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
Bharat Khanna  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. 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.