Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Regulatory Decision Tools Subgroup | Meeting Summary

December 8th, 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, 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 discussed respective proposed revisions to draft commitment letter language and the associated FDA resource requirements. In the previous meeting FDA had provided resource estimates for three potential levels of commitment for CID in PDUFA VII: the original proposal plus two proposals of reduced scope and fewer resources. In follow up, Industry had proposed revised commitment language for CID, including language on maintaining the current paired meeting program and other elements included in one of the FDA-proposed reduced scope proposals, but with Industry proposing fewer staff resources than FDA had indicated would be required for the proposed level of effort. Industry expressed uncertainty about whether FDA needed the level of resources estimated for the paired meeting program because to date, there had been no acceptances of paired meetings by CBER, although CBER had reported holding a number of CID consultations with sponsors through the traditional meeting request process. FDA indicated that CBER staff also participated in review of proposals for the paired meeting program, as well as leading guidance development to meet the PDUFA VI commitment. FDA indicated that the

resources were needed, and FDA would identify ways to reduce uncertainty about whether CBER would receive submissions and accepting paired meetings in the future.

FDA and Industry then reviewed and discussed Industry's proposed edits to FDA-proposed commitment language for MIDD, including language on continuing to implement the MIDD program. FDA indicated the need for time to review the details of the proposed commitment language and would provide further considerations at the next meeting.

FDA and Industry next reviewed Industry's proposed commitment language for PFDD, including language on sustainability of the PFDD program. Industry expressed general support for FDA's PFDD efforts, and while not committing to user fee funding to support the standard core COA grants for 3rd parties, Industry expressed a potential willingness to support some of the program staffing that would be needed to administer and manage such grants or contracts. Since the level of need for such staffing would be a function of the level of program activity which in turn will be a function of projected future availability of non-user fee funds for this purpose, it was requested that FDA try to clarify the level of expected future support from non-user fee funds. FDA expressed that it would follow up to further clarify as far as possible the expected future resourcing.

Plan for Future Meetings

At the next scheduled meeting on December 15th, the goal will be to review and further discuss FDA and Industry's proposed 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.