Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry CBER Breakout Subgroup | Meeting Summary

January 12th, 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 resource estimates for the CBER and Industry proposals related to the Cell and Gene Therapy (CGT) Program.

Resource Estimates

FDA and Industry discussed questions and clarifications on the amount and timing of resource estimates for the recruitment, hiring, training, and integration of staff resources to support the CGT program. CBER resources requested to support PDUFA VII proposals in other subgroups were briefly discussed to ensure there was no duplication or overlap with the CGT requested resources. Discussion regarding the cadence of hiring of new resources will continue in future negotiation meetings.

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