Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Manufacturing Subgroup | Summary

December 9th, 2020 | 1:00pm - 4:00pm

Virtual Format (Zoom)

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	CDER		
Carol Rehkopf	CBER		
Nicole Trudel	CBER		

The meeting discussion was focused on 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.

CMC Real-Time Review/CMC Readiness Pilot

FDA and Industry discussed Industry's proposal for accelerated review of Module 3 for expedited applications. FDA acknowledged some of industry's pain points with CMC development when clinical development is expedited; however, FDA reiterated concerns shared in previous meetings around the expedited review concept and noted it may not address the pain points with CMC development. As an alternative, FDA shared preliminary thoughts on a proposal for a CMC readiness pilot program. The proposed pilot program would involve FDA engagement with sponsors related to CMC development during the IND stage for products.

CMC Challenges and PAI/PLI Announcements

Industry and FDA continued to discuss proposals around communicating CMC challenges associated with expedited applications, the expedited program guidance, Pre-Approval Inspection/Pre-License Inspection notifications, and information requests. FDA and Industry also discussed the differences between types of FDA policy documents (MAPPs, SOPPs, guidances) and the appropriate utilization of each type in the context of the discussed proposal topics.

Innovative Manufacturing Technologies

Industry and FDA continued discussion around innovating manufacturing technologies. FDA and Industry discussed the idea of holding a workshop during PDUFA VII to share details on the Emerging Technology Team program (ETT) and CBER's Advanced Technology Team program (CATT). FDA suggested that providing sponsors with more information on how the programs operate, including the differences between programs and role in the review process, may be helpful to industry. FDA and Industry agreed to continue to discuss the idea and potential topics to cover during the workshop at a subsequent meeting.

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