FDA-Industry PDUFA VI Reauthorization Meeting
December 16, 2015, 9:30 -11:00am
FDA White Oak Campus, Silver Spring, MD
Building 32, Room 1227

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	Kay Holcombe	BIO
John Jenkins	CDER	Laurie Keating	BIO (Alnylam)
Christopher Joneckis	CBER	Robert Metcalf	PhRMA (Eli Lilly)
Sarah Pope Miksinski	CDER	Mark Taisey	PhRMA (Amgen)
Theresa Mullin	CDER		
Mary Parks	CDER		
Michael Pacanowski	CDER		
Vada Perkins	CBER		
Giuseppe Randazzo	CDER		
James Smith	CDER		
Sara Stradley	CDER		
Kelly Taylor	CDER		
Kimberly Taylor	CDER		

Discussion of Manufacturing Supplement Proposal

FDA proposed to state in the PDUFA VI commitment letter that all non-NME NDAs, BLAs, efficacy supplements, and manufacturing supplements are expected to contain a comprehensive and readily locatable list of manufacturing facilities, if applicable. In the PDUFA V letter, this expectation is currently specified as part of the NME Program for clinical sites and manufacturing facilities. The agency also proposed that if FDA identifies the need to inspect a manufacturing facility that was not included on the list in the application or supplement, it could trigger an extension of the PDUFA goal date. FDA stated this proposal would help the agency plan for inspection activities in situations where the need to inspect facilities may adversely impact FDA's ability to meet PDUFA goals. Industry and FDA agreed to continue discussing this proposal.

Discussion of Meeting Management Proposal

FDA proposed providing preliminary comments to Type B and C background packages earlier to streamline processes and allow sponsors more time to prepare for meetings after receiving FDA's comments.

Industry and FDA also discussed allowing a sponsor the ability to request the Written-Response-Only (WRO) option for any meeting type if the sponsor feels that written response would be sufficient. If FDA felt that more direct interaction was necessary given the meeting subject, FDA could instead consider it a face-to-face meeting or teleconference.

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