FDA-Industry BsUFA II Reauthorization Negotiation Meeting
Finance Sub-group
April 14, 2016, 3:00pm-5:00pm
FDA White Oak Campus, Silver Spring, MD
Building 52/72, Room 3100

Purpose

To continue the discussion on financial enhancements for BsUFA II including the BsUFA spending provision and the 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
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
Amanda Roache	CDER	Jennifer Nowak	Biosimilars Forum (Holland & Knight)
		John Pakulski	GPhA Biosimilars Council (Mylan)
		Juliana Reed	Biosimilars Forum (Coherus)

BsUFA II Spending Provision and User Fee Structure

FDA continued to discuss its challenges in accessing BsUFA user fee funds due to the BsUFA statutory provision ("spending trigger") 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.

FDA reiterated that the statutory spending triggers of other user fee programs, such as PDUFA and GDUFA, provide FDA flexibility to underspend by a certain percentage, relative to the specified amounts, while still being compliant with the requirements of the respective spending triggers. FDA discussed the need for this flexibility in the BsUFA program to provide the Agency more certainty that it can meet the spending trigger and spend user fees on the BsUFA program in a given fiscal year, especially during times of fiscal austerity measures.

FDA and industry discussed options for enhancing the spending trigger provision. FDA and industry continued to discuss FDA's proposed user fee structure.

Plan for Future Meetings

The goal for the next meeting on April 21, 2016 will be to continue discussion of the BsUFA spending provision and user fee structure.

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