Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Regulatory Decision Tools Subgroup | Meeting Summary

December 1st, 2020 | 9:00am-12:00pm

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 focused on further follow-up questions regarding perspectives on the proposals discussed to date, as well as initial suggestions for draft commitment language, including possible resource needs. FDA's proposed commitment language for CID outlined 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 expressed interest in continuing the CID program but also wanted to consider a continuation with fewer enhancements than were being proposed by FDA to limit the amount of additional resourcing that would be required to support a continuation under PDUFA VII. Industry asked that FDA provide estimates of the resources that would be required for two scaled-back alternatives to FDA's original proposal, and FDA provided these estimates. Industry indicated they would need time to discuss the details of the three options for the CID proposal and would provide considerations on commitment language at the next meeting.

FDA's proposed commitment language for MIDD outlined continuation of a paired-meeting program including the provision for possible future expansion based on the volume of industry requests. Although industry expressed interest in continuing the MIDD paired meeting program, they indicated that they did not support inclusion of a provision for possible expansion of this program, and preferred that the MIDD consultations that occur beyond the specified numbers of the paired meeting program under PDUFA VII be handled through the normal PDUFA meeting management processes. It was also suggested that a focus area might be identified to inform future guidance development. FDA and industry agreed to follow up internally to consider whether such a focus area could be identified for consideration. In addition, industry indicated they would further discuss the proposed language and would provide considerations on revised commitment language at the next meeting.

FDA's proposed commitment language for PFDD outlined a proposal for sustainability of the current review program, proposed enhancement related to Patient Preference Information including the conduct of patient preference studies in specific areas of identified need, and support for expansion of an FDA grant program for development of publicly-available standard core sets of clinical outcome assessments (COAs). Industry expressed interest in the proposal for sustainability of the current review program but was concerned regarding resource requests and potential value of FDA's proposal for inclusion of funding for 3rd party patient preference studies or grants to develop standard core sets of COAs in PDUFA VII. While not agreeing to additional funding for this work, Industry suggested that FDA consider the development of guidance on patient preference studies in regulatory decision making. Based on this feedback from industry FDA expressed that it would revise the proposed commitment letter language to reduce the scope of proposed PFDD enhancements for PDUFA VII. Industry indicated they also plan to further discuss the details of the proposed language and would provide considerations on revised commitment language at the next meeting.

Plan for Future Meetings

At the next scheduled meeting on December 8th, the goal will be to have a follow-up conversation in more detail about FDA and Industry's perspectives on 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.