FDA-Industry PDUFA VI Reauthorization Meeting
October 14th, 2015, 9:30-11:30am
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 Cruz	ORA	Cartier Esham	BIO
Joseph Franklin	OCC	Sascha Haverfield	PhRMA
Patrick Frey	CDER	Laurie Keating	BIO (Alnylam)
John Jenkins	CDER	Robert Kowalski	PhRMA (Novartis)
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 Current State of PDUFA Program

FDA discussed its concern that while current program performance has been very good during PDUFA V, other measures of work (e.g., industry meetings) are seeing significant increases that has put strain on the review process. Furthermore, over the past several years, there has also been an increase in meeting requests from external stakeholders to discuss drug development in specific therapeutic areas. In each case, the same review staff and division leadership are needed for these meetings, leading to challenges in finding time on review staff and particularly senior leaders' calendars within the goal dates for PDUFA meetings. FDA stated that the overall program strain manifests itself in two ways: excessive amounts of uncompensated staff overtime and an insufficient amount of time devoted to other critical areas, such as training and professional development and guidance and policy development. Additionally, the agency stated its concern about committing to new review performance goals as proposed by industry before being able to meet other internally-established goals related to FDA's oversight of drug development programs. Industry and FDA discussed various options for reducing program strain and industry highlighted its proposal for an enhanced time reporting and capacity planning system under the Finance subgroup.

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