Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Steering Committee | Meeting Summary

October 20th, 2020 | 2:00pm-3:30pm

Virtual Format

PURPOSE

To provide progress updates on each of the subgroups and to discuss Industry's proposal on HR and Hiring.

PARTICIPANTS

FDA		Industry	
Josh Barton	CDER	Rob Blanks	BIO (Ardelyx)
Amanda Edmonds	OC	E. Cartier Esham	BIO
Chris Joneckis	CBER	Danielle Friend	BIO
Andrew Kish	CDER	Carl Garner	PhRMA (Eli Lilly)
Ted Liazos	OC	Brad Glasscock	BIO (BioMarin)
Theresa Mullin	CDER	Kelly Goldberg	PhRMA
Carol Rehkopf	CBER	Mathias Hukkelhoven	PhRMA (BMS)
Khushboo Sharma	CDER	Robert Kowalski	PhRMA (Novartis)
Mary Ann Slack	CDER	Ann Kurowski	BIO (Alkermes)
Peter Stein	CDER	Heidi Marchand	BIO (Gilead and Kite)
Mary Thanh Hai	CDER	Mark Taisey	PhRMA (Amgen)
Terry Toigo	CDER	Lucy Vereshchagina	PhRMA
Patrick Zhou	CDER		

Regulatory Decision Tools High-Level Update

FDA presented their proposal on advancing translational models and tools. After answering industry's questions related to that proposal, industry followed up with additional questions on Model-Informed Drug Development and Patient-Focused Drug Development. More information can be found in the corresponding meeting summary for this subgroup.

CBER Breakout High-Level Update

FDA and industry advanced their conversations on the cell and gene therapy proposals, discussing the necessary staffing and resources to sustain the program, and set the agenda for upcoming weeks. More information can be found in the corresponding meeting summary for this subgroup.

Digital Health and Informatics High-Level Update
FDA and industry continued their discussion of digital health technologies (DHTs) and the agency agreed to begin drafting commitment language related to DHTs. More information can be found in the corresponding meeting summary for this subgroup.

Finance High-Level Update
FDA and industry agreed in principle on a proposal regarding the operating reserve adjustments with commitment letter and potential corresponding statutory language to be considered in a subsequent meeting. Industry presented a proposal regarding continued implementation of PDUFA VI financial reform, while FDA also discussed the limitation on certain allowable expenses. More information can be found in the corresponding meeting summary for this subgroup.

Post-Market High-Level Update
FDA provided background on the REMS program and presented their current thoughts on REMS assessments including their importance. The agency also discussed some of the program's challenges and the related resource requests in the proposal. More information can be found in the corresponding meeting summary for this subgroup.

Pre-Market High-Level Update
Industry began reviewing its proposals to FDA on enhancing the review process and will wrap presentations on its proposals in the next meeting. More information can be found in the corresponding meeting summary for this subgroup.

CMC and Inspections High-Level Update
FDA and industry further discussed real-time review in CMC and covered the potential challenges. FDA asked industry to provide additional examples of what their proposal could look like in practice. More information can be found in the corresponding meeting summary for this subgroup.

The following topics were discussed after the high-level updates.

Industry Presentation on Proposal for Human Resources and Hiring
Industry provided an overview of its proposed enhancements to ensure that the PDUFA program has the resources and personnel it needs. Their proposal seeks to build on PDUFA VI reforms by including initiatives to help FDA attract highly qualified candidates, hire the right people for positions efficiently and in a timely manner, and retain and continually develop staff once they are at the agency. FDA asked clarifying questions on the proposals offered and both parties discussed how best to move forward discussions on this topic. FDA and industry each agreed to develop their own sets of guiding principles to shape discussions on how HR/Hiring can best be addressed through the user fee agreements including what kind of meaningful data or information can be collected and reported.

Next Steps
FDA and industry agreed to use the next meeting to identify the areas of agreement on HR/Hiring principles before sending the topic to the Finance group for further brainstorming and discussion. Additionally, both sides agreed to continue sharing progress updates and to also review the upcoming timeline and calendar for negotiation.

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