FDA-Industry BsUFA Reauthorization Negotiation Meeting
March 24, 2016, 1:00pm-5:00pm
FDA White Oak Campus, Silver Spring, MD
Building 52/72, Room 3100

Purpose

- To discuss FDA and industry interests in financial enhancements for the BsUFA II reauthorization.
- To provide FDA and industry perspectives on BsUFA meeting management enhancements and plan for the discussions for future meetings.

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	Kim Greco	PhRMA (Amgen)
Patrick Frey	CDER	Sascha Haverfield	PhRMA
Christopher Joneckis	CBER	Kay Holcombe	BIO
Andrew Kish	CDER	Bruce Leicher	GPhA Biosimilars Council (Momenta)
Theresa Mullin	CDER	Scott McGoohan	BIO
Neel Patel	CDER	Jennifer Nowak	Biosimilars Forum (Holland & Knight)
Vada Perkins	CBER	John Pakulski	GPhA Biosimilars Council (Mylan)
Amanda Roache	CDER	Michael Werner	Biosimilars Forum (Holland & Knight)
Graham Thompson	CDER	Julie Zawisza	BIO (Baxalta)

Overview of the BsUFA Fee Structure and Finances

The FDA highlighted that its financial goals for the BsUFA II reauthorization are to ensure stable, predictable funding for the biosimilar review process and ensure predictability in user fee amounts for fee-payers.

FDA and industry reviewed the BsUFA I fee structure, which refers to the PDUFA V fees to determine biosimilar user fee amounts. The FDA noted that referencing PDUFA fees, without a target level of fee revenues for BsUFA, creates challenges for the biosimilar review program because it doesn't provide FDA with predictable funding levels from year to year. This is not such a problem for other drug user fee programs such as GDUFA and PDUFA because, under their respective statutory provisions, target fee revenue amounts are determined for each fiscal year.

FDA noted that the requirement that the Agency spend a minimum of $20 million in non-user fee appropriations (herein referred to as budget authority), adjusted for inflation, to meet the statutory "trigger" to enable FDA to spend user fees collected that fiscal year hinders FDA's ability to spend collected user fees each fiscal year. FDA reviewed the events that created constraints on existing

budget authority since FY 2013, including sequestration and continuing resolutions, as well as present operational challenges in meeting this spending trigger provision each fiscal year. FDA also noted that the BsUFA spending trigger as a percentage of total program obligations is proportionally much higher than the statutory spending triggers for GDUFA and PDUFA.

In addition to the discussion related to funding, FDA presented an estimate of potential future biosimilar review workload for the agency. The FDA and Industry reviewed FDA's preliminary estimate of biosimilars development programs and submissions and corresponding workload for the remaining years of BsUFA I (FY 2016-17) as well as BsUFA II (FY2018-22). FDA noted that the role of the estimate is to help anticipate BsUFA II resource capacity needs and help FDA and Industry identify adequate funding levels for BsUFA II.

FDA and Industry agreed to form a financial subgroup that will continue to pursue future BSUFA II financial discussions and that the group will report to the negotiations steering committee.

Industry Perspectives on Meeting Management

Each industry organization presented an overview of their meeting management enhancement proposals.

The Biosimilars Forum provided their perspective on FDA's meeting management proposals and discussed their proposed enhancements. The Forum expressed acceptance for FDA proposals to create a written response option for Biosimilar Initial Advisory (BIA) and Biosimilar Product Development Type 2 (BPD Type 2) meeting requests and to adjust the timeframe for holding BIA meetings. The Forum expressed their desire to maintain the existing scheduling goal date for BPD Type 2 meetings. The Forum then provided their view on meeting management enhancements, which included providing timely pre-meeting correspondence, increasing the ability of sponsors to engage with the Agency in post-meeting communication, and developing a mechanism for binding agreement on analytical and nonclinical study designs.

The GPhA Biosimilars Council discussed FDA's proposals and presented their enhancement proposals. The Council expressed support for FDA's proposals on written response options and scheduling for BIA meetings. The Council also expressed their desire to maintain the existing goal date of 75 days for BPD Type 2 meetings. The Council's proposals were similar to the Biosimilars Forum, including updates to pre- and post-meeting communications with FDA, and how FDA addresses analytical and nonclinical studies.

BIO and PhRMA jointly presented their goals for meeting management enhancements, and laid out their guiding principles for BsUFA reauthorization, including assuring appropriate implementation of the Biosimilar Price Competition and Innovation Act, increasing the clarity and timeliness of discussions following Agency feedback, and issuing and finalizing guidance documents.

FDA Perspectives on Meeting Management

The FDA provided feedback on industry proposals as well as clarity on FDA proposals addressing meeting management enhancements. FDA emphasized the need to update the timeframe for holding BPD Type 2 meetings. FDA discussed its proposal to extend the scope of the draft guidance on Best Practices for Communication Between IND Sponsors and FDA During Drug Development to biosimilars; this draft guidance was developed to meet a PDUFA V goal and addresses issues related to requesting and

obtaining feedback to inquiries during product development including post-meeting communication with FDA. FDA also addressed industry proposals on binding agreements for analytical and nonclinical studies, expressing concern over limiting flexibility for sponsors and the Agency.

The industry parties expressed that they would need to consider FDA's proposals further and would provide additional perspective at a later meeting.

Plan for Future Meetings

The goal for the BsUFA steering committee on March 31, 2016 will be to have a more detailed discussion of FDA and industry proposals related to application review topics. Additionally, the finance subcommittee meeting will be to discuss industry feedback on the BsUFA submission forecast and begin discussion of the cost model structure during the meeting on March 31.

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