FDA-Industry PDUFA VI Reauthorization Steering Committee Meeting
October 13, 2015, 1:00pm-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	
Josh Barton	CDER	Beatrice Biebuyck	BIO (Alexion)
Steve Berman	CDER	Jennifer Boyer	BIO (Alkermes)
Amanda Edmonds	OC	Cartier Esham	BIO
Ron Fitzmartin	CDER	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 Kowalski	PhRMA (Novartis) PhRMA (Novartis)
Theresa Mullin	CDER	Robert Metcalf	PhRMA (Eli Lilly)
Mary Parks	CDER	Sandra Milligan	PhRMA (Merck)
Grail Sipes	CDER	Michelle Rohrer	BIO (Roche Genentech)
Melissa Segal	OC	Mark Taisey	PhRMA (Amgen)
Graham Thompson	CDER		
Terry Toigo	CDER		

Pre-Market Group Progress Report & Next Steps
The Pre-Market working group completed initial review of all Industry and FDA proposals. FDA conveyed concerns over the potential workload impact of proposals adding significant new review metrics. Industry expressed a need to understand the current state of hiring and current vacancies to be able to discuss potential workload impacts of new commitments.

FDA suggested that, in view of the growing number of formal meetings (Type A, B, & C), the current timeframes for meetings goals should be explored. FDA observed that the ability to meet procedural meeting goals is constrained by the number of senior-level employees on staff and noted that the complexity of scientific and regulatory issues addressed by formal meetings have increased since the procedural goals were first established. Industry agreed to further explore the proposal for extending meeting timeframes within the Pre-Market working group.

Financial Group Progress Report & Next Steps
The Financial working group noted that they had outlined a calendar of topics to discuss over the next few months. The group stated that they had reviewed data on the historical components of the annual target revenue and agreed to further discuss the mechanics of the workload adjuster. Industry noted an interest in understanding how the workload adjuster distributes resources to direct review functions.

FDA noted that the lack of future year predictability of the workload adjuster adversely impacts the ability to hire with workload adjuster funds, as the funds are not guaranteed to recur every year.

The group also reviewed the impact of updating the percentage of the annual target revenue allocated to each fee type (currently 1/3 of the annual target revenue is allocated to each of the application, product and establishment fees). The group noted they would be looking at additional data regarding the impact of updating the target allocation.

Regulatory Decision Tools Group Progress Report & Next Steps

The Regulatory Decision Tools working group noted that they had discussed FDA and Industry proposals on Patient-Focused Drug Development and Benefit-Risk, and would be reviewing additional proposals including a proposal related to innovative clinical trials design, at the next meeting. Industry noted there appeared to be some overlap in intent among the FDA and Industry proposals, particularly for Patient-Focused Drug Development.

Post-Market Group Progress Report & Next Steps

The Post-Market working group stated that they had reviewed FDA and Industry's proposals on real-world evidence. FDA's real world evidence proposal included expanding Sentinel as well as exploring the potential for uses of public data such as social media in regulatory decision making. Industry noted they would be sharing case studies and a literature review describing examples of the use of real world evidence in regulatory decision making. The working group noted they would be addressing their proposals in more detail at their next meeting.

Information Technology Group Report & Next Steps

The Information Technology (IT) working group noted that there appeared to be alignment around the major themes outlined by FDA and Industry concerning relevant areas of IT. These themes include predictability, consistency, and transparency of electronic submission systems. Industry noted that they had proposed additional approaches for tracking the status of an application throughout the review process. FDA noted there are already communication milestones within its managed review processes and that additional tracking throughout the review process would be perceived as micromanagement by Industry and would be counterproductive.

Hiring Strategy Proposal

FDA provided a high-level overview of the current challenges FDA faces in hiring qualified individuals and presented a strategy to enhance targeted recruitment, onboarding, and retention of scientific personnel. Industry expressed support for FDA's proposal.

FDA stated that they planned to present additional details regarding current status of hiring efforts and proposals in the coming weeks.

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