Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Steering Committee | Meeting Summary

January 12th, 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
There were no updates since the subgroup did not meet since the break.

Pre-Market High-Level Update
FDA and Industry have reached preliminary agreement on draft commitment language to refer to the Steering Committee on numerous commitments. Outstanding details need to be discussed on a

few commitments including new pilot programs but there is general alignment. More information can be found in the corresponding meeting summary for this subgroup.

CBER Breakout High-Level Update
FDA and Industry reviewed the overall CBER resource ask to ensure that there was no overlap on asks across groups and also discussed the cadence of hires over the duration of PDUFA VII. The subgroup has also completed draft commitment letter language to refer to the Steering Committee. More information can be found in the corresponding meeting summary for this subgroup.

Digital Health and Informatics High-Level Update
FDA and Industry indicated that more discussion on a proposal related to IT modernization is necessary as both sides seek to better address concerns. More information can be found in the corresponding meeting summary for this subgroup.

Regulatory Decision Tools High-Level Update
FDA and Industry are nearing completion of draft commitment language to refer to the Steering Committee on several topics. More information can be found in the corresponding meeting summary for this subgroup.

Post-Market High-Level Update
Though the subgroup did not meet over the break, both FDA and Industry exchanged documents and commitment language for consideration related to Sentinel. More information can be found in the corresponding meeting summary for this subgroup.

Finance High-Level Update
FDA and Industry are nearing agreement on draft commitment letter language to refer to the Steering Committee on most of the agreed-upon proposals. The subgroup hopes to resolve outstanding issues in the coming weeks. 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 a spreadsheet that summarizes a snapshot of the overall resource request for the tentatively agreed-upon set of proposals. The agency indicated that it would update this sheet as negotiations progressed. FDA and Industry discussed how best to account for the costs agreed-to under this negotiation, including, for example, the impact on fees and the delineation of which costs would be one-time costs. There was also a discussion and clarification on the various line-item costs that were covered under PDUFA VI and on what would be covered in PDUFA VII.

Third-Party Hiring Assessment
FDA and industry discussed the parameters of a potential hiring assessment with draft commitment language drafted by the agency. The agency also presented a potential timeline for such an assessment and discussed the feasibility of having the assessment be conditional on certain metrics early in PDUFA VII. Based on the discussion, FDA agreed to revise the proposal for further discussion next week.

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.