FDA-Industry PDUFA VI Reauthorization Meeting
January 19th, 2016, 3:00-4:30am
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	
Steven Berman	CDER	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		

Breakthrough therapy program
FDA and industry discussed commitment letter language related to how additional resources for the breakthrough therapy program will be utilized to continue the current program.

Early consultation on the use of new surrogate endpoints
FDA and industry discussed draft commitment letter language describing a process for early consultation on the use of new surrogate endpoints during drug development. FDA and industry agreed on the focus and intent of the consultations and agreed to continue discussions on the requirements for sponsors who wish to take advantage of early consultations for their drug development programs.

Meeting management
FDA and industry identified and agreed upon a small number of minor clarifying edits to the meeting management section of the commitment letter.

Combination product review
FDA discussed draft language to enhance the agency's capacity to conduct cross-center regulatory activities for the review of combination products. FDA described its intended approach of using enhanced procedures, documentation, and training, along with additional resources and communications, to enhance its review activities. Industry indicated that it was supportive overall of proposed efforts in this area and would consider FDA's proposed language.

The need to review and revise other sections of the PDUFA V commitment letter to determine whether they were still necessary was also discussed.

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