Prescription Drug User Fee Act (PDUFA) Reauthorization

Manufacturing and Inspections Workgroup | Meeting Summary

September 30th, 2020 | 1:30pm-4:00pm

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	Danielle Friend	BIO
Laurie Graham	CDER	Carl Garner	PhRMA (Eli Lilly)
Don Henry	CDER	Ryan Kaat	PhRMA
Andrew Kish	CDER		
Ted Liazos	OCC		
KaLonna Maull	CDER		
Steven Oh	CBER		
Mahesh Ramanadham	CBER		
Carole Rehkopf	CBER		
Nicole Trudel	CDER		

The meeting discussion was focused on exploring Industry's PDUFA VII manufacturing and inspection interests.

Industry explained the main themes of interest in manufacturing and inspections are on enhancing pre-market and post-market communication, increasing understanding of the decision framework around inspections, and streamlining quality-related regulatory submission content. Industry shared details on their proposed topic areas, including the problems they would like to address or opportunities they are meant to pursue, and clarified questions from FDA. Both parties noted that some industry topics presented may be addressed through the existing work streams. FDA and Industry agreed to develop the agenda for future meetings after meeting internally.

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