Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Pre-market subgroup | Meeting Summary

December 9th, 2020 | 1:00pm-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		

At the tenth 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 agreed to discuss overall resource requests for both sides' proposals at a subsequent negotiation meeting.

Real World Evidence (RWE)

FDA and Industry continued discussions about a proposal for a RWE pilot program to increase the use of Real World Data (RWD) during the review of applications and in regulatory decision-making. FDA proposed additional details about the pilot program's objectives and structure, including the role and constitution of a centralized RWE subcommittee with representation from both CDER and CBER. Industry asked clarifying questions about criteria and processes for applying to and participating in the pilot program. Both sides discussed clarifying questions about public meetings, public documents, and other outputs potentially associated with the pilot program.

NME Milestones and Postmarketing Requirements (PMRs)/Postmarketing Commitments (PMCs) under 505(o)(3) of the FDCA

FDA and Industry continued discussions about a proposal to improve timely discussions of postmarketing studies during the marketing application review process. FDA asked clarifying questions about Industry's intent to include both PMRs and PMCs versus only PMRs in proposal discussions, and Industry agreed to provide confirmation at a subsequent negotiation session. The Agency discussed the existence of MAPPs and SOPPs that explain the processes, roles and responsibilities for developing PMR/PMCs and proposed to update all relevant MAPPs, SOPPs or guidances regarding PMR/PMCs followed by training of staff to ensure better understanding and consistency in implementing PMR/PMCs. Next, FDA discussed a proposal to establish formal timelines and reporting metrics for the communication of intended PMRs to Sponsors of NME NDAs and BLAs; specifically, six weeks prior to the action goal date for standard applications, and four weeks prior to the action goal date for priority applications, with the expectation that necessary information for a comprehensive safety review is provided by the applicant with the initial submission. Both sides discussed a proposal to establish a mechanism for engaging senior Center leadership in disagreements about feasibility of existing postmarketing requirements.

FDA/Sponsor Interactions (Meeting Management)

Industry agreed to provide feedback on FDA'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 at a subsequent negotiation meeting.

Innovative Review Approaches

Industry agreed to provide feedback on FDA's counterproposal for a 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 at a subsequent negotiation meeting.

Bioinformatics Review Expertise

FDA and Industry continued discussions about a proposal to enhance CBER and CDER's expertise in various aspects of bioinformatics to support the Agency's ability to provide detailed and consistently timed feedback to Industry earlier in the development cycle. Industry asked clarifying questions about FDA's resource request and will provide their thoughts at a subsequent meeting.

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