Prescription Drug User Fee Act (PDUFA) Reauthorization

Manufacturing and Inspections Workgroup | Meeting Summary

October 28th, 2020 | 1:00pm-3:30pm

Virtual Format (Zoom)

PURPOSE

To discuss Industry's manufacturing and inspections related topics 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	Ryan Kaat	PhRMA
Sau Lee	CDER		
Tom O'Connor	CDER		
Steven Oh	CBER		
Mahesh Ramanadham	CDER		
Carol Rehkopf	CBER		
Nicole Trudel	CBER		
Grant Young	OCC		
Patrick Zhou	CDER		

The meeting discussion was focused on exploring Industry's PDUFA VII manufacturing and inspection topics. FDA began by reviewing the upcoming schedule for negotiation meetings and then recapped the outstanding action items for both sides.

Innovative Manufacturing Technologies

Industry began by presenting introductory remarks and highlighting their interest in leveraging lessons learned and best practices between CDER's Emerging Technology Team (ETTs) program and CBER's Advanced Technology Teams (CATT) program. Industry provided their perspectives on the programs and interest in a framework between the two programs that would enhance efficiency, regulatory predictability, and consistency. Industry also provided answers to questions FDA had posed.

FDA responded by providing additional background and history on how the two programs developed, highlighting similarities and necessary differences between the ETT and the CATT programs. The agency clarified what types of topics are suitable for each and what interactions could

be available for different scenarios. FDA and industry also discussed how these programs may further develop, facilitate external feedback, and document lessons learned.

Prior Approval Supplements (PAS)

FDA and industry discussed perspectives on prior approval manufacturing supplements. Industry highlighted challenges with FDA communication during the review cycle, including when information requests are issued. FDA highlighted challenges with the review timeline. Industry sought clarification on data related to the first-cycle approval rate for PAS reviews. Both sides agreed to share additional data on both topics of discussion.

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