Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Steering Committee | Meeting Summary

September 22nd, 2020 | 2:00pm-4:00pm

Virtual Format

PURPOSE

To review the negotiation timeline, discuss questions on FDA and industry's proposed enhancements, and assign topics to subgroups.

PARTICIPANTS

FDA		Industry	
Josh Barton	CDER	Rob Blanks	BIO (Ardelyx)
Amanda Edmonds	OC	E. 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		

The meeting discussion was focused on the issues of interest to industry and FDA and on the assignment of these topics to subgroups for negotiation. There were no other substantive proposals, significant controversies, or differences of opinion discussed at this meeting.

Negotiation Timeline

FDA reviewed the overall timeline for the reauthorization of PDUFA VII. There were no additional comments or questions.

Assigning Subgroup Topics

FDA asked industry counterparts to clarify their interest in some proposed enhancement topics and to understand their proposed subgroup assignments. Industry asked FDA for additional detail on FDA's proposed topics and interests. FDA and Industry then discussed the assignment of proposal topics to the designated subgroups. Both parties noted that some topics would require discussion

across multiple working groups. Though most topic assignments were agreed upon, FDA and Industry agreed to finalize the remaining topics after meeting internally.

Next Steps

The goals for the next meeting on September 29th will be to review the timeline for communicating with authorizing Congressional Committees and to give a presentation on FDA's current operating environment under COVID-19. Subgroups were agreed to begin next week.