FDA-Industry BsUFA Reauthorization Steering Committee Meeting
April 14, 2016, 1:00pm-2:50pm
FDA White Oak Campus, Silver Spring, MD
Building 52/72, Room 3100

Purpose

The purpose of the meeting was to obtain industry's perspective on the Biosimilar Program review model that was discussed on March31, and to review proposals related to meeting management and inspections in more detail.

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)
Leah Christl	CDER	Jeffrey Francer	PhRMA
Joseph Franklin	OC	David Gaugh	GPhA Biosimilars Council
Patrick Frey	CDER	Kim Greco	PhRMA (Amgen)
Christopher Joneckis	CBER	Sascha Haverfield	PhRMA
Andrew Kish	CDER	Mark Hendrickson	GPhA Biosimilars Council
Theresa Mullin	CDER	Kay Holcombe	BIO
Neel Patel	CDER	Bruce Leicher	GPhA Biosimilars Council (Momenta)
Amanda Roache	CDER	Scott McGoohan	BIO
Graham Thompson	CDER	Jennifer Nowak	Biosimilars Forum (Holland & Knight)
		John Pakulski	GPhA Biosimilars Council (Mylan)
		Juliana Reed	Biosimilars Forum (Coherus)
		Julie Zawisza	BIO (Baxalta)

FDA and Industry Perspectives on Meeting Management Proposals

FDA began the discussion by providing a response to industry's previous proposals related to meeting management that were presented during the April 7 negotiations meeting. FDA and industry discussed the Agency's counterproposals and came to a provisional agreement on the meeting management proposals, including a timeline for FDA to provide a preliminary response to sponsors in advance of Type 2 and Type 3 meetings; an adjusted timeline for Biosimilar Initial Advisory meetings and Type 2 meetings; an option for a written-response-only in lieu of a face-to-face meeting with FDA; and expansion of the scope of the FDA draft guidance on *Best Practices for Communication Between IND Sponsors and FDA During Drug Development* to include biosimilar biological product development. FDA agreed to draft commitment letter language for these meeting management proposals for consideration at a later meeting.

FDA and Industry Follow-up on Previously Presented Proposals

FDA and industry revisited several proposals that were presented during prior meetings. The FDA reviewed its proposal originally presented during the March 17 negotiation meeting for the extension of the review goal date when facilities are not adequately listed in an application or supplement, which hinders FDA's ability to schedule necessary inspections prior to approval. Industry expressed tentative acceptance of this FDA proposal. FDA then conveyed tentative acceptance of an industry proposal to review post-approval Manufacturing Supplements within 4-months of receipt with a specified phase-in of this goal in BSUFA II.

FDA also provided its views on industry's proposal to initiate a process to clarify its regulatory definition of a biological product. FDA indicated that it did not consider the biosimilar user fee commitment letter to be the most appropriate vehicle for consideration of this modification to regulations, particularly considering that such modification would impact products beyond 351(k)s.

FDA and industry then discussed other industry proposals related to inspection reporting and maintenance of the Purple Book without reaching conclusions on these proposals, and agreed to discuss these proposals further at a subsequent meeting.

In addition, in follow up to an earlier discussion of industry administrative proposals, industry agreed to develop draft commitment letter language for its proposals related to guidance development for FDA's consideration.

Industry Perspectives on a Review Program for Biosimilars

FDA and industry discussed industry's feedback on a previous proposal made by the FDA for a Biosimilar Program review model. Industry requested additional information on how the Program review model, originally developed in the context of New Molecular Entity and 351(a) BLA review under PDUFA, would be tailored specifically to BsUFA 351(k) BLAs, including possible discussion topics for sponsor-FDA meetings, and how more frequent communication will benefit sponsors. FDA agreed to provide some examples of the specific types of interactions industry could expect to have with FDA under the model prior to the next meeting.

Plan for Future Meetings

The goal for the BsUFA steering committee on April 21, 2016 will be for FDA to provide an overview of the BsUFA hiring plan for fiscal years 2016 and 2017, and to provide its perspective on a proposed dedicated biosimilar unit, and for FDA and industry to discuss draft commitment letter language.

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