Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Manufacturing Subgroup | Meeting Summary

February 3rd, 2021 |2:00pm - 4:00pm

Virtual Format (Zoom)

PARTICIPANTS

FDA		Industry	
David Burrow	CDER	Rob Blanks	BIO (Ardelyx)
Alonza Cruse	ORA	Danielle Friend	BIO
Laurie Graham	CDER	Carl Garner	PhRMA (Eli Lilly)
Don Henry	CDER	Olivia Shopshear	PhRMA
Andrew Kish	CDER		
Ted Liazos	OCC		
KaLonna Maull	CDER		
Steven Oh	CBER		
Mahesh Ramanadham	CDER		
Carol Rehkopf	CBER		
Nicole Trudel	CBER		

The meeting discussion was focused on reviewing updates to draft commitment language.

FDA and Industry discussed the need for the title of the new manufacturing section to be general to maintain flexibility in discussions for manufacturing-related topics in future PDUFA cycles and allow for more context in the preamble. Both parties reviewed each draft commitment line by line and discussed any concerns in real time. Minor updates were made to the commitment language regarding product quality information requests to provide more context on the four-part harmony principles. Industry and FDA discussed the commitment language for enhancing inspection communication for applications, not including supplements. Both parties also discussed eligibility requirements for the Chemistry, Manufacturing, and Controls Readiness Pilot program and what information would be publicly disclosed related to applications accepted into the Pilot.

FDA and Industry agreed to finalize any additional edits to the draft language via email.

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