



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup | Minutes

January 13, 2021 | 10:00am-12:00pm

Virtual Format (Zoom)

PARTICIPANTS

FDA

Josh Barton	CDER
Yanming Chae	CBER
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
Mark Taisey	PhRMA (Amgen)
Lucy Vereshchagina	PhRMA

MEETING SUMMARY

Inflation Adjustment / Strategic Hiring and Retention

FDA and Industry continued discussions of approaches to support the strategic hiring and retention needs of the PDUFA program. FDA and Industry discussed options for how this could work within the existing annual revenue setting process. FDA agreed to provide additional detail on the projected need for the next meeting.

Financial Transparency

FDA and Industry reviewed the draft commitment letter language regarding continued financial transparency initiatives. The group will continue to discuss this topic in the next meeting.

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