Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry CBER Breakout Subgroup | Meeting Summary

November 3rd, 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 revised resource estimates for FDA's Cell and Gene Therapy (CGT) Program and draft commitment language for Industry's Patient Focused Drug Development proposal.

Cell and Gene Therapies Revised Estimates

FDA and Industry discussed resource estimates for the CGT Program which were revised to account for future growth of the program. The model for forecasting growth adjustments was explained and discussed. Additional non-staffing resource needs, and the approach for hiring and training of new staff, were also discussed.

Patient Focused Drug Development

FDA and Industry continued discussions of the proposal and commitment language to hold a patient focused drug development meeting to better understand patient and caregiver's perspectives on gene therapy products. Additional discussion to refine the commitment language will continue in future negotiation meetings.

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