Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Regulatory Decision Tools Subgroup | Meeting Summary

November 17th, 2020 | 9:30am-11:30am

Virtual Format

PURPOSE

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

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
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.

FDA & Industry Discussion on Model-Informed Drug Development (MIDD), Patient-Focused Drug Development (PFDD), and Complex Innovative Designs (CID)

In this meeting FDA and Industry both focused on further follow-up questions regarding perspectives on the proposals discussed to date, as well as initial suggestions for possible commitment language, including possible resource needs. FDA provided responses to prior questions by industry on the details of the PFDD proposal including support for development of publicly-available standard core sets of clinical outcome assessments (COAs). FDA also provided proposed draft commitment language for PFDD related to sustainability of the current review program and a proposed enhancement related to Patient Preference Information. Industry asked clarifying questions and then indicated they would need time to discuss internally, so would need to defer further discussion with FDA until a future meeting.

FDA then provided proposed draft commitment language for CID based on conversations held to date, outlining continuation of a paired-meeting program, information sharing of case examples from the paired meeting program via web-postings and/or conferences, and issuance of guidance

related to CID. FDA also provided information on the associated resource needs. Industry asked clarifying questions and then indicated they would need time to discuss internally, so would need to defer further discussion with FDA until a future meeting.

FDA then provided proposed draft commitment language for MIDD outlining continuation of a paired-meeting program and a provision for possible future expansion based on the volume of industry requests and provided information on related possible resource needs. Industry asked clarifying questions and then indicated they would need time to discuss internally, so would need to defer further discussion with FDA until a future meeting.

Plan for Future Meetings

At the next scheduled meeting on December 1st, the goal will be to have a follow-up conversation in more detail about FDA and Industry's perspectives on initial considerations for commitment language for 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.