

Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Steering Committee | Meeting Summary

December 8th, 2020 | 2:00pm-3:45pm

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

Josh Barton	CDER
Amanda Edmonds	OC
Chris Joneckis	CBER
Andrew Kish	CDER
Ted Liazos	OC
Theresa Mullin	CDER
Carol Rehkopf	CBER
Khushboo Sharma	CDER
Mary Ann Slack	CDER
Peter Stein	CDER
Mary Thanh Hai	CDER
Terry Toigo	CDER
Jay Tyler	OFBA
Patrick Zhou	CDER

Industry

Rob Blanks	BIO (Ardelyx)
Cartier Esham	BIO
Danielle Friend	BIO
Carl Garner	PhRMA (Eli Lilly)
Brad Glasscock	BIO (BioMarin)
Kelly Goldberg	PhRMA
Mathias Hukkelhoven	PhRMA (BMS)
Robert Kowalski	PhRMA (Novartis)
Ann Kurowski	BIO (Alkermes)
Heidi Marchand	BIO (Gilead and Kite)
Mark Taisey	PhRMA (Amgen)
Lucy Vereshchagina	PhRMA

Limited Allowable Expenditures Under FDARA Section 905(b)

FDA and Industry discussed the limitation of allowable expenses that under current law will take effect on October 1st, 2023. After the FDA highlighted the anticipated adverse impacts of this section on the program, FDA and Industry discussed if this can be addressed through the PDUFA reauthorization process.

CMC and Inspections High-Level Update

FDA and Industry are close to completing draft commitment language to refer to the Steering Committee on innovative manufacturing technologies. While both sides believe they are close to wrapping discussion around certain topics, they agreed that a few remaining topics will require

further negotiation. More information can be found in the corresponding meeting summary for this subgroup.

Pre-Market High-Level Update

FDA and Industry continue to draft and edit commitment language on several proposal topics, acknowledging that there still needs to be conversation in numerous areas. There was discussion of whether some cross-cutting topics would benefit from joint discussions with other subgroups, but it was decided that it would be premature to do so. More information can be found in the corresponding meeting summary for this subgroup.

CBER Breakout High-Level Update

FDA stated that they are working on sending Industry draft commitment language for topics that are still outstanding but noted that both sides otherwise are prepared to refer their other draft commitment language and resource requests 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 continue to work on revising language on its proposals with the most discussion needed on Data/IT modernization. The agency stated that it will send revised language to Industry. More information can be found in the corresponding meeting summary for this subgroup.

Regulatory Decision Tools High-Level Update

Though there are still outstanding questions on Complex Innovative Designs, FDA and Industry have made progress on draft commitment language for the remaining proposal areas that could be referred to the Steering Committee in the coming weeks. More information can be found in the corresponding meeting summary for this subgroup.

Post-Market High-Level Update

FDA and Industry continue to discuss both FDA proposals related to REMS and Sentinel. Based on the ongoing conversations, FDA will draft potential commitment language for Industry to review. More information can be found in the corresponding meeting summary for this subgroup.

Finance High-Level Update

FDA and Industry believe they are close to a tentative draft agreement on several topics and acknowledged that they require some continued discussion on others. The group did indicate that they need another week to discuss the human resources and workforce metrics before raising for conversation at the Steering Committee. More information can be found in the corresponding meeting summary for this subgroup.

FDA then offered a summary of the tentative draft agreement related to the Operating Reserve Adjustment, stating that both parties' positions and interests are aligned.

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 but there were not any changes to the table and emphasized that further progress needed to be made for more to be added.

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 to discuss metrics that relate to human resources and workforce metrics and Industry's proposal for a third-party hiring assessment.

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