FDA-Industry BsUFA Reauthorization Negotiation Meeting
March 17, 2016, 1:00pm-4:00pm
FDA White Oak Campus, Silver Spring, MD
Building 52/72, Room 2100

Purpose

- To agree on negotiation ground rules and proposed time line.
- To provide FDA and industry perspectives on BsUFA enhancements.

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

Overview of Reauthorization Process

To facilitate the planning and scheduling of future discussions, FDA began by providing an overview of the statutory provisions for the BsUFA reauthorization process, and presented a proposed timeline for the completion of FDA-industry negotiations. The industry parties provided an estimate of the time needed for their respective organizations to review a draft package of proposed recommendations following the face-to-face negotiations, to further inform the development of a timeline for future discussions.

Ground Rules for Negotiations

The ground rules governing the BsUFA reauthorization negotiations were discussed. FDA proposed that all parties would present all enhancement proposals by no later than the March 24, 2016 negotiation meeting. It was acknowledged that the more detailed discussion surrounding any of the original high-level proposals may warrant introduction of new components under such proposals at a later date. All parties agreed to the set of ground rules as proposed by FDA.

FDA Perspectives on Reauthorization

FDA provided a high-level overview of its experiences during the first three years of BsUFA. This included a discussion of the Biologics Price Competition and Innovation Act (BPCI Act) and background on the range of offices engaged in the review of biosimilars. FDA highlighted the novel and complex nature of

issues involved with biosimilar product development from a technical perspective. FDA also noted that the challenges associated with this novelty and complexities were compounded by a greater than expected biosimilar-related workload.

FDA then highlighted its goals for BsUFA II reauthorization, which include a negotiation process that supports timely reauthorization; enhancements to capacity and coordination of review for biosimilars; enhancements to biosimilar review process communication, consistency and efficiency; and, financial stability for the biosimilar review process with predictability for the FDA and fee-payers. FDA briefly summarized each of its specific proposals supporting to these goals.

Industry Perspectives on Reauthorization
Industry representatives communicated their goals for BsUFA reauthorization and each industry organization provided an overview of their enhancement proposals.

BIO and PhRMA jointly presented their goals for BsUFA II enhancements, including science-based implementation of the Biologics Price Competition and Innovation Act; an efficient and transparent regulatory process with appropriate timelines, guidance, and feedback to sponsors; and long-term stability of the BsUFA program through transparent and sustainable financing.

The Biosimilars Forum presented their perspective on the reauthorization and included support for the proposals mentioned by the other parties in addition to measures to enhance the soundness and sustainability of the financing model, enhancement to the exchange of information, and procedural enhancements.

The GPhA Biosimilars Council presented their views on the BsUFA reauthorization and provided an overview of their enhancement proposals in the areas of meeting management, meeting performance, application review, policy, fees, education, and other.

FDA requested that the industry parties work to coordinate their enhancement proposals to develop a unified set to the extent possible to facilitate FDA-industry discussions in future meetings in these negotiations.

Plan for Future Meetings
The goal for the next meeting on March 24, 2016 will be to review the BsUFA user fee finances and to have more detailed discussion of FDA and industry proposals related to meeting management topics.

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