

Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry CBER Breakout Subgroup | Meeting Summary

November 17th, 2020 | 10:00am-12:00pm

Virtual Format (Zoom)

PURPOSE

To discuss FDA and industry CBER specific enhancement proposals.

PARTICIPANTS

FDA

Rachael Anatol	CBER
Angela Granum	CBER
Chris Joneckis (FDA Lead)	CBER
Bharat Khanna	CDER
Erik Laughner	CBER
Darlene Martin	CBER
Carol Rehkopf	CBER

Industry

E. Cartier Esham	BIO
Brad Glasscock (Lead)	BIO (BioMarin)
Mathias Hukkelhoven	PhRMA (BMS)
Robert Kowalski (Co-Lead)	PhRMA (Novartis)
Heidi Marchand	BIO (Gilead and Kite)
Lucy Vereshchagina	PhRMA

The PDUFA VII CBER Breakout subgroup discussion focused on refinement of draft commitment language.

Industry Proposals

FDA and Industry discussed further refinement of the proposed commitment language for each of Industry's proposals including: Patient Focused Drug Development, Leveraging Knowledge, Evidentiary Standards, and Update of FDA Guidance for Industry for RMAT. Discussion will continue in future negotiation meetings.

Other Proposals

Clarification was provided that the Cell and Gene Therapy Program (CGTP) proposal does not overlap with any Digital Health Proposals, including the CBER IT Modernization Proposal. The CBER IT Modernization Proposal does support CBER PDUFA products and is critical to ensuring success of the CGTP.

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