Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Pre-market subgroup | Meeting Summary

October 7th, 2020 | 1:00pm-4:00pm

Virtual Format (Zoom)

PURPOSE

To continue introducing and addressing clarifying questions about FDA and Industry pre-market review process enhancement proposals.

PARTICIPANTS

FDA		Industry	
Chris Joneckis	CBER	E. Cartier Esham	BIO
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)
Carol Rehkopf	CBER		
Khushboo Sharma	CDER		
Jim Smith	CDER		
Peter Stein	CDER		
Mary Thanh Hai	CDER		

At the second meeting of the PDUFA VII pre-market subgroup, FDA and Industry continued discussions about several proposals to enhance the review process.

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

As requested by Industry at the previous meeting, FDA provided additional data and information about current workload and activities related to regulatory submissions and formal meeting requests involving HF protocols. FDA also provided additional information on its proposal for the review of URRA. FDA and Industry agreed to continue discussing this proposal at subsequent negotiation sessions.

Bioinformatics Review Expertise

FDA and Industry discussed a proposal to enhance the Agency's expertise in various aspects of bioinformatics, including next generation sequencing (NGS) and computational biology, which should meet the needs of both CBER and CDER. FDA and Industry agreed to continue discussing this proposal at subsequent negotiation sessions.

FDA/Sponsor Interactions (Meeting Management)
Industry noted that PDUFA VI introduced several pilot programs involving more intensive interactions between FDA and Industry for certain types of products applications, and that more frequent and effective communication has benefited product development. Industry proposed to enhance collaboration between Sponsors and FDA throughout the drug development process and product lifecycle to support innovation. FDA and Industry agreed to continue discussing this proposal at subsequent negotiation sessions.

NME Milestones and PMRs/PMCs
Industry noted that inconsistency of communication practices during the marketing application review process results in late-stage negotiations on labeling, Post Marketing Requirements (PMRs)/Post Marketing Commitments (PMCs), and pediatric plans. Industry proposed several mechanisms to mitigate this challenge. FDA and Industry agreed to continue discussing this proposal at subsequent negotiation sessions.

Medical Product Information
Industry discussed a proposal to modernize the content, format, and delivery of medical product information to enhance accuracy and availability for both patients and providers. FDA and Industry agreed to continue discussing this proposal at subsequent negotiation sessions.

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