FDA-Industry PDUFA VI Reauthorization Meeting
January 13th, 2015, 9:30-11:00 AM
FDA White Oak Campus, Silver Spring, MD
Building 51, Room 1211

Purpose: To discuss FDA and Industry pre-market review process enhancement proposals.

Participants

FDA		Industry	
Alonza Cruse	ORA	Cartier Esham	BIO
Joseph Franklin	OCC	Sascha Haverfield	PhRMA
Patrick Frey	CDER	Kay Holcombe	BIO
John Jenkins	CDER	Laurie Keating	BIO (Alnylam)
Christopher Joneckis	CBER	Robert Metcalf	PhRMA (Eli Lilly)
Theresa Mullin	CDER	Mark Taisey	PhRMA (Amgen)
Michael Pacanowski	CDER		
Mary Parks	CDER		
Sara Stradley	CDER		
Kellie Taylor	CDER		
Kimberly Taylor	CDER		
Sarah Pope Miksinski	CDER		
James Smith	CDER		

Communication, coordination and review division consistency
FDA and industry identified and agreed upon a small number of minor clarifying edits to the commitment letter language regarding a third-party assessment of current FDA and sponsor communication practices during drug development.

Goal extensions and manufacturing facility information
FDA and industry identified and agreed upon a small number of minor clarifying edits to the commitment letter language regarding the extension of the PDUFA goal for applications that omit in their list of manufacturing facilities one that FDA identifies for pre-approval inspection.

Combination product review
Industry stated that FDA's combination product proposal as discussed in the previous meeting was well-received. However, industry reiterated that it would like it to include the drafting of technical guidance for patient-oriented labeling (IFU's) and bridging studies. Industry also proposed a third-party evaluation of combination product review, once process changes have been implemented. FDA agreed this would be helpful, especially if the assessment evaluated industry interactions as well. FDA and Industry agreed to continue discussing this proposal.

Meeting management
FDA and industry agreed to modify the timelines for PDUFA meetings that occur at the end of a phase of drug development. Typically, these meetings occur at the End-of-Phase 2 or, in the case of some development programs (e.g. for certain programs where the sponsor intends to rely on an endpoint other than a clinical endpoint), at the End-of-Phase 1. Such meetings are currently categorized as Type B meetings in PDUFA V and would be categorized as Type B (EOP) meetings in the next reauthorization with a 70 day scheduling goal. Additional modifications were made for Type B (EOP) and Type C meetings that will allow additional time for FDA

to review the background package and for industry to review FDA's response to sponsor questions before determining whether a meeting is still needed.

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