Prescription Drug User Fee Act (PDUFA) Reauthorization

Manufacturing and Inspections Workgroup | Meeting Summary

November 4th, 2020 | 1:00pm-3:30pm

Virtual Format (Zoom)

PURPOSE

To discuss Industry's manufacturing and inspections related interests in PDUFA VII.

PARTICIPANTS

FDA		Industry	
David Burrow	CDER	Rob Blanks	BIO (Ardelyx)
Alonza Cruse	ORA	Anne-Virginie Eggimann	BIO (bluebird bio)
Laurie Graham	CDER	Danielle Friend	BIO
Don Henry	CDER	Carl Garner	PhRMA (Eli Lilly)
Andrew Kish	CDER		
Steven Oh	CBER		
Mahesh Ramanadham	CDER		
Carol Rehkopf	CBER		
Nicole Trudel	CBER		

The meeting focused on reviewing the status of all proposals and identifying areas of agreement and areas that need more discussion.

FDA and Industry tentatively agreed to enhancements to Information Requests and Mid-cycle communications. FDA and Industry then discussed details around the remaining proposal areas including CMC topics related to expedited programs, inspections, submission content, ETT and CATT programs, prior approval supplement communications and timelines.

FDA and Industry discussed the agenda for the remaining meetings in the calendar year. The group agreed to not meet on November 11th, due to the Veteran's Day holiday. FDA and Industry agreed to reconvene on November 18th.

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