Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Manufacturing Subgroup | Meeting Summary

December 2nd, 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	Anne-Virginie Eggimann	Bluebird
Ted Liazos	OCC		
KaLonna Maull	CDER		
Steven Oh	CBER		
Mahesh Ramanadham	CDER		
Carol Rehkopf	CBER		
Nicole Trudel	CBER		
Manuel Osorio	CBER		
Thomas O'Connor	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.

Emerging Technology Team/CBER Advanced Technology Team

FDA and Industry continued to discuss draft commitments related to ETT/CATT. FDA proposed holding a workshop to educate and share information around the ETT and CATT programs. FDA and industry discussed potential topics and how this workshop may inform guidance and how single submission-related topics could be incorporated in the workshop. FDA and industry agreed to continue to discuss this proposal area in a future meeting.

Prior Approval Manufacturing Supplements

FDA shared its response to industry's proposal to increase the number of FDA and sponsor touch points during prior-approval manufacturing supplement review, noting that a mid-cycle meeting/touchpoint would provide the most benefit. FDA noted the current commitment letter, which includes the goal to "Review and act on 90 percent of manufacturing supplements requiring

prior approval within 4 months of receipt, and review and act on 90 percent of all other manufacturing supplements within 6 months of receipt." FDA maintained that the existing 4-month timeline for prior approval manufacturing supplements is challenging given the volume of submissions and complexity of some of the reviews. Thus, adding more touchpoints would not be feasible without increasing the review timeline by 2 months (4 to 6 months).

Industry did not agree with an additional 2 months for prior approval manufacturing supplement reviews. Industry and FDA discussed potential solutions, including if additional resources would help with increasing touchpoints within the existing 4-month review clock. FDA maintained that resources are not the primary rate limiting factor, it is the time.

Industry and FDA continued to discuss draft commitment language for other proposals including information requests, mid-cycle language and Pre-Approval Inspection/Pre-License Inspection notifications. Industry and FDA discussed how the impact of these commitments could be measured in PDUFA VII, particularly regarding information requests. FDA and industry agreed to continue to discuss the feasibility of assessing the impact of these commitments during PDUFA VII at a future meeting. FDA and industry agreed to discontinue discussing the industry's proposal for PAI/PLI waivers.

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