Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Regulatory Decision Tools Subgroup | Meeting Summary

December 15th, 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 focused on review and discussion of further proposed edits to draft commitment language from FDA and Industry, including the associated resource needs.

The discussion first considered proposed draft language for CID provided by FDA to Industry to which Industry offered further proposed edits. The edits were discussed in terms of whether they added clarification or introduced any potentially unintended constraints, and would therefore need further adjustment. For example, the PDUFA VI provision for meetings to occur 120 days apart was removed because both FDA and Industry found the 120-day stipulation limited desired flexibility, but Industry expressed that it would be helpful to provide a nominal timeframe for the interval between paired meetings to provide an indication to sponsors of the time frame to be expected. FDA indicated the need to follow up internally to determine the timeframe that should generally be achievable for the CID paired meeting program. FDA also discussed additional language FDA proposed to ensure the expected level of participation by sponsors submitting CID

meeting requests to CBER. In addition, the substantive differences of opinion related to the level of resourcing required to support the CID commitment was discussed. FDA restated that the CID commitment language under discussion would require the estimated staffing shared with Industry in the previous two meetings and could not be agreed by FDA for the reduced level of staffing that Industry had proposed at the previous meeting. FDA agreed to follow up with further edits to the commitment language based on the December 15th discussion with Industry. Industry indicated they would follow up on FDA residual questions and the contingent need for required resourcing.

The discussion next addressed the proposed draft commitment language from FDA and Industry on MIDD. This language includes Industry-proposed edits that were somewhat parallel with suggested edits for the CID paired meeting program including a proposed time interval between paired meetings. FDA expressed concerns that the language to clarify expectations not overly constrain or set expectations that were not achievable. Similar to the CID discussion, FDA indicated the need to follow up internally to determine the timeframe that should generally be achievable for the MIDD paired meeting program. FDA agreed to follow up with further edits to the commitment language based on the December 15th discussion with Industry.

The final topic of discussion was the review of proposed draft language from FDA and Industry on PFDD, including possible draft guidance on patient preference studies and how the scope of the proposal would change with changed resources. FDA expressed that, with various competing demands on staff time and end-of-year availability, there had not been enough time to have a follow up with the staff who could help provide more clarity related to non-user fee funding for the standard core COA grant program. Further follow up time was needed. FDA and Industry indicated they would revisit this topic in future meetings when it was hoped that additional information would be available.

Plan for Future Meetings

FDA and Industry agreed to follow up on the possibility of having the next meeting during the first week of January. It was also agreed that FDA would provide its next round of revisions to the proposed draft commitment letter language in advance of the next meeting with Industry. Assuming that the needed information is available, at the next scheduled meeting on January 12th, the aim of the discussion will be to reach to tentative agreement on commitment language for the proposals: 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.