FDA-Industry PDUFA VI Reauthorization Meeting
December 8, 2015, 3:00pm-5:00pm
FDA White Oak Campus, Silver Spring, MD
Teleconference

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

Participants

FDA		Industry	
Joseph Franklin	OCC	Cartier Esham	BIO
Patrick Frey	CDER	Sascha Haverfield	PhRMA
John Jenkins	CDER	Laurie Keating	BIO (Alnylam)
Christopher Joneckis	CBER	Robert Metcalf	PhRMA (Eli Lilly)
Michael Pacanowski	CDER	Mark Taisey	PhRMA (Amgen)
Mary Parks	CDER		
Sara Stradley	CDER		
Kellie Taylor	CDER		
Kimberly Taylor	CDER		

Discussion of NME Program Modification Proposal

FDA and Industry reviewed draft commitment letter language regarding modifications to the NME Program. The draft language also included enhanced communication with sponsors during the review process regarding FDA's review activities associated with a scheduling recommendation for products with abuse potential.

Discussion of Communication, Coordination and Review Division Consistency Proposal

FDA stated that the formal tracked performance goals for individual sponsor-review team interactions proposed by industry would reduce FDA's flexibility and put the agency's recent progress in regulatory operations at risk. FDA instead proposed an independent assessment of current FDA and sponsor communication practices during drug development based on a random subset of drug development programs. The proposed assessment would identify best practices and areas for improvement in communication by FDA review staff and sponsors. FDA also proposed a public workshop to discuss the findings of the independent assessment and stated the agency would update the recently published draft guidance on "Best Practices for Communication between IND Sponsors and FDA during Drug Development" as appropriate. FDA and industry agreed to continue discussing this proposal.

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