FDA-Industry PDUFA VI Reauthorization Meeting
January 26th, 2015, 1:00-4:00 PM
FDA White Oak Campus, Silver Spring, MD
Building 32, Room 1211

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)
Theresa Mullin	CDER	Mark Taisey	PhRMA (Amgen)
Michael Pacanowski	CDER		
Mary Parks	CDER		
Sara Stradley	CDER		
Kellie Taylor	CDER		
Kimberly Taylor	CDER		
James Smith	CDER		

Combination product review
Industry and FDA discussed and agreed upon a timeline for the issuance of MAPPs, SOPPS and guidances related to combination product review. Industry and FDA also discussed and agreed upon the timing of when the agency will outline the roles and responsibilities of those involved with combination product review across CDER, CBER, CDRH and the Office of Combination Products. Industry also proposed that the MAPP and SOPP on quality assessment of combination products discuss the coordination of facility inspections. FDA agreed to this addition.

Meeting management
Industry and FDA discussed and agreed upon the timing of the issuance of a revised draft or final guidance on "Best Practices for Communication between IND Sponsors and FDA during Drug Development," including any updates that FDA determines are appropriate after the third-party evaluation is completed.

Early consultation on the use of new surrogate endpoints
FDA and Industry discussed commitment letter language related to Type C meetings on the use of new surrogate endpoints. FDA asked that the language clarify that the outcome of this meeting may necessitate further investigation by the sponsor and discussion and agreement with the agency before the surrogate endpoint could be used as the primary basis for product approval. Industry agreed to this addition.

Enhancing regulatory science
FDA and industry discussed commitment letter language related to FDA's regulatory science program. FDA agreed to language regarding continuation of the current success of the program, particularly in the area of rare diseases.

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