FDA-Industry PDUFA VI Reauthorization Steering Committee Meeting
January 13, 2016, 12:30pm-2:30pm
FDA White Oak Campus, Silver Spring, MD
Building 51, Room 1219

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	Jeffrey Francer	PhRMA
Patrick Frey	CDER	Sascha Haverfield	PhRMA
John Jenkins	CDER	Kay Holcombe	BIO
Chris Joneckis	CBER	Laurie Keating	BIO (Alnylam)
Andrew Kish	CDER	Robert Metcalf	PhRMA (Eli Lilly)
Theresa Mullin	CDER	Sandra Milligan	PhRMA (Merck)
Mary Parks	CDER	Paula Rinaldi	PhRMA (Novartis)
Graham Thompson	CDER	Michelle Rohrer	BIO (Roche Genentech)
Terry Toigo	CDER	Mark Taisey	PhRMA (Amgen)
Brad Wintermute	OIMT		

Update on Hiring Proposals
FDA shared proposed draft commitment language related to hiring and retention of review staff. The draft language included an assessment of current hiring practices and strategies, enhancements to the hiring system's infrastructure and capacity, establishment of a dedicated function to ensure needed scientific staffing, and setting goals for drug product review hiring. Industry voiced general support for the draft language and provided suggestions for possible edits.

Pre-Market Group Progress Report
The Pre-Market group reported completing discussions on draft commitment letter language for proposals related to enhancing communication between FDA and sponsors during drug development, and updates to the NME Review Program language. The group noted that discussions regarding draft commitment letter language were ongoing for enhancements related to combination product review, meeting management updates, and early consultation on the use of new surrogate endpoints.

Financial Group Progress Report
The Financial group reported that they had begun reviewing draft commitment letter language related to financial commitments, and had begun reviewing draft edits to the financial section 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 Patient-Focused Drug Development and Benefit-Risk. The group stated that they were continuing discussion of draft language for enhancements related to supporting innovation in complex trials, analysis data standards, and biomarker qualification.

Post-Market Group Progress Report
The Post-Market group stated that they were continuing discussions on draft commitment letter language related to enhancements for the Sentinel System, real world evidence, and communications related to drug safety issues.

Information Technology Group Report
The Information Technology working group reported that they were continuing discussions regarding commitment language related to enhancing predictability of e-submission processes, as well as transparency and communications more generally related to FDA IT to support the process for the review of human drugs.

Allergenic Extract Products Proposal
The Center for Biologics Evaluation and Research provided a brief summary description of a new proposal to expand the scope of the PDUFA program to include new allergenic extract products. Representatives indicated this proposal would be formally presented at the next steering committee meeting.

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