



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry CBER Breakout Subgroup | Meeting Summary

December 17th, 2020 | 3:00pm-4:00pm

Virtual Format (Zoom)

PURPOSE

To discuss FDA and industry CBER specific enhancement proposals.

PARTICIPANTS

FDA

Rachael Anatol CBER
Chris Joneckis (FDA Lead) CBER
Darlene Martin CBER

Industry

E. Cartier Esham BIO
Brad Glasscock (Lead) BIO (BioMarin)
Lucy Vereshchagina PhRMA

The PDUFA VII CBER Breakout subgroup discussion focused on revising commitment language for the FDA and Industry proposals to enhance CBER's capacity to support development and approval of cell and gene therapy products.

FDA and Industry Commitment Language

FDA and Industry discussed commitment language to include CBER's and Industry's proposals for the Cell and Gene Therapy Program (CGTP). Discussion focused on revisions of commitment language for the CGTP and Industry's proposals including: Patient Focused Drug Development, Leveraging Knowledge, Novel Approaches to Development of Cell and Gene Therapy, and Expedited Programs for the Development of Regenerative Medicine Therapies. Discussion regarding commitment language will continue in future negotiation meetings. Commitment language for inclusion of allergenics will be provided in the future.

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