



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup | Minutes

November 4, 2020 | 10:00am-12:00pm

Virtual Format (Zoom)

PARTICIPANTS

FDA

Josh Barton	CDER
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Industry

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Brad Glasscock	BIO (BioMarin)
Kelly Goldberg	PhRMA
Ann Kurowski	BIO (Alkermes)
Kristy Lupejkis	PhRMA
Mark Taisey	PhRMA (Amgen)
Lucy Vereshchagina	PhRMA

MEETING SUMMARY

Health of the Workforce Discussion

FDA and Industry discussed a proposal to develop metrics to describe the status of the PDUFA workforce and gaps in staffing, and that could help identify barriers to realizing staffing requirements. FDA and Industry discussed their perspectives on guiding principles for such metrics. This proposal will be discussed further at a subsequent meeting.

Inflation Adjustment Assumptions

Industry presented its analysis on the impact of the Inflation Adjustment proposal for FDA review. FDA and Industry discussed factors which could impact the proposal. FDA will present its assessment of the impact in a subsequent meeting.

Resource Capacity Planning Related Topics

FDA and Industry agree that there is initial alignment on the Resource Capacity Planning-related proposals. FDA will bring proposed commitment language to a subsequent meeting.

Performance Reporting Proposals

Industry provided initial comments on the annual reporting proposals for FDA response. These proposals will be discussed further at a subsequent meeting.

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