Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Steering Committee | Meeting Summary

November 17th, 2020 | 2:00pm-3:00pm

Virtual Format

PURPOSE

To provide progress updates on each of the subgroups and to discuss how to further advance discussions around resource requests.

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	Robert 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		

After introductions, FDA displayed its subgroup progress tracker to help facilitate the discussion around updates and the remaining proposals within each subgroup. Throughout the discussions below, Industry and FDA discussed and clarified how FDA was determining progress and advancement in the discussions.

Regulatory Decision Tools High-Level Update

Both FDA and Industry clarified and discussed various remaining proposals on Model-Informed Drug Development, Patient-Focused Drug Development and Complex Innovative Designs. More information can be found in the corresponding meeting summary for this subgroup.

CBER Breakout High-Level Update
FDA and Industry have exchanged draft proposed commitment language on several commitments, with FDA having provided its resource request, based on those discussions, for the allergenic products and cell and gene therapy proposal.

During this discussion, FDA clarified the need to get industry's feedback on resource requests and draft commitment language to properly scope out draft proposals. More information can be found in the corresponding meeting summary for this subgroup.

Pre-Market High-Level Update
FDA and Industry discussed numerous proposals, identifying aligned interest in several areas including, but not limited to, pilot programs and FDA/sponsor interactions. FDA and Industry each acknowledged the need to provide feedback on certain proposals and plan to do so in coming meetings. More information can be found in the corresponding meeting summary for this subgroup.

Digital Health and Informatics High-Level Update
Both FDA and Industry continued discussing its remaining proposals in Digital Health Technologies and IT modernization where there appears to be alignment in interests and objectives. More information can be found in the corresponding meeting summary for this subgroup.

Finance High-Level Update
FDA and Industry, per the previous meeting, began discussing and brainstorming useful metrics related to the health of FDA's workforce and continued discussion on other outstanding proposal areas. Remaining topics will be discussed in the upcoming weeks. More information can be found in the corresponding meeting summary for this subgroup.

Post-Market High-Level Update
For most of the meeting, FDA and Industry discussed the agency's thinking on its Sentinel proposal and resource request. They agreed to discuss Sentinel further in a future meeting along with more discussion on the REMS proposal. More information can be found in the corresponding meeting summary for this subgroup.

CMC and Inspections High-Level Update
FDA and Industry made progress on several topical areas including a tentative agreement related to information requests and mid-cycle communications. They also discussed the future schedule for meetings. 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 displayed a table meant to show the resource information for proposals under discussion but noted that the subgroups are still discussing proposal resource requests, to fully populate the resource table. Both sides agreed that it was important to make continued progress in the coming weeks.

Next Steps
For next week's meeting, FDA and Industry agreed to continue sharing progress updates, to review any updates to the total resource request table of tentatively agreed-upon potential proposals, and to receive an update from the Finance subgroup on the status of the Health of the Workforce discussions.

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