Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry CBER Breakout Subgroup | Meeting Summary

November 10th, 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 refinement of CBER's and Industry's proposals and draft commitment language.

Cell and Gene Therapies (CGT) Program Proposal

FDA and Industry discussed further refinement of resource estimates for the CGT Program proposal and responded to previously asked questions form Industry. Additional discussion to finalize resource estimates and commitment language will continue as needed in future negotiation meetings.

Allergenic Products Proposal

FDA provided Industry with a formal proposal for including certain allergenic extract products in the PDUFA program under PDUFA VII. FDA clarified aspects of its proposal in response to Industry questions. Industry will provide feedback at a future negotiation meeting.

Industry Proposals

FDA and Industry discussed questions and comments regarding each of Industry's proposals including: Patient Focused Drug Development, Leveraging Knowledge, Evidentiary Standards, and Update of FDA Guidance for RMAT. 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.