



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup | Minutes

February 3, 2021 | 10:00am-12:00pm

Virtual Format (Zoom)

PARTICIPANTS

FDA

Josh Barton	CDER
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Angela Granum	CBER
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Industry

E. Cartier Esham	BIO
Carl Garner	PhRMA (Eli Lilly)
Brad Glasscock	BIO (BioMarin)
Kelly Goldberg	PhRMA
Ann Kurowski	BIO (Alkermes)
Kristy Lupejkis	PhRMA
Stephen Mason	Greenleaf Health
Lucy Vereshchagina	PhRMA

MEETING SUMMARY

Finance Draft Commitment Letter Language

FDA and Industry reviewed the draft commitment language. FDA addressed Industry edits and comments. FDA and Industry agreed to address any additional feedback as needed.

Inflation Adjustment / Strategic Hiring and Retention

FDA and Industry discussed the proposed approach to support the strategic hiring and retention needs of the PDUFA program. FDA will provide proposed draft Statutory and Commitment Letter language for Industry to review.

Fee Impact Estimates

FDA and Industry discussed approaches to phasing in hiring at the start of PDUFA VII. FDA answered Industry questions clarifying the preparations to increase hires and the potential impact on fees.

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