FDA-Industry BsUFA Reauthorization
Steering Committee Meeting
April 7, 2016, 1:15pm-2:45pm
FDA White Oak Campus, Silver Spring, MD
Building 52/72, Room 1100

Purpose

The purpose of the meeting was to review several proposals that were presented by industry during the initial meeting on March 17 in more detail and to obtain additional perspective from industry on meeting management proposals.

Participants

FDA		Industry	
Michelle Adams	OC	David Ceryak	BIO (Eli Lilly)
Josh Barton	CDER	Hillel Cohen	Biosimilars Forum (Sandoz)
Leah Christl	CDER	Andrew Emmett	PhRMA (Pfizer)
Joseph Franklin	OC	Jeffrey Francer	PhRMA
Patrick Frey	CDER	David Gaugh	GPhA Biosimilars Council
John Jenkins	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	Carolyn Huntenburg	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)
		Michael Werner	Biosimilars Forum (Holland & Knight)
		Julie Zawisza	BIO (Baxalta)

Discussion of Industry Proposals

The industry parties provided more detail on a number of industry proposals introduced in previous meetings, including a measure to initiate a process to clarify the regulatory definition of a biological product, as well as the desire for several guidance documents to be developed. The FDA noted that many guidance documents were already under development and more are planned as listed under the 2016 CDER Guidance Agenda but that FDA would consider what guidance development goals may apply within the timeframe of BsUFA II.

Industry expressed a desire to establish a performance goal for timely action on reference product exclusivity determinations for instances when a sponsor of a BLA submitted under section 351(a) of the PHS Act elects to submit information relevant to the exclusivity determination to the FDA. The FDA expressed concerns about the scope of the proposal and whether it would fall within the process for the review of biosimilar applications and thus within the scope of the negotiations. Industry also proposed enhancements to the revision and maintenance of the Purple Book, and following FDA discussion of the

feasibility of the enhancement as originally proposed, industry agreed to further consider how the proposal might be revised for discussion at a later date.

Industry also discussed a proposal for agency annual reporting of the number of inspections for facilities that manufacture biological products, in the US or overseas. FDA noted that such reporting was not done as part of other drug user fee commitments and noted that information about inspection of drug manufacturing facilities was already available on the FDA website.

Industry Perspectives on Meeting Management Enhancements

Industry presented an updated proposal for meeting management enhancements following the discussion held during the March 24 negotiations meeting. The proposal included views on a new BsUFA II timeline for each type of sponsor-FDA meeting and included a decreased time for the FDA to grant meetings, a goal for FDA to provide preliminary responses 5 days in advance of a meeting, and a process to address clarifying questions. FDA stated that a shortened time frame to review the background package prior to FDA-sponsor meetings may hinder the FDA's ability to provide advice to sponsors during meetings. Additionally, FDA noted that in some instances novel issues are being considered and that reducing the amount of time the Agency has to review the background package would not allow adequate time for consideration of such issues. Furthermore, the Agency explained that draft guidance currently exists for sponsors to obtain answers to clarifying questions following a meeting and that these practices can also be applied for meetings associated with the Biosimilar Development Program. It was agreed by FDA and industry that the meeting management proposals would be further discussed at a later meeting.

Plan for Future Meetings

The goal for the BsUFA steering committee on April 14, 2016 will be to obtain additional perspectives from industry on the biosimilar review program proposal that was discussed on March 31, and to further review proposals related to meeting management and pre-approval inspections.

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