Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry CBER Breakout Subgroup | Meeting Summary

December 1st, 2020 | 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 CBER's third party support request for the Cell and Gene Therapy Resource proposal and Industry's draft commitment language.

FDA Proposals

FDA and Industry discussed CBER's support requests to assist with recruitment, hiring, training, and integration of staff resources to support the CGT program. Discussion to refine and draft commitment language will continue in future negotiation meetings.

Industry Proposals

FDA and Industry discussed revisions of commitment language for each of Industry's proposals including: Patient Focused Drug Development, Leveraging Knowledge, Evidentiary Standards/Novel Approaches to Develop Cell and Gene Therapy Products, and Update of FDA Guidance for Industry for RMAT.

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