FDA-Industry PDUFA VI Reauthorization Steering Committee Meeting
December 1, 2015, 1:30pm-4:00pm
FDA White Oak Campus, Silver Spring, MD
Building 71, Room 1208/1210

Purpose
To provide progress updates for each working group and discuss next steps for the Steering Committee.

Participants

FDA		Industry	
Jill Adleberg	OC	Beatrice Biebuyck	BIO (Alexion)
Josh Barton	CDER	Jennifer Boyer	BIO (Alkermes)
Steve Berman	CDER	Cartier Esham	BIO
Amanda Edmonds	OC	Jeffrey Francer	PhRMA
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		

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
The Pre-Market working group noted that discussions were continuing on a number of possible areas of enhancement. This includes discussion of potential options to enhance meeting management to ensure FDA can provide input and advice to drug development programs through an increasing number of formal meetings requested by industry sponsors each year. The group also reported discussing a set of modifications to codify best practices and enhance flexibility within the NME Review Program; this may also include the addition of language regarding FDA's review activities associated with a controlled substances scheduling recommendation within the NME Review Program, where applicable.

Financial Group Progress Report
The Financial working group noted that discussions were continuing on a package of 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 had recently discussed potential options to improve PDUFA annual financial reports and would be discussing potential enhancements to the PDUFA workload adjuster.

Regulatory Decision Tools Group Progress Report
The Regulatory Decision Tools working group noted that discussions were continuing on proposed enhancements related to Patient-Focused Drug Development, the Benefit-Risk Framework, and a proposal to enhance processes and capacity for FDA to provide input on innovative clinical trials. The group noted that it would be discontinuing discussions related to a proposal to address statistical issues related to sub-group analysis.

Post-Market Group Progress Report
The Post-Market working group noted that discussions were continuing on proposals related to real world evidence and potential enhancements to the Sentinel System.

Information Technology Group Report
The Information Technology working group noted that discussion were continuing on draft 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.

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