Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Steering Committee | Meeting Summary

November 10th, 2020 | 2:00pm-3:15pm

Virtual Format

PURPOSE

To provide progress updates on each of the subgroups and to plan for future conversations 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	Robert Kowalski	PhRMA (Novartis)
Khushboo Sharma	CDER	Ann Kurowski	BIO (Alkermes)
Mary Ann Slack	CDER	Heidi Marchand	BIO (Gilead and Kite)
Mary Thanh Hai	CDER	Mark Taisey	PhRMA (Amgen)
Terry Toigo	CDER	Lucy Vereshchagina	PhRMA
Patrick Zhou	CDER		

Regulatory Decision Tools High-Level Update

FDA and Industry had further discussion on the Complex Innovative Designs proposal and also agreed to discontinue discussion on another proposal on advancing translational models and tools. In order to make additional progress, the subgroup may extend the next meeting by an additional hour. More information can be found in the corresponding meeting summary for this subgroup.

CBER Breakout High-Level Update

FDA and Industry continued to refine the Cell and Gene Therapies Program proposal, agreeing to develop resource estimates and draft proposed commitment language in future meetings. FDA also provided Industry with a proposal related to inclusion of allergenic products into PDUFA. FDA and Industry also followed-up on Industry's proposals and agreed to additional discussion in future meetings. More information can be found in the corresponding meeting summary for this subgroup.

Digital Health and Informatics High-Level Update
FDA and Industry discussed remaining areas on alignment and further details related to a proposal on Digital Health Technology. Both sides also continued their discussion on Data/IT Modernization, identifying points of alignment and potential commitment language. More information can be found in the corresponding meeting summary for this subgroup.

Finance High-Level Update
FDA and Industry continued their discussions related to various topics including the inflation adjustment proposal, resource capacity planning, and performance reporting. Additionally, FDA and Industry began discussing metrics that could describe the status of the PDUFA workforce. More information can be found in the corresponding meeting summary for this subgroup.

Post-Market High-Level Update
FDA and industry discussed FDA's proposals on Sentinel and the associated resource requests. The discussion also centered around potential health outcomes of interest that could be of interest to both FDA and industry, acknowledging that Sentinel to date has largely focused on safety outcomes. More information can be found in the corresponding meeting summary for this subgroup.

Pre-Market High-Level Update
FDA and industry continue to review and discuss the details of the various proposals, including what implementation of certain proposals could look like. Both sides have also begun to identify areas of shared interest and potential enhancements. More information can be found in the corresponding meeting summary for this subgroup.

CMC and Inspections High-Level Update
FDA and industry tentatively identified shared interest in enhancements to information requests and mid-cycle communications. Both sides also discussed details and responded to questions around the remaining topic areas. 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
After some discussion, FDA and industry agreed to discuss potential tabulation of the overall resource request in subsequent meetings. FDA presented the proposed table that would be used to display this estimate of agreed-upon proposals; industry had no additional immediate feedback.

Public Stakeholders Meetings
FDA provided industry with background on the concurrent PDUFA VII public stakeholders meetings, explaining that these meetings occur monthly for as long as the negotiations with industry are ongoing. FDA also gave a high-level update on those discussions thus far and explained the general topics that public stakeholders have expressed an interest in discussing.

Next Steps
For next week's meeting, FDA and industry agreed to continue sharing progress updates, to review the table of tentatively agreed-upon potential proposals and the associated resource request, and to discuss potential topics to cover in future meetings.

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