Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Regulatory Decision Tools Subgroup | Meeting Summary

September 29th, 2020 | 9:00am-11:00am

Virtual Format

PURPOSE

To provide FDA and Industry perspectives on Regulatory Decision Tools enhancements (Model-Informed Drug Development) for PDUFA VII, and to discuss schedule of meetings moving forward.

PARTICIPANTS

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

The meeting discussion was focused on the issues of interest to industry and FDA and on planning for the negotiations process.

Ground Rules for Negotiations and Virtual Environment

The ground rules governing the PDUFA VII reauthorization negotiations were reviewed and agreed-upon by both parties. The ground rules were the same as those agreed to at the Steering Committee. FDA also presented the operating processes and rules for conducting negotiations in a virtual environment. There were no additional comments or questions.

FDA Perspectives on Reauthorization & Topics for Regulatory Decision Tools

FDA identified several areas for proposed enhancement of regulatory decision tools in PDUFA VII, including Model-Informed Drug Development (MIDD), Complex Innovative Trial Designs (CID), Patient-Focused Drug Development (PFDD), and Advancing Translational Models and Tools for Drug Development (ATMT). FDA also proposed a schedule for discussing these areas for the next several negotiation meetings. Industry agreed with the proposed schedule.

In this meeting FDA discussed its proposals related to the first area, Model-Informed Drug Development. FDA identified its interest in building upon lessons learned from PDUFA VI to create enhancements to integrate MIDD in drug development. These lessons included a need to ensure the sustainability of the MIDD program, to continue public engagement, to advance regulatory acceptance of MIDD, and to keep up with the growing demand and pace of innovation. To address this, FDA proposed to enhance early regulatory engagement for MIDD-focused meetings, to use public workshops and dedicated programs to increase stakeholder engagement and education, and to invest in a comprehensive end-to-end guidance development and implementation to ensure timely publication of contemporary MIDD guidance documents. FDA noted that ensuring sustainability of the MIDD program would require increased staffing. Industry asked questions related to the current operation of the MIDD program, CBER's participation in the MIDD program, the current resource allocations for MIDD, and for more information regarding the potential need for additional staffing.

Plan for Future Meetings

The goals for the next meeting on October 6th will be to have a follow up discussion on potential enhancements related to Model-Informed Drug Development, as well as to introduce and discuss in more detail potential enhancements related to Complex Innovative Trial Designs.

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