



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup | Minutes

January 27, 2021 | 10:00am-12:00pm

Virtual Format (Zoom)

PARTICIPANTS

FDA

Josh Barton	CDER
Yanming Chae	CBER
Angela Granum	CBER
Bharat Khanna	CDER
Ted Liazos	OC
Alison Lyndaker	CDER
Robert Marcarelli	OO
Patrick Zhou	CDER

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 and reached tentative agreement on the approach. FDA agreed to provide draft commitment language for the next meeting.

At this point, both sides agreed to take a 45 minute break due to a conflict for some negotiating members.

Fee Impact Estimates

FDA and Industry addressed a potential approach to 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.