Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Steering Committee | Meeting Summary

January 19th, 2021 | 2:00pm-3:30pm

Virtual Format

PURPOSE

To provide progress updates on each of the subgroups, review the overall resource request of proposals with significantly advanced discussions, 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		

CMC and Inspections High-Level Update

FDA and Industry have reached preliminary agreement on several proposals and are drafting commitment letter language. Though some issues are still outstanding, the subgroup hopes to make additional progress this week. More information can be found in the corresponding meeting summary for this subgroup.

Pre-Market High-Level Update

For the outstanding issues, FDA and Industry are generally aligned but are hoping to agree on details around scope and resource requests. More information can be found in the corresponding meeting summary for this subgroup.

CBER Breakout High-Level Update
FDA and Industry report that the remaining item to discuss is the cadence of hiring over the duration of PDUFA VII. 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 conversation on IT modernization and have more feedback and edits to share this week. More information can be found in the corresponding meeting summary for this subgroup.

Regulatory Decision Tools High-Level Update
FDA and Industry indicated that they are close to coming to agreement on the remaining proposals with draft commitment language to refer to the Steering Committee. More information can be found in the corresponding meeting summary for this subgroup.

Post-Market High-Level Update
FDA and Industry are drafting commitment letter language reflecting their agreement on REMS and are still sharing materials related to Sentinel for further discussion. More information can be found in the corresponding meeting summary for this subgroup.

Finance High-Level Update
FDA and Industry have one or two remaining issues that requires discussion but consider themselves close to agreement. More information can be found in the corresponding meeting summary for this subgroup.

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

Resource Tabulation
FDA presented the spreadsheet that summarizes a snapshot of the overall resource request for the tentatively agreed-upon set of proposals. There were no additional questions at this time.

Third-Party Hiring Assessment
FDA presented Industry with new draft commitment letter language regarding the hiring assessment. FDA acknowledged the challenges with implementing a conditional assessment triggered by certain metrics and the advantages of a planned third-party hiring assessment during PDUFA VII. Both FDA and Industry had additional discussions related to the specifics of the hiring assessment, then Industry agreed to review the proposed commitment in more detail and to provide feedback.

Next Steps
For the next meeting, FDA and Industry agreed to continue sharing progress updates, to review the resource tabulation of agreed-upon proposals, to continue discussion on a potential third-party hiring assessment, and to review the remaining schedule for negotiations.

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