

Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup | Minutes

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Virtual Format (Zoom)

PARTICIPANTS

FDA

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Industry

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Ann Kurowski	BIO (Alkermes)
Kristy Lupejkis	PhRMA
Stephen Mason	Greenleaf Health
Mark Taisey	PhRMA (Amgen)
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MEETING SUMMARY

Resource Capacity Planning

FDA and Industry agreed at the subgroup level on this proposal. The proposal would commit FDA to publishing an implementation plan describing the further maturation of the resource capacity planning capability over the course of PDUFA VII.

RCP 3rd Party Study

FDA and Industry agreed at the subgroup level on this proposal. The proposal would commit FDA to commissioning a third-party assessment of the resource capacity planning capability during PDUFA VII.

Continuation of Financial Transparency Initiatives

FDA and Industry reviewed the commitment letter updates for the continuation of the PDUFA VI financial transparency initiatives during PDUFA VII.

Inflation Adjustment

Industry expressed concerns about the potential long-term financial impacts of changing the inflation adjustment. Industry confirmed they are committed to helping ensure the ability of the PDUFA program to support its strategic hiring and retention needs and suggested considering alternative approaches to doing so. FDA and Industry agreed to explore other approaches in subsequent meetings.

Performance and Financial Reporting

FDA answered Industry questions on the proposed commitment letter language and statutory updates for the FDA's annual reporting proposals. Industry indicated it would like to revisit this proposal in a subsequent meeting.

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