

Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Steering Committee | Meeting Summary

February 12th, 2021 | 2:00pm-2:40pm

Virtual Format

PURPOSE

To reach general agreement at the negotiation team level on commitment letter language describing a package of enhancement proposals for PDUFA VII.

PARTICIPANTS

FDA

Josh Barton	CDER
Amanda Edmonds	OC
Chris Joneckis	CBER
Andrew Kish	CDER
Ted Liazos	OC
Carol Rehkopf	CBER
Khushboo Sharma	CDER
Mary Ann Slack	CDER
Terry Toigo	CDER
Patrick Zhou	CDER

Industry

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

Commitment Letter Review

After FDA and Industry agreed to delay the normally scheduled Tuesday Steering Committee meeting to allow time for both sides to review and exchange feedback on the overall text, FDA and Industry met to discuss the remaining changes/edits before coming to general agreement on the commitment letter. FDA walked through the proposed changes/edits, showing where changes were accepted while also explaining why some changes were not accepted. FDA agreed to clarify the language in some areas and to share the latest version with Industry following the meeting.

Conclusion of Negotiation Meetings

FDA and Industry agreed that this would be the final negotiation meeting for the Steering Committee, and plan to resolve any outstanding issues with the generally agreed-upon commitment letter, proposed statutory changes, and statutory justifications via email before recommending the package to their respective senior management for ratification.

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