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
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Industry
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Carl Garner    PhRMA (Eli Lilly)
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Kelly Goldberg PhRMA
Ann Kurowski  BIO (Alkermes)
Kristy Lupejklis 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.