Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Steering Committee | Meeting Summary

October 13th, 2020 | 2:00pm-4:00pm

Virtual Format

PURPOSE

To provide progress updates on each of the subgroups and to give industry an overview on FDA's PDUFA VI hiring commitments. FDA will also share the results of the interim hiring assessment and discuss FDA's management response to the assessment.

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	Robert Kowalski	PhRMA (Novartis)
Khushboo Sharma	CDER	Ann Kurowski	BIO (Alkermes)
Mary Ann Slack	CDER	Heidi Marchand	BIO (Gilead and Kite)
Peter Stein	CDER	Mark Taisey	PhRMA (Amgen)
Mary Thanh Hai	CDER	Lucy Vereshchagina	PhRMA
Terry Toigo	CDER		
Patrick Zhou	CDER		

FDA began the meeting by summarizing the agreed-upon transfer of one topic of discussion (communication of ARIA sufficiency determinations) from the post-market to pre-market subgroup. There followed a brief, high-level update on progress in the subgroups.

Regulatory Decision Tools High-Level Update

FDA presented on the PDUFA VI experience with the Complex Innovative Trial Designs pilot, discussed potential enhancements, and listened to industry's related interests in the space. The agency also discussed its plan for the future meetings. More information can be found in the corresponding meeting summary for this subgroup.

CBER Breakout High-Level Update
FDA and industry primarily discussed the cell and gene therapy proposals and discussed the current and upcoming needs of the program. Both parties agreed to continue the discussions in future meetings. More information can be found in the corresponding meeting summary for this subgroup.

Digital Health and Informatics High-Level Update
In addition to a discussion of digital health technologies proposal topics, FDA and industry discussed how IT decisions are made at the FDA. The agency also provided a walk-through of its technology roadmap for CDER and CBER. More information can be found in the corresponding meeting summary for this subgroup.

Finance High-Level Update
After industry addressed clarifying questions from the FDA, the agency presented its understanding of a proposal with shared interest related to the Operating Reserve Adjustment. FDA also discussed its proposal on further implementation of the Resource Capacity Planning capability. More information can be found in the corresponding meeting summary for this subgroup.

Post-Market High-Level Update
FDA presented and provided background on the PDUFA VI commitments related to Sentinel and furthered conversations on CBER's BEST System. FDA and Industry agreed to discuss REMS the following week. More information can be found in the corresponding meeting summary for this subgroup.

Pre-Market High-Level Update
FDA completed its overview of the agency's proposals and industry began its presentations on their proposals. Topic areas of discussion included FDA-sponsor interactions during the review, INTERACT meetings, and PMRs/PMCs. More information can be found in the corresponding meeting summary for this subgroup.

CMC and Inspections High-Level Update
FDA and Industry agreed on a sequence of topics and how to walk through them over the coming weeks. Both sides then discussed COVID-related topics and issues around communications, such as information requests and issue identification. More information can be found in the corresponding meeting summary for this subgroup.

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

Overview of PDUFA VI Hiring Data and Hiring Commitments
FDA asked if there were any questions related to the latest PDUFA VI hiring data and presented an overview of FDA's PDUFA VI hiring commitments.

Reviewing the Interim Hiring Assessment Findings and FDA's Response
FDA presented the overall findings and recommendations that resulted from Booz Allen Hamilton's interim hiring assessment report. The assessment identified five main challenge areas for FDA: Strategy, Data Management and Systems, HR Staff Capability and Capacity, Culture and Communication, and Recruiting and Hiring. FDA gave its views relating to each of these areas and described the efforts currently underway to address the challenges and also emphasized that the period of data collection for the analysis preceded recent advancements and process changes like

increased use of 21st Century Cures hiring. FDA and industry discussed the challenges and agreed to explore further whether it is possible to address them through the user fee agreements.

Next Steps
FDA and industry agreed to discuss industry's perspectives on human resource issues related to PDUFA and to have the subgroup leads continue to provide a high-level read-out as to the progress of their negotiations.

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