



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup | Minutes

January 6, 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
Mark Taisey	PhRMA (Amgen)
Lucy Vereshchagina	PhRMA

MEETING SUMMARY

PDUFA VII Information Request

FDA presented the cost model for a fully loaded full-time employee (FTE) and addressed Industry questions.

Inflation Adjustment / Strategic Hiring and Retention

FDA and Industry continued discussion regarding FDA’s inflation adjustment proposal. FDA and Industry discussed other potential options to ensure the ability of the PDUFA program to support its strategic hiring and retention needs. FDA and Industry agreed to further assess these options and discuss in future meetings.

Streamline Reporting

Industry agreed to make a minor adjustment to the reporting of performance goals relating to resubmissions. Industry indicated it could not agree to FDA’s proposed changes to reporting requirements in the annual Performance Report.

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