FDA-Industry PDUFA VI Reauthorization Steering Committee Meeting
October 6, 2015, 3:00pm-4:00pm
FDA White Oak Campus, Silver Spring, MD
Building 71, Room 1208/1210

Purpose
To provide a summary of discussions in the Pre-Market and Financial working groups, and discuss a schedule for addressing topics in other working groups.

Participants

FDA		Industry	
Josh Barton	CDER	Beatrice Biebuyck	BIO (Alexion)
Amanda Edmonds	OC	Jennifer Boyer	BIO (Alkermes)
Patrick Frey	CDER	Cartier Esham	BIO
John Jenkins	CDER	Jeffrey Francer	PhRMA
Chris Joneckis	CBER	Sascha Haverfield	PhRMA
Andrew Kish	CDER	Kay Holcombe	BIO
Theresa Mullin	CDER	Robert Kowalski	PhRMA (Novartis)
Mary Parks	CDER	Robert Metcalf	PhRMA (Eli Lilly)
Grail Sipes	CDER	Michelle Rohrer	BIO (Roche Genentech)
Graham Thompson	CDER	Mark Taisey	PhRMA (Amgen)
Terry Toigo	CDER		
Brad Wintermute	OIMT		

Working Group Meetings
The time allotted for the Steering Committee meeting was reduced to allow for the Pre-Market working group to meet.

Working Group Report-Out
The Pre-Market working group provided a brief summary of their discussions. The Pre-Market group reported they have completed an initial review of all but two FDA proposals; these remaining two proposals would be addressed in the working group meeting scheduled for the following day. They also stated that they plan to discuss Industry proposals in more detail at the next meeting. FDA noted that a number of Industry proposals included new metric goals and expressed a general concern with the current level of workload demand on the human drug review program and the potential workload impact of such additional metric goals.

The Financial working group provided a summary of their discussions from the previous week. The representatives stated that they reviewed all proposals at a high level, which included a proposal to change FDA time reporting practices, and that they would be discussing a few proposals in more detail at the next working group meeting. FDA stated that they had agreed to a site visit in order to learn about industry time reporting practices.

FDA asked whether Industry would be able to share a sense of priorities among proposal topics. Industry responded that they would prefer to discuss priorities at the Steering Committee level after all proposals had been discussed in detail.

The Post-Market, Regulatory Decision Tools, and Information Technology working groups stated they would present FDA and Industry proposals at their first working group meetings, which would occur the following day.

FDA and Industry agreed to discuss developing a planned schedule for addressing topics in future working group meetings.

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