FDA-Industry PDUFA VI Reauthorization Steering Committee Meeting
November 17, 2015, 1:00pm-3:00pm
FDA White Oak Campus, Silver Spring, MD
Building 71, Room 1208/1210

Purpose
To discuss FDA and Industry priorities going forward in the PDUFA negotiations

Participants

FDA		Industry	
Josh Barton	CDER	Beatrice Biebuyck	BIO (Alexion)
Steve Berman	CDER	Jennifer Boyer	BIO (Alkermes)
Amanda Edmonds	OC	Cartier Esham	BIO
Joe Franklin	OC	Jeffrey Francer	PhRMA
Patrick Frey	CDER	Sascha Haverfield	PhRMA
Mark Gray	CBER	Kay Holcombe	BIO
John Jenkins	CDER	Laurie Keating	BIO (Alnylam)
Chris Joneckis	CBER	Robert Metcalf	PhRMA (Eli Lilly)
Andrew Kish	CDER	Sandra Milligan	PhRMA (Merck)
Theresa Mullin	CDER	Paula Rinaldi	PhRMA (Novartis)
Mary Parks	CDER	Michelle Rohrer	BIO (Roche Genentech)
Melissa Segal	OC	Mark Taisey	PhRMA (Amgen)
Graham Thompson	CDER		
Terry Toigo	CDER		

Discussion of FDA and Industry Priorities
FDA presented a proposed list of priority areas of potential PDUFA program enhancements for continued discussion at the working group level. FDA considered that this list would represent a minimum set of enhancements to be included in an agreement. This list included enhancements to Patient-Focused Drug Development, Breakthrough Therapy program capacity, exploration and knowledge development related to use of Real World Evidence, and post-market safety surveillance. FDA indicated that it was open to discussing additional areas for potential enhancement as well. FDA communicated its view that the new drug review program currently has an adequate number of formal tracked goals and that it would continue to apply continuous improvement principles to its internal processes.

Industry emphasized its view that the PDUFA program would benefit from additional enhancements to administrative functions, including hiring as well as resource management and capacity planning functions. FDA indicated it was open to continuing discussions on enhancements to these key administrative functions underpinning the performance of the user fee program.

Industry asked if FDA remained interested in continuing discussions on proposals to enhance the Phonetic and Orthographic Computer Analysis (POCA) tool. FDA indicated that it had determined that it

could enhance POCA with existing fee resources and therefore it did not warrant further discussions for additional resourcing within the context of the reauthorization of PDUFA VI.

FDA and Industry agreed to discontinue discussions of a proposal to enhance capacity to mine social media data for safety information in recognition that other private sector organizations are in a stronger position to pursue this.

FDA and Industry agreed to continue discussions within the working groups to further prioritize the remaining proposal areas.

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