Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Pre-market subgroup | Meeting Summary

October 21th, 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 fourth 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 respond to questions raised.

Bioinformatics Review Expertise

FDA and Industry continued discussions about a proposal to enhance the Agency's expertise in various aspects of bioinformatics to support FDA's ability to provide detailed and consistently timed feedback to Industry earlier in the development cycle. FDA provided additional details about resources potentially required to expand current activities related to bioinformatics in both CBER and CDER. Industry asked clarifying questions about how additional resources requested would be allocated and utilized across different groups within each Center. 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 discussed experiences related to CBER's INTERACT meetings, a mechanism that Sponsors may use to request non-

binding feedback during early-phase development for certain products (prior to pre-IND submission), and Industry discussed a proposal for establishing a similar program in CDER. Industry also discussed a proposal to expand options to existing formal PDUFA meeting types, intending to establish additional opportunities for obtaining the Agency's feedback on focused issues. FDA and Industry agreed to continue discussing these proposals at subsequent negotiation sessions.

Innovative Review Approaches
FDA and Industry continued discussions about a proposal to enhance the efficiency of efficacy supplement, and potentially original application, review in order to expedite patient access to innovative treatments. FDA discussed experiences with the Summary Level Review mechanism, introduced in the 21st Century Cures Act – Section 3031, and provided clarifying details about the Agency's interpretation of submissions qualified for the program. Industry discussed additional details about a proposal to expand the scope and utilization of real-time review, as utilized in the Real-Time Oncology Review (RTOR) Pilot Program, to additional product types and review disciplines. Both sides discussed clarifying questions about the review timelines associated with the proposed expansion. 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.