FDA-Industry PDUFA VI Reauthorization Steering Committee Meeting
January 20, 2016, 9:00am-11:00am
FDA White Oak Campus, Silver Spring, MD
Building 32, Room 1243

Purpose
To provide progress updates for each working group and discuss next steps for the reauthorization process.

Participants

FDA		Industry	
Jill Adleberg	OC	Beatrice Biebuyck	BIO (Alexion)
Josh Barton	CDER	Jennifer Boyer	BIO (Alkermes)
Steve Berman	CDER	Cartier Esham	BIO
Joe Franklin	OC	Sascha Haverfield	PhRMA
Patrick Frey	CDER	Kay Holcombe	BIO
John Jenkins	CDER	Laurie Keating	BIO (Alnylam)
Chris Joneckis	CBER	Robert Metcalf	PhRMA (Eli Lilly)
Andrew Kish	CDER	Sandra Milligan	PhRMA (Merck)
Theresa Mullin	CDER	Paula Rinaldi	PhRMA (Novartis)
Mary Parks	CDER	Michelle Rohrer	BIO (Roche Genentech)
Grail Sipes	CDER	Mark Taisey	PhRMA (Amgen)
Graham Thompson	CDER		
Terry Toigo	CDER		
Brad Wintermute	OIMT		

Update on Progress of Hiring Initiatives
FDA provided an update on current initiatives to enhance FDA's hiring system, including the implementation of a position-based management program, a position classification system, an expansion of a corporate recruiting initiative, as well as efforts to increase hiring capacity.

Update on Hiring Commitment Language
Industry indicated general support for the latest version of proposed hiring commitment letter language, particularly the provision to include a comprehensive and continuous third party assessment of FDA hiring and retention performance modeled after the comprehensive evaluation of the PDUFA V NME Review Program.

Pre-Market Group Progress Report
The Pre-Market group reported that discussions were continuing on enhancement proposals related to Meeting Management processes, ensuring capacity for the Breakthrough Therapy program, enhancing combination product review, and providing for early consultation on the use of new surrogate endpoints. The group noted they had completed discussions of updates to the NME

review program and enhancements to communication practices between FDA and sponsors during drug development.

Financial Group Progress Report
The Financial group reported that they were continuing to review draft commitment letter language related to financial commitments as well as draft edits to the relevant financial sections of the statute.

Regulatory Decision Tools Group Progress Report
The Regulatory Decision Tools group reported that they had completed discussion of draft language for proposals relating to analysis data standards. The group reported that some discussions remained on proposals relating to enhancing capacity to review complex innovative trial designs, and enhancing the drug development tools qualification pathway.

Post-Market Group Progress Report
The Post-Market group reported that they were close to agreement on draft commitment letter language for proposals relating to enhancements to the Sentinel System, exploring use of real-world evidence, and timely communication of post-market safety information.

Information Technology Group Report
The Information Technology working group reported that they had largely reached agreement on IT commitment letter language, and were continuing to discuss a few minor outstanding issues.

Allergenic Extracts Products Proposal
The Center for Biologics Evaluation and Research (CBER) presented a proposal to expand the scope of the PDUFA program to include new allergenic extract products. CBER noted that though allergenic extract products are currently specifically exempted in statute from the PDUFA program, many of these products have evolved considerably and are now complex, sophisticated products requiring significant review resources. CBER proposed that newly licensed allergenic products be added to the PDUFA program beginning in PDUFA VI.

Industry indicated that while they believed this may be a worthy proposal, the late introduction of this proposal was somewhat problematic as not enough time remained in the jointly-agreed upon timeframe to be able to give the proposal adequate consideration. Industry noted that many of the sponsors of allergenic products are not represented by either PhRMA or BIO, and as such PhRMA and BIO are not in a position to represent industry interests on this specific proposal at this time.

FDA agreed to discontinue consideration of this proposal.

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