Prescription Drug User Fee Act (PDUFA) Reauthorization

Manufacturing and Inspections Workgroup | Meeting Summary

October 14th, 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	CDER		
Carol Rehkopf	CBER		
Nicole Trudel	CBER		

The meeting discussion was focused on exploring Industry's PDUFA VII manufacturing interests related to pre-market content. FDA and Industry reviewed action items from the previous meeting and discussed additional updates to the schedule for the negotiation process.

Industry discussed their proposals related to pre-market content around accelerated chemistry, manufacturing, and controls (CMC) review and clarification on the CMC content expected to be in a regulatory application for expedited pathway products. Industry provided examples of how they believe guidance on FDA's expectations relating to CMC content in expedited programs would allow for more efficient planning and processes. FDA noted the nuances of various products and expedited applications and how providing a general guidance on the topic may not be helpful. Industry and FDA discussed the concept of CMC real-time or rolling review applied to certain expedited pathway products. FDA shared concerns with the inefficiencies this may create for the review process. FDA and Industry agreed to continue discussing the concept at a future meeting and share pertinent information that could help inform the discussion.

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FDA and Industry also discussed Industry's interests in delineating what content should be included in a submission and what content should be included for inspection. FDA and Industry agreed to continue discussing the topic at a future meeting and share pertinent information that could help inform the discussion. FDA and Industry agreed to discuss inspection related topics and communication topics at the next meeting.

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