Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Steering Committee | Meeting Summary

September 29th, 2020 | 2:00pm-4:00pm

Virtual Format

PURPOSE

To review the timeline for submitting a final package to Congress, to finalize agreement on proposal topic assignments for subgroups, and to present FDA's update on impact of COVID-19 on FDA operations.

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		

Timeline for Submitting Package to Congress

FDA presented and discussed the current timeline and general practice of communicating with authorizing Congressional Committees. There were no additional comments or questions.

Agreeing on Proposal Topic Assignments

FDA and Industry came to agreement on the subgroups where each proposal topic would begin negotiation.

Impact of COVID and FDA Operations

FDA and industry discussed the impact of COVID-19 on the agency's workload and resources. Industry made a point to express their appreciation of the agency's commitment to addressing the

pandemic. Though FDA expressed that the workload was not sustainable in the long run, the agency acknowledged the Industry's interests in the possibility of lessons learned from COVID-19 translating into improved processes. FDA then summarized the existing and upcoming workstreams that may account for some potential lessons learned, including upcoming guidances on Real-World Evidence and Data, Decentralized Clinical Trials, and Digital Health Technologies. Given the overlap between ongoing COVID-work and some PDUFA interests, both parties discussed what may be best-suited and permissible under the user free framework.

Next Steps

FDA and industry agreed to discuss FDA's existing PDUFA program resources, a current status update on PDUFA VI hires, and a walk-through of progress made under the capacity planning and resource management capability at the next meeting on October 6th. Additionally, the subgroups will be expected to provide a high-level read-out as to the progress of their discussions.

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