Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Pre-market subgroup | Meeting Summary

October 14th, 2020 | 1:00pm-3:30pm

Virtual Format (Zoom)

PURPOSE

To continue introducing and addressing clarifying questions 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)
Alex May	CDER	Kelly Goldberg	PhRMA
Mike Pacanowski	CDER	Heidi Marchand	BIO (Gilead and Kite)
J. Paul Phillips	CDER	Mark Taisey	PhRMA (Amgen)
Carolina Reese	CDER		
Khushboo Sharma	CDER		
Jim Smith	CDER		
Peter Stein	CDER		
Mary Thanh Hai	CDER		

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

FDA/Sponsor Interactions (Meeting Management)

FDA and Industry continued discussions about a proposal for enhanced communication and more iterative interactions between FDA and Sponsors for certain types of product development programs. Industry's proposal is intended to increase collaboration and support innovation throughout the drug development process. FDA asked clarifying questions. FDA and Industry agreed to continue discussing this proposal at subsequent negotiation sessions.

Innovative Review Approaches

Industry discussed a proposal to enhance the efficiency of efficacy supplement and potentially original application review in order to expedite patient access to innovative treatments. Industry referenced the Real-Time Oncology Review (RTOR) Pilot Program and Summary Level Review (introduced in the 21st Century Cures Act - Section 3031), each of which is intended to streamline the review process. Several deliverables were introduced with potential to expand the scope and

utilization of these programs within FDA. FDA and Industry agreed to continue discussing this proposal at subsequent negotiation sessions.

Real World Evidence (RWE)
Industry discussed a proposal to expand on activities introduced by PDUFA VI and the 21st Century Cures Act to broaden the application of RWE in regulatory decision-making. Industry suggested building on lessons learned from submissions containing RWE throughout the COVID-19 pandemic and proposed processes to increase the acceptance of RWE by providing opportunities for transparency and knowledge sharing between FDA and public stakeholders. 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.