Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Steering Committee | Meeting Summary

December 1st, 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)
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		

CMC and Inspections High-Level Update

FDA and Industry have advanced their conversations on information request context and rationale and consider themselves close to reaching a tentative agreement. Both sides acknowledged still needing a lot of discussion to make progress on other commitments and plan to do so in the coming weeks. More information can be found in the corresponding meeting summary for this subgroup.

Finance High-Level Update

FDA has shared numerous documents and language on most proposal topics. Industry plans to respond to these and discuss further in the meeting this week. FDA also stated that it will defer discussion on Industry's third-party assessment of financial topics until after the subgroup has addressed its others substantive topics. More information can be found in the corresponding meeting summary for this subgroup.

Pre-Market High-Level Update
FDA and Industry have begun sharing commitment language on about half of the proposal topics, having identified a shared interest in proposals related to pilots and FDA meetings, and will move toward sharing resource information in the coming weeks. The group also hopes to make progress on the remaining topics in the coming weeks. More information can be found in the corresponding meeting summary for this subgroup.

CBER Breakout High-Level Update
FDA and Industry believe that they are making significant progress and hope to wrap up most of their discussions in the coming weeks. FDA did acknowledge that it still needs to provide Industry commitment language on a few topics. More information can be found in the corresponding meeting summary for this subgroup.

Digital Health and Informatics High-Level Update
FDA and Industry also agreed on having made progress, coming close to finalizing tentative language on both proposals in consideration. More information can be found in the corresponding meeting summary for this subgroup.

Regulatory Decision Tools High-Level Update
After a three-hour session in the morning, FDA and Industry were able to discuss and clarify the level of interest and required resources for the remaining proposals under discussion: MIDD, CID, and PFDD. More information can be found in the corresponding meeting summary for this subgroup.

Post-Market High-Level Update
FDA and Industry agreed that further discussion is needed on the Sentinel and REMS related proposals and hope to make additional progress in this week's meeting. 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 table that included proposals of potential shared interest to both parties that were advanced enough to include resource requests. This included two proposals from the CBER Breakout group and the DHI subgroup. Industry posed several questions to clarify the components of the table and how the total figures are being calculated. FDA then reviewed one of the DHI proposals in more detail, explaining the proposed commitments and the related costs. Both sides agreed to review this table on a regular basis as more proposals reach this stage.

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 requests, and to discuss metrics that relate to the health of FDA's workforce.

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