Prescription Drug User Fee Act (PDUFA) Reauthorization

Manufacturing and Inspections Workgroup | Meeting Summary

December 16th, 2020 | 1:00pm-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	Olivia Shopshear	PhRMA
Andrew Kish	CDER	Anne-Virginie Eggiman	BIO (Bluebird)
Steven Oh	CBER		
Mahesh Ramanadham	CDER		
Carol Rehkopf	CBER		
Nicole Trudel	CBER		

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

<u>CMC Readiness Pilot Proposal</u>

Industry and FDA discussed ways to optimize the proposed pilot. FDA clarified their thoughts on how the pilot would differ from what is currently being done with Breakthrough and RMAT applications. FDA and Industry discussed their goals for the pilot. FDA explained that they see potential for the pilot to be expanded, if successful, and become standard practice for the benefit of sponsors and public health. Industry indicated a desire to set a timeframe on the pilot duration and for lessons learned from the pilot to be shared with industry, potentially through guidance. FDA explained that it is standard practice to develop guidance as experience is gained with new products and guidance to industry would be useful. Industry and FDA also discussed the parameters of the potential pilot including how many applications would be feasible during PDUFA VII and the resource needs.

Information Requests and Late-Cycle Communications

FDA and Industry continued discussions around draft proposal language to ensure context and rationale is clear in information requests and late-cycle communications. Industry communicated their concern with not being made aware of inspection issues that could prevent approvability. FDA explained how inspectional issues are communicated and what can be communicated during the review cycle. Industry asked how FDA can assess the impact of the proposed IR enhancements during PDUFA VII. Both parties agreed to think about what meaningful metrics focused on information requests could be tracked during PDUFA VII.

Inspection Complementary Tools

FDA and Industry continued to discuss draft commitment language for a guidance on complementary tools to inspections. FDA clarified the difference between inspection and assessments.

Advanced Manufacturing

FDA and Industry continued conversations around the Emerging Technology Team/CBER Advanced Technology Team proposals. Industry explained their thoughts on the need for a mechanism or pathway to streamline manufacturing supplement submissions to FDA. FDA discussed the existing pathways and also noted the agency does not approve technologies but specific drug products. FDA and industry continued to discuss an advanced manufacturing workshop during PDUFA VII and the potential output from the workshop.

FDA and Industry discussed the agenda for 2021. The team agreed to reconvene meetings on January 13th, 2021.

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