Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Pre-market subgroup | Meeting Summary

December 16th, 2020 | 1:30pm-4:00pm

Virtual Format (Zoom)

PURPOSE

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

PARTICIPANTS

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

At the eleventh meeting of the PDUFA VII pre-market subgroup, FDA and Industry continued discussions about FDA and Industry proposals to enhance the review process. Both sides acknowledged the need to continue discussions about overall proposal resource requests at a subsequent negotiation meeting.

NME Milestones and Postmarketing Requirements (PMRs) under PREA and 505(o)(3) of the FDCA

FDA and Industry continued discussions about a proposal to improve timely notification of postmarketing requirements during the marketing application review process. Industry agreed that iPSPs required under PREA will not be included in the proposal because they are already addressed in existing statute that established both process and timelines for iPSPs. FDA committed to further consider the types of PMRs that would be subject to the formal timeline goal and reporting of the PDUFA metric. Industry asked that FDA also consider all PMR types to be eligible under this proposal for requesting post-approval review of feasibility.

Industry requested FDA establish timelines for conducting the Active Risk Identification and Analysis (ARIA) sufficiency determination. FDA noted that inclusion of ARIA timelines in a PDUFA commitment would most likely not be feasible due to variable safety evaluation timelines.

FDA further pointed out that in a previous negotiation meeting FDA committed to revise all relevant MAPPs, SOPPs, and guidance documents. Industry agreed to consider whether this potential commitment would address the request.

Real World Evidence (RWE)
FDA and Industry continued discussions about a proposal for an RWE pilot program to increase the use of Real World Data (RWD) during the review of applications and in regulatory decision-making. Both sides discussed clarifying questions about criteria and processes for applying to and participating in the pilot program, including potential tracking and reporting metrics that would be feasible within current FDA databases. FDA agreed to provide additional details about resources potentially required to establish and maintain the pilot program at a subsequent negotiation meeting.

Use-Related Risk Analysis (URRA) and Human Factor (HF) Protocol Review
FDA and Industry continued discussions about a proposal to enhance the review of HF protocols and URRAs submitted by Sponsors, especially during combination product development programs. FDA clarified its original proposal to establish formal timelines for the review of URRAs in exchange for resources and noted its intention to develop URRA-specific guidance for industry as part of the proposal. Industry noted challenges associated with HF protocol reviews extending past 60 days, and the Agency referenced the component of its original proposal stating that due to the increasing complexity of HF protocol submissions, continuing to meet the 60-day timelines established during PDUFA VI would not be feasible, even with increased resources.

Innovative Review Approaches
FDA and Industry continued discussions about FDA's counterproposal for a Split Real-Time Application Review (STAR) pilot program that would expand the split submission and review of required sections of marketing applications to additional product types and review disciplines outside of Oncology. FDA provided additional details about resources potentially needed to establish and maintain STAR, answered clarifying questions from Industry about resources, and agreed to provide further details at a subsequent negotiation meeting. Industry asked clarifying questions about FDA's proposal to conduct a mid-program assessment, and FDA discussed potential outputs and timing associated with the assessment, including metrics and reporting.

FDA/Sponsor Interactions (Meeting Management)
FDA asked clarifying questions about Industry's written feedback on the Agency's counterproposals for establishing and communicating best practices related to PDUFA meeting management, establishing a novel type of formal meeting, and formalizing CBER's INTERACT program while establishing a similar program in CDER. Industry addressed FDA questions about a new proposal from Industry for FDA to develop a guidance and conduct a public workshop to discuss process improvements for Advisory Committees (AC). FDA referenced current and planned internal activities to enhance internal OND processes in preparing for AC meetings, but pointed out that those internal efforts were not focused on making changes to the AC process nor would they affect Industry's role in the AC meeting. However, FDA agreed to consider whether there was a need to look more broadly at AC meetings and holding a public meeting to discuss the process.

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