Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Pre-market subgroup | Meeting Summary

September 30th, 2020 | 2:00pm-4:00pm

Virtual Format (Zoom)

PURPOSE

To introduce and address clarifying questions about FDA and Industry pre-market review process enhancement proposals.

PARTICIPANTS

FDA		Industry	
Chris Joneckis	CBER	E. Cartier Esham	BIO
Hylton Joffe	CDER	Brad Glasscock	BIO (BioMarin)
Alex May	CDER	Kelly Goldberg	PhRMA
Lubna Merchant	CDER	Mathias Hukkelhoven	PhRMA (BMS)
Mike Pacanowski	CDER	Heidi Marchand	BIO (Gilead and Kite)
J. Paul Phillips	CDER	Mark Taisey	PhRMA (Amgen)
Carolina Reese	CDER		
Carol Rehkopf	CBER		
Khushboo Sharma	CDER		
Jim Smith	CDER		
Peter Stein	CDER		
Mary Thanh Hai	CDER		

This was the first negotiation session for the PDUFA VII pre-market subgroup.

User Related Risk Analysis (URRA) and Human Factor (HF) Protocol Review

FDA and Industry discussed a proposal to extend the existing user fee timeline for review of HF protocols. The FDA indicated that the current timeline and user fee goal would be unsustainable in the future due to increased complexity and volume of HF protocol submissions and the requirement for cross-center collaboration within FDA.

FDA and Industry also discussed a companion proposal to create a user fee goal and timeline for review of URRA.

FDA and Industry agreed to continue discussion of these two companion proposals at the next negotiation session.

Advancing Development of Efficacy Endpoints for Rare Disease
FDA and Industry discussed a proposal for a pilot program that would provide additional interaction between FDA and Industry to facilitate development of rare disease clinical endpoints. Industry asked FDA to consider expanding the proposal to include programs beyond rare diseases, where similar challenges might exist.

FDA and Industry agreed to continue discussing this proposal at subsequent negotiation sessions.

Other
FDA and Industry agreed to discuss additional proposals on other topics not covered during this meeting, at subsequent negotiation sessions.

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