Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup | Minutes

October 14, 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

Operating Reserve Adjustment
Industry and FDA agreed in principle at the subgroup level to recommend clarifying both the maximum and minimum amount of operating reserves to be maintained each fiscal year.

Financial Reform Implementation Plan
Industry and FDA continued discussions about Industry's proposal to enhance the management of PDUFA programmatic resources, including addressing the next phase of the financial reforms that began in PDUFA VI. FDA noted that the scope and definition of "financial reforms" here appeared to be scoped to how FDA will continue to implement and utilize resource capacity planning. Industry confirmed this. FDA agreed to review this proposal and discuss further in subsequent meetings.

Limitation on Allowable Expenses
FDA presented its proposal regarding a limitation on certain allowable expenses that would become effective on October 1, 2023. The goal of this proposal is to avoid adverse impacts on the program by maintaining the status quo since PDUFA I regarding the allowable costs of the PDUFA program. Industry and FDA agreed to review this request again in a subsequent meeting.

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