Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Regulatory Decision Tools Subgroup | Meeting Summary

November 10th, 2020 | 9:00am-11:00am

Virtual Format

PURPOSE

To have a follow up discussion on previously discussed topics: Model-Informed Drug Development, Patient-Focused Drug Development, Complex Innovative Designs, and Advancing Translational Models and Tools.

PARTICIPANTS

FDA		Industry	
Robyn Bent	CDER	Rob Blanks	BIO (Ardelyx)
Richard Forshee	CBER	Kristin Dolinski	PhRMA
Rajanikanth Madabushi	CDER	Danielle Friend	BIO
Theresa Mullin	CDER	Carl Garner	PhRMA (Eli Lilly)
Dionne Price	CDER	Kelly Goldberg	PhRMA
David Strauss	CDER	Ann Kurowski	BIO (Alkermes)
Graham Thompson	CDER	Mark Taisey	PhRMA (Amgen)
Julia Tierney	CBER		

The meeting discussion was focused on the issues of interest to industry and FDA.

FDA & Industry Discussion on Model-Informed Drug Development (MIDD), Patient-Focused Drug Development (PFDD), Complex Innovative Designs (CID), and Advancing Translational Models and Tools (ATMT).

In this meeting FDA and Industry both focused on further follow-up questions regarding perspectives on the proposals discussed to date. FDA and industry began by discussing ATMT. Industry shared their perspective that they currently did not have a proposal related to ATMT and wanted to focus on the other proposals under the regulatory decision tools discussion. FDA and Industry agreed to remove the ATMT proposal from consideration.

FDA then provided additional detail on its proposal for CID and responses to Industry questions. FDA and Industry discussed details about the potential proposal, including questions on guidance documents, timeframe for guidance development and posting, and how the program might operate going forward. Industry and FDA also discussed how different resource scenarios might affect the existing program.

FDA then provided additional detail on its proposal for PFDD sustainability and patient preference information (PPI), including on increasing capacity to facilitate development and use of Patient-Focused methods to inform drug development and regulatory decisions, and potential resource needs for both PFDD sustainability and PPI.

FDA and Industry also briefly discussed topics related to the MIDD proposal.

Plan for Future Meetings

At the next scheduled meeting on November 17th, the goal will be to have another follow-up conversation in more detail about three proposal areas discussed to date: Model-Informed Drug Development, Patient-Focused Drug Development, and Complex Innovative Designs.

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