FDA-Industry BsUFA Reauthorization Steering Committee Meeting

Day 1: May 18, 2016, 12:30 pm - 2:00 pm FDA White Oak Campus, Silver Spring, MD Building 52/72, Room 4340	**Day 2: May 19, 2016, 12:30 pm – 1:30 pm** FDA White Oak Campus, Silver Spring, MD Building 52/72, Room 2100

Purpose

To reach agreement at the negotiation team level on draft commitment letter language describing a package of enhancement proposals for BsUFA II.

Participants

FDA		Industry	
Michelle Adams	OC	David Ceryak	BIO (Eli Lilly)
Leah Christl	CDER	Hillel Cohen	Biosimilars Forum (Sandoz)
Joseph Franklin	OC	Andrew Emmett	PhRMA (Pfizer)
Patrick Frey	CDER	Jeffrey Francer	PhRMA
John Jenkins	CDER	Kim Greco	PhRMA (Amgen)
Chris Joneckis	CBER	David Gaugh	GPhA Biosimilars Council
Andrew Kish	CDER	Sascha Haverfield	PhRMA
Theresa Mullin	CDER	Mark Hendrickson	GPhA Biosimilars Council
Neel Patel	CDER	Kay Holcombe	BIO
Amanda Roache	CDER	Bruce Leicher	GPhA Biosimilars Council (Momenta)
Graham Thompson	CDER	Micheal Levey	PhRMA
		Scott McGoohan	BIO
		Jennifer Nowak	Biosimilars Forum (Holland & Knight)
		John Pakulski	GPhA Biosimilars Council (Mylan)
		Juliana Reed	Biosimilars Forum (Coherus)
		Michael Werner	Biosimilars Forum (Holland & Knight)
		Julie Zawisza	BIO (Baxalta)

Program Enhancement Proposals

FDA and industry began by reviewing the meeting management goals section in the BsUFA II commitment letter. FDA agreed to industry's proposal for a sponsor to have the ability to request a face to face meeting, or to request a written response only, but not to propose both options in a single request. FDA also agreed with industry's proposal that the BsUFA II commitment letter would not provide a process for converting a face to face meeting request into a written response only. Industry acknowledged that, since the commitment letter would not provide a process for FDA to provide a written response if a face to face meeting was denied, that the sponsor would have to submit a new request to obtain a written response if an earlier-submitted meeting request was denied.

FDA and industry reviewed draft commitment letter language for the Program Review Model. Industry expressed a desire for more granularity on the process for the review of supplements to approved

applications and FDA agreed to include some text from the BsUFA I commitment letter which would apply to supplements with clinical data.

FDA and industry discussed industry's proposal for FDA to regularly update the information in the Purple Book. FDA provided an estimate of the resources that would be required to perform the work associated with industry's proposal.

FDA and industry then discussed resource requirements for other proposals such as the development of guidance documents; the development of MAPPs and SOPs related to new policy and guidance; ensuring timely training of staff; and development and delivery of information to improve public understanding of biosimilarity and interchangeability.

Commitment Letter Review

Following review of specific program enhancement proposals, FDA and industry reviewed a complete version of the draft commitment letter. FDA and industry discussed additional clarifying edits and corrections to the draft language including minor revisions to the preamble and introductory language for the commitment letter.

The Steering Committee agreed to recommend the draft commitment letter and proposed statutory changes to their respective senior management for ratification. The process and timeline for receiving ratification of the draft commitment letter and proposed statutory changes from the respective senior management from each organization was discussed. It was estimated that these processes could be conducted by by mid-July.

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