Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry CBER Breakout Subgroup | Meeting Summary

January 26th, 2021 | 10:00am-12:00pm

Virtual Format (Zoom)

PURPOSE

To discuss FDA and industry CBER specific enhancement proposals.

PARTICIPANTS

FDA		Industry	
Rachael Anatol	CBER	E. Cartier Esham	BIO
Angela Granum	CBER	Brad Glasscock (Lead)	BIO (BioMarin)
Chris Joneckis (FDA Lead)	CBER	Mathias Hukkelhoven	PhRMA (BMS)
Bharat Khanna	CDER	Robert Kowalski (Co-Lead)	PhRMA (Novartis)
Erik Laughner	CBER	Heidi Marchand	BIO (Gilead and Kite)
Darlene Martin	CBER	Lucy Vereshchagina	PhRMA
Carol Rehkopf	CBER		

The PDUFA VII CBER Breakout subgroup discussion focused on the commitment language and resource estimates for the CBER and Industry proposals related to the Cell and Gene Therapy (CGT) Program.

Resource Estimates

FDA and Industry discussed revisions to the commitment language for the CGT related proposals. The cadence of hiring of new resources across PDUFA VII to support the CGT program was discussed. Additional refining of the commitment language will continue as needed.

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