FDA-Industry PDUFA VI Reauthorization Steering Committee Meeting
October 20, 2015, 2:00pm-3:30pm
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
Patrick Frey	CDER	Jeffrey Francer	PhRMA
John Jenkins	CDER	Sascha Haverfield	PhRMA
Chris Joneckis	CBER	Kay Holcombe	BIO
Andrew Kish	CDER	Robert Kowalski	PhRMA (Novartis)
Theresa Mullin	CDER	Robert Metcalf	PhRMA (Eli Lilly)
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 provided a series of updates from various subgroup discussions focused on pre-market review, financial issues, regulatory decision tools, post-market review and information technology.

Pre-Market Group Progress Report & Next Steps
The Pre-Market working group noted that they had reviewed performance data related to FDA-sponsor formal meeting (Type A, B, & C) process timeframes and discussed the timing of background packages. FDA said that one of the biggest rate-limiting steps in achieving the target timeframes for the increasing numbers of meetings is the difficulty finding time in senior-level staff schedules to ensure their participation in the meetings. FDA noted that there are now about 10 meetings per day led by CDER's Office of New Drugs. The group also reviewed data on the review of labeling supplements, including both Changes Being Effected (CBE) and Prior Approval Supplements (PAS).

The group reported discussing the new drug review program's current resource needs and challenges. FDA noted that, as a public health agency, it is important to maintain some flexibility within its operating environment to ensure that the Agency can manage numerous priorities required in fulfilling its public mission. With this in mind, FDA was hesitant to formally commit to additional metric goals that could over burden the system. FDA noted that it was reviewing the status of current resources for the review program to help to reduce the stress and strain on reviewers. FDA noted that it would be sharing additional details on this plan, as well as details on resources required to meet timeframes for all other current internal goals at future meetings.

The group reported planning to discuss review performance data on post-marketing requirements and post-marketing commitment study protocols as well as manufacturing supplements at its next meeting, which would occur the following day.

Financial Group Progress Report & Next Steps
The Financial working group reported that they had spent the majority of their last meeting providing an overview of current staff time reporting practices in both CDER and CBER. This included an overview of the challenges experienced while implementing a recent change to CDER's time reporting system. FDA noted their current time reporting systems are cost effective.

FDA asked Industry how often employees of their member companies would be reporting to multiple projects on a given day, noting that FDA staff often managed numerous different projects. For example, it was noted that an FDA reviewer could have well over 100 INDs in their portfolio, in addition to other work. Industry representatives stated that the number of projects per staff could vary. It was noted in one company most staff might have one to four projects while a few staff could have up to thirty. Industry noted that staff in leadership positions would often report a significant amount of their time to general categories.

The group also reported that they had begun to discuss the mechanics of the current PDUFA workload adjuster. Industry expressed an interest in better understanding how the resources provided by the workload adjuster are allocated. Industry conveyed an interest in assuring the resources provided through the workload adjuster are utilized by the review offices experiencing increases in workload. The group noted they would continue their discussions of the workload adjuster in their next meeting.

Regulatory Decision Tools Group Progress Report & Next Steps
The Regulatory Decision Tools working group stated that they had had initial discussions of Industry's proposal on innovative clinical trial design as well as proposals from the FDA on innovative clinical trials, improving subgroup analysis, and building statistical programmer capacity to enhance implementation of data standards. FDA noted that while both sides had areas of agreement regarding innovative clinical trials, FDA did not believe that it would be feasible to conduct meetings with sponsors under the Industry-proposed type B meeting timeframes nor under a process analogous to the Special Protocol Assessment process (currently these are type C meetings).

The group noted they would be further discussing innovative clinical trials at a future meeting and would be discussing each side's proposals on Patient-Focused Drug Development at their next meeting.

Post-Market Group Progress Report & Next Steps
The Post-Market working group noted that they had reviewed both Industry and FDA proposals relating to the use of real world evidence in regulatory decision making. Industry had shared a compendium of literature on the use of real world evidence and would be providing a set of case studies in the next group meeting. The group noted that that FDA's proposal included additional resources for the Sentinel Initiative; the group would be discussing current resourcing for Sentinel.

Information Technology Group Report & Next Steps
The Information Technology (IT) working group stated that they had spent most of their meeting discussing the performance of the Electronic Submission Gateway (ESG). Industry noted an interest in knowing which version of relevant software FDA is using in order to be able to test submissions internally before sending to the Agency. Industry also expressed an interest in additional information

concerning maintenance schedules for the ESG, as well as a better understanding of current status of rejection rates of submissions by the system.

Steering Committee Next Steps

The steering committee agreed to reschedule working group meetings for the second week of November to the morning of Tuesday, November 10, as November 11th is a Veteran's Day, a federal holiday.

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