Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Steering Committee | Meeting Summary

December 15th, 2020 | 2:00pm-3:15pm

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)
Chris Joneckis	CBER	Cartier Esham	BIO
Andrew Kish	CDER	Danielle Friend	BIO
Ted Liazos	OC	Carl Garner	PhRMA (Eli Lilly)
Theresa Mullin	CDER	Brad Glasscock	BIO (BioMarin)
Carol Rehkopf	CBER	Kelly Goldberg	PhRMA
Khushboo Sharma	CDER	Mathias Hukkelhoven	PhRMA (BMS)
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

In the past week, FDA and Industry furthered discussion on a proposal related to accelerated CMC review. This week, the group intends to check in on the overall status of the proposals. More information can be found in the corresponding meeting summary for this subgroup.

Pre-Market High-Level Update

FDA and Industry continued to refine details related to numerous remaining proposals, acknowledging that there is still some ground to cover. FDA plans to share associated resource requests on some of those proposals this week. More information can be found in the corresponding meeting summary for this subgroup.

CBER Breakout High-Level Update
Though the subgroup did not meet in the past week, FDA plans to share additional draft commitment language with Industry related to allergenic products. 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 understand the 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 alignment on draft commitment language to refer to the Steering Committee on several topics. Both sides will try to meet the first week of January to continue the discussion. More information can be found in the corresponding meeting summary for this subgroup.

Post-Market High-Level Update
FDA and Industry discussed a revised REMS proposal that FDA provided based on Industry's feedback and proceeded to have discussions on topics related to Sentinel. More information can be found in the corresponding meeting summary for this subgroup.

Finance High-Level Update
After aligning on some proposals and producing draft commitment language that is ready for referral to the Steering Committee, FDA and Industry further discussed several outstanding topics. 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 table that included proposals of potential shared interest to both parties that were advanced enough to include resource requests. The agency also provided clarification to questions and stated that they would also provide a more detailed sheet next week.

Health of Workforce and Third-Party Hiring Assessment
After discussion, the Finance subgroup referred back to the Steering Committee two topics: a potential report on the health of FDA's workforce and a third-party assessment on the agency's hiring practices. FDA and Industry discussed the merits of a third-party hiring assessment. FDA indicated that they do not see the utility of another independent assessment conducted before PDUFA VIII negotiations, considering there will be an additional PDUFA VI hiring assessment due in FY22. Both sides said they would continue discussion on the topic after the holidays.

Next Steps
FDA and Industry reviewed the schedule for January and agreed that the Steering Committee would not reconvene until January 12th. For the next meeting, FDA and Industry agreed to continue sharing progress updates, to review the table of tentatively agreed-upon potential proposals, and to continue discussion on a potential third-party hiring assessment.

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