Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Steering Committee | Meeting Summary

January 26th, 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 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		

CMC and Inspections High-Level Update

FDA and Industry have reached preliminary agreement on several proposals and continue to draft commitment letter language. Some issues remain pertaining to guidances and advanced manufacturing. More information can be found in the corresponding meeting summary for this subgroup.

Pre-Market High-Level Update

FDA and Industry have aligned on most topics and proposals of discussion with the remaining significant topic of discussion around a new pilot, specifically with regard to its scope. More information can be found in the corresponding meeting summary for this subgroup.

CBER Breakout High-Level Update
FDA and Industry met to review minor changes in the draft commitment letter language. Both sides also discussed the timing of CBER's hires under the commitment. More information can be found in the corresponding meeting summary for this subgroup.

Digital Health and Informatics High-Level Update
FDA and Industry made minor edits to the proposal around digital health technologies while additional discussions regarding Data and IT Modernization are needed. More information can be found in the corresponding meeting summary for this subgroup.

Regulatory Decision Tools High-Level Update
Though some slight re-wording remains on the Patient-Focused Drug Development proposal, FDA and Industry have completed draft commitment letter 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 continue to discuss Sentinel and clarify outstanding questions around the proposal. More information can be found in the corresponding meeting summary for this subgroup.

Finance High-Level Update
FDA and Industry have one outstanding proposal to discuss and also need to review the agency's proposed technical fixes, but otherwise have draft commitment letter language to refer to the Steering Committee. More information can be found in the corresponding meeting summary for this subgroup.

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

Hiring Goals
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. Additionally, Industry agreed with FDA's new draft commitment language regarding a third-party hiring assessment, pending minor edits.

Guidance Language in Commitments
FDA and Industry discussed the draft commitment letter language around the timing of publication from draft guidance to final guidance. FDA explained that its goal is to finalize guidances, but also explained the circumstances when FDA believes issuing revised draft guidance prior to finalization may be needed, as it allows time for public stakeholders to provide feedback on certain substantial edits (to the initial draft guidance) prior to finalization of guidance. The agency also acknowledged Industry's preference to work toward finalization of guidance and offered to share draft language with Industry.

Resource Tabulation and Impact on Fees
FDA presented the spreadsheet that summarizes a snapshot of the overall resource request for the tentatively agreed-upon set of proposals and acknowledged that one of the remaining outstanding items is to decide on the cadence of annual hiring over PDUFA VII. Additionally, the agency presented a spreadsheet including calculations, based on the tentative agreement, on the projected fees for PDUFA VII and fielded clarifying questions from Industry.

Next Steps
For the next meeting, FDA and Industry agreed to review the same agenda and to also consider the final steps in the process toward reauthorization.

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