FDA-Industry BsUFA II Reauthorization Negotiation Meeting
Finance Sub-group
April 21, 2016, 3:00pm-5:00pm
FDA White Oak Campus, Silver Spring, MD
Building 52/72, Room 3100

Purpose

To continue discussing financial enhancements for BsUFA II including the BsUFA spending provision and the user fee structure.

Participants

FDA		Industry	
Mark Ascione	CDER	Tiffany Fletcher	Biosimilars Forum (Sandoz)
Josh Barton	CDER	Sascha Haverfield	PhRMA
Yanming Chae	CBER	Mark Hendrickson	GPhA Biosimilars Council
Joseph Franklin	OC	Kay Holcombe	BIO
Azada Hafiz	CDER	Stacy Holdsworth	PhRMA (Eli Lilly)
Andrew Kish	CDER	Bruce Leicher	GPhA Biosimilars Council (Momenta)
Robert Marcarelli	OC	Scott McGoohan	BIO
Theresa Mullin	CDER	John Pakulski	GPhA Biosimilars Council (Mylan)
Amanda Roache	CDER	Juliana Reed	Biosimilars Forum (Coherus)
James Tyler	OC	Michael Werner	Biosimilars Forum (Holland & Knight)

BsUFA Spending Provision and User Fee Structure

FDA and industry continued to discuss options for modifying the spending trigger including by incorporating the flexibility to underspend by a certain percentage, relative to the specified amount, and still be compliant with the legal requirements of the BsUFA spending trigger. As FDA reiterated, this flexibility would provide the Agency more certainty that it can meet the spending trigger each fiscal year, which would allow FDA to spend collected user fees to build needed biosimilar program staff capacity. Industry expressed the need for FDA to expend collected BsUFA user fees to build organizational capacity for the BsUFA program during BsUFA I. Industry expressed the need for FDA to develop a capacity planning function and modernize time reporting to enhance BsUFA resource management. FDA and industry agreed to continue discussing capacity planning and time reporting in a future meeting.

FDA and industry continued to discuss FDA's proposed BsUFA II user fee structure. FDA emphasized the need for a user fee structure that provides the Agency the flexibility to make annual adjustments to the target allocation to mitigate volatility in funding and fee amounts because of volatility in the number of fee paying submissions. Industry requested FDA demonstrate the impact of the proposed annual adjustments to the fees under certain fee paying submission scenarios. FDA agreed to provide the requested analysis at a future meeting.

Plan for Future Meetings

The goal for the next meeting on April 28, 2016 will be to have a more detailed discussion of the user fee structure.

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