Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup | Minutes

October 7, 2020 | 10:00am-12:00pm

Virtual Format (Zoom)

PARTICIPANTS

FDA		Industry	
Josh Barton	CDER	E. Cartier Esham	BIO
Yanming Chae	CBER	Carl Garner	PhRMA (Eli Lilly)
Angela Granum	CBER	Brad Glasscock	BIO (BioMarin)
Bharat Khanna	CDER	Kelly Goldberg	PhRMA
Ted Liazos	OC	Ann Kurowski	BIO (Alkermes)
Alison Lyndaker	CDER	Kristy Lupejkis	PhRMA
Robert Marcarelli	OO	Mark Taisey	PhRMA (Amgen)
		Lucy Vereshchagina	PhRMA

MEETING SUMMARY

FDA Questions from Kickoff on Industry Proposals
Industry addressed clarifying questions around their financial reform implementation plan, the updates to the 5-year plan, and the 3rd party assessment proposals.

Operating Reserve Adjustment
FDA presented its understanding of a combined proposal incorporating Industry and FDA perspectives on the need to clarify both the maximum and minimum amount of operating reserves to be maintained each fiscal year. Industry asked clarifying questions and then both sides agreed to further discuss this proposal in the subsequent meeting.

Resource Capacity Planning
The goal of this proposal is to further the implementation of the Resource Capacity Planning (RCP) capability in PDUFA VI. FDA intends to enhance its analytical infrastructure, integrate RCP data into budget and resource planning and execution processes, and continually improve the RCP capability. The discussion focused on the approach for achieving these goals and the current progress to date. Industry and FDA agreed to follow up on questions around current methodologies in an upcoming meeting.

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