would rather allow for better integration and a more centralized approach to reviews. Following this presentation, industry offered that further revisions be made to proposed commitment letter language, for discussion at the next negotiation meeting.

Plan for Future Meetings

The goal for the next meeting will be to continue to discuss revisions to the commitment letter language.

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