FDA-Industry PDUFA VI Reauthorization Steering Committee Meeting
December 16, 2015, 1:00pm-2:30pm
FDA White Oak Campus, Silver Spring, MD
Building 2, Room 2047

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)
Grail Sipes	CDER	Michelle Rohrer	BIO (Roche Genentech)
Urvi Shah	CDER	Mark Taisey	PhRMA (Amgen)
Graham Thompson	CDER		
Terry Toigo	CDER		

The meeting discussion was focused on progress reports from each of the working groups, which includes Pre-Market, Financial, Regulatory Decision Tools, Post-Market, and Information Technology

Pre-Market Group Progress Report
Industry suggested delegating proposed enhancements relating to drug development tools to the Regulatory Decision Tools group as a number of other proposals requiring additional discussion remain within the Pre-Market group's purview. FDA agreed to delegate a proposal related to the drug development tool qualification process to the Regulatory Decision Tools group, but indicated that a proposal related to proprietary use of drug development tools was more appropriate to remain within the Pre-Market group; discussion of this latter proposal would be prioritized when the group re-convenes in January. The group noted that they had continued discussions of draft commitment letter language relating to updates to the NME Review Program and communication with sponsors during drug development. The group had continued discussions on approaches to enhance the management of formal meetings requested by sponsors within the drug development phase, and noted that potential enhancements to drug-led combination product review processes would be further explored in future discussions.

Financial Group Progress Report
The Financial group reported that, while details remain, they had outlined a package of potential enhancements designed to improve the long-term stability of the program by enhancing the predictability of fee funds as well as enhancing capacity planning and resource management functions of the program. The group noted it would be drafting commitment letter and proposed statutory language, as appropriate, in January.

Regulatory Decision Tools Group Progress Report
The Regulatory Decision Tools group stated that they had continued discussion on draft commitment letter language for all their remaining proposals, including proposals relating to patient-focused drug development, the benefit-risk framework, innovative clinical trials, and analysis data standards. The group noted that a discussion on resourcing would need to occur at a future Steering Committee meeting within the full context of resource needs for all potential enhancements under discussion for PDUFA VI.

Post-Market Group Progress Report
The Post-Market group stated that they had continued discussions regarding proposals related to exploring the use of real-world evidence for efficacy and safety evaluation post approval.

Information Technology Group Report
The Information Technology working group noted that discussions were focused on finalizing 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.

Update on Hiring Proposals
FDA noted it planned to share proposed draft commitment language related to recruitment and retention of key scientific and technical staff in January.

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