Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Pre-market subgroup | Meeting Summary

October 28th, 2020 | 1:00pm-3:30pm

Virtual Format (Zoom)

PURPOSE

To continue discussion about FDA and Industry pre-market review process enhancement proposals.

PARTICIPANTS

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

At the fifth meeting of the PDUFA VII pre-market subgroup, FDA and Industry continued discussions about FDA and Industry proposals to enhance the review process. After addressing each topic noted below, both sides agreed to further exploration of each proposal and preparation of responses to questions raised.

Innovative Review Approaches

FDA and Industry continued discussions about a proposal to bring the action date for efficacy supplements, and potentially original applications, earlier to expedite patient access to innovative treatments. Industry discussed additional details about the proposal to expand the scope and utilization of innovative review approaches to additional product types and review disciplines, providing suggested review timelines and criteria for submission package elements. Both sides discussed the potential impact of the expansion on the Agency's resource requirements. FDA and Industry agreed to continue discussing this proposal at subsequent negotiation sessions.

Real World Evidence (RWE)

FDA and Industry continued discussions about a proposal for a RWE pilot program for use of Real World Data during the review of applications and in regulatory decision-making. FDA provided additional details about a proposed pilot program intended to create opportunities for multiple early interactions between Sponsors and the Agency to discuss design, collection and use of RWE. Both

sides discussed clarifying questions about potential aspects of the proposed pilot program. FDA and Industry agreed to continue discussing this proposal at subsequent negotiation sessions.

Medical Product Information
Industry provided additional context about current and planned initiatives across various countries and international regulatory agencies related to advancements in communication of medical product information. FDA and Industry agreed to continue discussing this proposal at subsequent negotiation sessions.

FDA/Sponsor Interactions (Meeting Management)
FDA and Industry continued discussions about proposals for more iterative interactions between FDA and Sponsors for certain types of product development programs, focusing on promoting consistency of such interactions across all FDA review divisions. FDA asked further questions to determine the potential feasibility of implementing Industry's proposed novel formal meeting for innovative product development programs and a CDER-specific equivalent of CBER's INTERACT program. FDA and Industry agreed to continue discussing these proposals at subsequent negotiation sessions.

NME Milestones and PMRs/PMCs
FDA and Industry continued discussions about proposals to increase the consistency and predictability of communication practices related to PMRs/PMCs and labeling during the marketing application review process. Both sides discussed the feasibility of proposed approaches for reducing instances of late-stage negotiations related to PMRs/PMCs and labeling. FDA and Industry agreed to continue discussing these proposals at subsequent negotiation sessions.

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