Prescription Drug User Fee Act (PDUFA) Reauthorization

Manufacturing and Inspections Workgroup | Meeting Summary

October 7th, 2020 | 2:00pm-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	CBER		

The meeting discussion was focused on planning for the negotiation process and exploring Industry's PDUFA VII manufacturing interests related to communications. FDA and Industry reviewed action items from the previous meeting and discussed the schedule for the negotiation process. FDA and Industry agreed on the topic areas and order of discussing those topics over the course of the negotiation process.

Industry presented their interests in PDUFA VII related to communications, particularly around information request (IRs) that are issued during the review process and mid-cycle meeting communications. Industry provided insight on the issues with these types of communications and provided examples of how improved communications would allow for more efficient processes for their firms. FDA shared information on current practices and guidelines for IRs and mid-cycle communications. FDA and Industry agreed to continue the discussion on communications at a future meeting.

FDA and Industry also agreed to discuss Industry's interests in COVID-19 lessons learned and practices as they relate to ongoing Agency workstreams and applicability to PDUFA VII at a future meeting.

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