FDA-Industry BsUFA Reauthorization Steering Committee Meeting
April 21, 2016, 1:00pm-3:00pm
FDA White Oak Campus, Silver Spring, MD
Building 52/72, Room 2100

Purpose

The purpose of the meeting was to discuss FDA's hiring plan for the remainder of BsUFA I, review FDA's proposal to establish a dedicated biosimilar unit, obtain perspective from industry on a biosimilar Program review model, and to review draft commitment language for other proposals.

Participants

FDA		Industry	
Michelle Adams	OC	David Ceryak	BIO (Eli Lilly)
Mark Ascione	CDER	Andrew Emmett	PhRMA (Pfizer)
Josh Barton	CDER	Tiffany Fletcher	Biosimilars Forum (Sandoz)
Leah Christl	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
Andrew Kish	CDER	Kay Holcombe	BIO
Theresa Mullin	CDER	Bruce Leicher	GPhA Biosimilars Council (Momenta)
Neel Patel	CDER	Jennifer Nowak	Biosimilars Forum (Holland & Knight)
Amanda Roache	CDER	John Pakulski	GPhA Biosimilars Council (Mylan)
Graham Thompson	CDER	Juliana Reed	Biosimilars Forum (Coherus)
		Michael Werner	Biosimilars Forum (Holland & Knight)
		Julie Zawisza	BIO (Baxalta)

Overview of FDA BsUFA Hiring

FDA began by providing an overview of the BsUFA hiring plan for FY2016-17. The presentation addressed challenges to hiring staff during BsUFA I, FDA's approach to executing their hiring plan, and longer-term enhancements planned to support adequate staffing. FDA explained that carry-over funds from BsUFA I would be used to resource the FY 2016-17 hiring plan, and that the plan was separate from any potential hiring under BsUFA II.

FDA Perspective on a Dedicated Biosimilar Unit

FDA then presented its proposal to establish a dedicated biosimilar unit. FDA stated that the new unit would be developed to provide a more focused and better resourced capacity to coordinate key scientific, regulatory, and policy functions. Additionally, the new unit would provide a central point of coordination and focus on key functions such as scientific coordination, policy, operations management, governance, training, and external outreach. FDA then discussed how establishment of the unit would address several enhancement proposals raised by industry targeted towards improving consistency, transparency, and communication during review of biosimilar applications and would also support policy

coordination and oversight. Industry conveyed that it was supportive of FDA's proposal and both parties agreed that it would be helpful to have related commitment letter language drafted that could be discussed at a later meeting.

Industry Perspective on Other Proposals

In follow up to FDA's proposal presented during the March 31 negotiations meeting to establish a biosimilar review model similar to "the Program" initiated for new drugs under PDUFA V, the FDA provided additional details of how such a program could apply more specifically for biosimilars and what types of interactions sponsors could expect to have with the FDA. FDA provided industry with potential draft commitment letter language for a biosimilar review Program model and described the expected benefits that such a Program would provide to public health by reducing potentially unnecessary review cycles before biosimilar approval and thus allowing patients earlier access to biosimilars. Additionally, the FDA described the benefits anticipated for less experienced biological product sponsors resulting from the opportunity for more frequent communication with the FDA that would occur with this Program. Industry inquired if the Program could be optional, and FDA declined to support that idea due to the operational inefficiency and uncertainty that this would create. Industry expressed concerns about the lack of data to show that the Program would be as successful for BsUFA as it has been for PDUFA but indicated that it would further consider FDA's proposal and provide additional feedback at a subsequent meeting.

Industry provided the FDA with draft commitment letter language related to industry's guidance development proposals that were discussed during a previous meeting.

Additionally, FDA provided draft commitment letter language that covered several industry and FDA proposals including proposals related to meeting management that were discussed during previous negotiations meetings. Both parties agreed to further consider the commitment letter language provided and discuss further at a later meeting.

Plan for Future Meetings

The goal for the BsUFA steering committee on April 28, 2016 will be to obtain feedback on draft commitment letter language provided by FDA or industry on various enhancement proposals previously discussed by FDA and industry.

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