FDA-Industry BsUFA Reauthorization Steering Committee Meeting
May 12, 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 discuss industry and FDA feedback on draft commitment letter language.

Participants

FDA		Industry	
Michelle Adams	CDER	David Ceryak	BIO (Eli Lilly)
Mark Ascione	CDER	Hillel Cohen	Biosimilars Forum (Sandoz)
Josh Barton	CDER	Andrew Emmett	PhRMA (Pfizer)
Leah Christl	CDER	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	Bruce Leicher	GPhA Biosimilars Council (Momenta)
Neel Patel	CDER	Michael Levy	PhRMA
Amanda Roache	CDER	Scott McGoohan	BIO
Graham Thompson	CDER	John Pakulski	GPhA Biosimilars Council (Mylan)
		Juliana Reed	Biosimilars Forum (Coherus)
		Michael Werner	Biosimilars Forum (Holland & Knight)
		Julie Zawisza	BIO (Baxalta)

Biosimilar Program Review Model

FDA presented its feedback to industry's comments to the draft commitment letter language originally drafted by FDA to establish a review model similar to "the Program" initiated for new drugs under the Prescription Drug User Fee Act (PDUFA) V commitment letter. Additional edits to the text were discussed that included changes to the section on the 74-day letter, the late cycle meeting, and the assessment of the Program.

Meeting Management

FDA and industry discussed the proposal to establish a Written Response Only (WRO) option for certain FDA-sponsor meetings. FDA reiterated its preferred approach to allow the Agency to respond to meeting requests in writing instead of a face-to-face meeting when the questions posed by the sponsor can be sufficiently answered in writing. FDA explained that this allowed the agency to manage its meeting workload appropriately across multiple drug and biologic review programs while still providing advice to sponsors on their development programs. FDA stated that the agency's alternative to managing the BsUFA meeting workload would be to deny more meeting requests. FDA maintained that

using a similar approach for WRO as is currently used under PDUFA would minimize administrative burden and allow for a more efficient process since the same review divisions manage both innovator and biosimilar products. Industry maintained its view that only the sponsor should be able to determine the format of the meeting and proposed that meeting requests comprise one of three options as requested by the sponsor: a face-to-face meeting, a written response, or either. FDA and industry agreed to discuss the WRO proposal further at the next meeting.

Dedicated Biosimilar Unit

Industry provided feedback and asked clarifying questions about FDA's proposal to establish a dedicated biosimilars unit. FDA explained that the new unit would function to consolidate the activities of the program and maintain the program's integrity as it continues to grow. Industry requested further information on how the unit would be structured, and stated that further feedback would have to wait until staffing and financial details of the proposal were discussed with the finance subcommittee.

Other Proposals

Industry expressed agreement with FDA's edits to the draft commitment letter language related to new guidance development. Additionally, industry indicated that it would provide further information on its proposal to update the Purple Book at a later time.

Plan for Future Meetings

Industry and FDA agreed to meet on May 18th and May 19th to continue to develop and revise the draft commitment letter language for BsUFA II.

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