Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup | Minutes

October 28, 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

Performance Reporting Proposals
FDA presented its annual reporting proposals. The goals of these proposals are to streamline annual reporting and to expedite the availability of core performance and financial data to stakeholders. These proposals will be discussed further at a subsequent meeting.

Resource Capacity Planning
FDA addressed clarifying questions on Resource Capacity Planning (RCP). Industry and FDA discussed the scope of work included in the Capacity Planning Adjustment and clarified the difference from the Inflation Adjustment proposal. These proposals will be discussed further at a subsequent meeting.

Health of the Workforce Proposal
FDA and Industry agreed to discuss the guiding principles for potential metrics describing the health of the workforce at a subsequent meeting.

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