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

Rachael Anatol  CBER
Angela Granum  CBER
Chris Joneckis (FDA Lead)  CBER
Bharat Khanna  CDER
Erik Laughner  CBER
Darlene Martin  CBER
Carol Rehkopf  CBER

Industry

E. Cartier Esham  BIO
Brad Glasscock (Lead)  BIO (BioMarin)
Mathias Hukkelhoven  PhRMA (BMS)
Robert Kowalski (Co-Lead)  PhRMA (Novartis)
Heidi Marchand  BIO (Gilead and Kite)
Lucy Vereshchagina  PhRMA

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.