FDA-Industry PDUFA VI Reauthorization Meeting
December 2, 2015, 9:30-11:30am
FDA White Oak Campus, Silver Spring, MD
Building 51, Room 1215

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

Participants

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

Discussion of Meeting Management

FDA and industry brainstormed alternatives to the current Type B and C meeting timelines with the goal of identifying a more efficient and effective timeline and process for both parties. FDA reiterated its interest in receiving the meeting background package earlier. Industry expressed an interest in receiving the preliminary responses from FDA earlier to allow more time to prepare for the meeting or potentially cancel the meeting, if the agency's preliminary responses are considered sufficient. 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.