Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Steering Committee | Meeting Summary

February 5th, 2021 | 2:00pm-3:00pm

Virtual Format

PURPOSE

To walk through the sections of the draft commitment letter at a high level, then review the next steps in the process.

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	Rob Kowalski	PhRMA
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		

Commitment Letter Walk-Through

After spending the week to assemble the draft commitment letter language prepared by the subgroups into a single document, FDA presented the draft text to Industry, walking through the overall structure while highlighting minor changes that Industry may not have seen yet. The agency also noted that the CMC group had not finalized commitment language yet and it would be provided as soon as agreement was reached. Additionally, other high-level areas will be further revisited at the Steering Committee level once the commitment letter in its entirety can be reviewed adequately by both parties.

Next Week

FDA and Industry agreed to revisit the timeline for the next meeting to give both sides adequate time to review the commitment letter and other components of the package together.

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