Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Negotiation Regulatory Decision Tools Subgroup | Meeting Summary

January 19th, 2021 | 10:00am-10:40am

Virtual Format

PURPOSE

To finalize discussion and draft commitment language on previously discussed topics: Model-Informed Drug Development, Patient-Focused Drug Development, and Complex Innovative Designs.

PARTICIPANTS

FDA		Industry	
Robyn Bent	CDER	Rob Blanks	BIO (Ardelyx)
Richard Forshee	CBER	Kristin Dolinski	PhRMA
Rajanikanth Madabushi	CDER	Danielle Friend	BIO
Theresa Mullin	CDER	Carl Garner	PhRMA (Eli Lilly)
Dionne Price	CDER	Kelly Goldberg	PhRMA
Graham Thompson	CDER	Ann Kurowski	BIO (Alkermes)
Julia Tierney	CBER	Mark Taisey	PhRMA (Amgen)

The meeting discussion was focused on the issues of interest to industry and FDA.

FDA & Industry Discussion on Finalizing Draft Commitment Language

In this meeting FDA and Industry focused on review of draft commitment language from FDA FDA and Industry agreed to all proposed language discussed at the previous meeting on January 12 with only minor edits for clarity. Both sides acknowledged that final clearance and agreement on the overall package would happen at the steering committee and ratifier level. No substantial edits or updates were made to the language discussed at the previous meeting. FDA and Industry agreed to standardize across subgroups the language on timeframes for developing and publishing guidances and to update those sections of the proposed draft commitment language once the standard language had been agreed to at the steering committee. FDA and Industry agreed that further meetings would not be necessary as final agreement has been reached on all proposals at the subgroup level.

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