FDA-Industry BsUFA II Reauthorization Negotiation Meeting
Finance Sub-group
April 7, 2016, 3:00pm-5:00pm
FDA White Oak Campus, Silver Spring, MD
Building 52/72, Room 2100

Purpose

To discuss financial enhancements for BsUFA II reauthorization including the BsUFA spending provision and the BsUFA II user fee structure.

Participants

FDA		Industry	
Mark Ascione	CDER	David Gaugh	GPhA Biosimilars Council
Josh Barton	CDER	Sascha Haverfield	PhRMA
Yanming Chae	CBER	Mark Hendrickson	GPhA Biosimilars Council
Leah Christl	CDER	Kay Holcombe	BIO
Joseph Franklin	OC	Stacy Holdsworth	PhRMA (Eli Lilly)
Azada Hafiz	CDER	Scott McGoohan	BIO
Kirk Kerr	CDER	John Pakulski	GPhA Biosimilars Council (Mylan)
Andrew Kish	CDER		
Robert Marcarelli	OC		
Amanda Roache	CDER		

BsUFA Spending Provision

FDA provided an overview of the BsUFA spending provision that requires FDA to allocate no less than $20 million, adjusted for inflation, in non-user fee funding each fiscal year in order for FDA to spend user fees to defray costs of the process for the review of biosimilar biological products for that fiscal year. (This requirement is referred to below as the "spending trigger.") FDA provided their perspective on the operational implications of the spending trigger and a history of how the provision has worked for other user fee programs. FDA explained that the spending trigger for other user fee programs such as the Prescription Drug User Fee Program (PDUFA) and Generic Drug User Fee Program (GDUFA) allows for flexibility to underspend the spending trigger amount by a certain percentage and still be compliant with the provision. This flexibility provides the Agency more certainty that it can allocate sufficient non-user fee funds to meet the spending trigger, especially during times of fiscal austerity measures. FDA explained that no such flexibility exists for the BsUFA program. Additionally, FDA pointed out that the proportion of the trigger amount to total program costs for BsUFA is considerably higher than for PDUFA and GDUFA.

The Agency highlighted that uncertainty around meeting the trigger provision is restricting its ability to expend BsUFA resources and hinders its ability to build organizational capacity. FDA and industry agreed to discuss options for the BsUFA trigger provision in a future meeting.

BsUFA II User Fee Structure

FDA stated one of its financial goals for BsUFA II is to establish an independent user fee structure and fee amounts based on BsUFA program costs and to ensure stable, predictable user fee funding for the BsUFA program. FDA shared a proposed user fee structure model for BsUFA II. Industry agreed to review FDA's proposal and provide feedback in a future meeting. FDA and industry agreed to continue discussing the BsUFA II user fee structure in a future meeting.

Plan for Future Meetings

The goal for the next meeting on April 14, 2016 will be to discuss the user fee structure and the product fee.

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