Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Steering Committee | Meeting Summary

February 2nd, 2021 | 2:00pm-2:30pm

Virtual Format

PURPOSE

To provide progress updates on each of the subgroups, review the overall resource request of proposals with its impact on fees, and discuss the next meeting's agenda.

PARTICIPANTS

FDA		Industry	
Josh Barton	CDER	Rob Blanks	BIO (Ardelyx)
Amanda Edmonds	OC	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	Rob 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		

Pre-Market High-Level Update

FDA and Industry have a few minor wording changes left on draft commitment letter language but not much substance remains for discussion. More information can be found in the corresponding meeting summary for this subgroup.

CMC and Inspections High-Level Update

FDA and Industry plan to meet tomorrow to resolve issues regarding several outstanding proposals. FDA also acknowledged receipt of additional edits to the proposals and plan to respond soon. More information can be found in the corresponding meeting summary for this subgroup.

Regulatory Decision Tools High-Level Update

FDA and Industry have largely completed the draft commitment letter language to refer to the Steering Committee with only minor edits outstanding. More information can be found in the corresponding meeting summary for this subgroup.

Post-Market High-Level Update
FDA and Industry continue to draft commitment letter language around the Sentinel proposal and hope to reach agreement in the next day or two. More information can be found in the corresponding meeting summary for this subgroup.

CBER Breakout High-Level Update
Pending confirmation on one item, FDA and Industry agree with the draft commitment letter language for their subgroup. More information can be found in the corresponding meeting summary for this subgroup.

Digital Health and Informatics High-Level Update
FDA and Industry are nearing agreement on draft commitment letter language with only minor edits outstanding. More information can be found in the corresponding meeting summary for this subgroup.

Finance High-Level Update
FDA and Industry indicate general alignment at the subgroup level with some items needing resolution at the subgroup meeting tomorrow. FDA is also preparing the technical package required for reauthorization. More information can be found in the corresponding meeting summary for this subgroup.

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

Hiring Assessment and Hiring Goals
FDA and Industry agreed to the draft commitment letter language regarding the third-party hiring assessment. They also discussed the challenges related to the hiring goals and FDA's preparation to meet them. As FDA and Industry reach further agreements on commitments, both groups discuss how PDUFA VII hires should be reported publicly and what data/format would be most useful to stakeholders.

Next Steps
FDA indicated that its goal is to send Industry a draft of the commitment letter by Thursday. Additionally, FDA and Industry agreed to schedule an additional meeting on Friday for FDA to walk Industry through the draft commitment letter for an initial high-level overview. Next Tuesday, FDA and Industry plan to meet to respond to and review the draft commitment letter in its entirety.

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