FDA-Industry PDUFA VI Reauthorization Steering Committee Meeting
November 3, 2015, 3:00pm-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
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)
Graham Thompson	CDER	Mark Taisey	PhRMA (Amgen)
Terry Toigo	CDER		
Brad Wintermute	OIMT		

The Steering Committee convened to discuss the current allocation of fee-funded resources within the review program and to provide updates on the status of the various working groups.

Discussion of Resource Issues & Hiring
FDA presented an overview of its plan to allocate fee resources to the review program to help to address workload demands. FDA provided an estimate of the number of employees it planned to hire as well as the offices and disciplines that would be targeted for this effort. FDA projected that available resources would likely be sufficient to sustain the additional hires provided that the fiscal year 2017 inflation and workload-adjusted target revenue be used as the basis of the PDUFA VI statutory base funding level. FDA presented a targeted timeline for the on-boarding on these hires, as well as an overview of an integrated hiring strategy for PDUFA.

FDA noted that it would discuss hiring processes within the federal government and share additional details of its hiring strategies in the next Steering Committee meeting.

Pre-Market Group Progress Report & Next Steps
The Pre-Market group stated that they had reviewed data describing current workload stress on the review program. The group also reviewed data describing the growth of workload related to the breakthrough therapy program.

Financial Group Progress Report & Next Steps
The Financial working group noted that they had discussed FDA's current work developing cost allocation models for shared services, addressing challenges presented by the statutory five-year offset provision, as well as Industry proposals relating to the enhancement of PDUFA capacity planning and resource management.

Regulatory Decision Tools Group Progress Report & Next Steps
The Regulatory Decision Tools group stated that they had been discussing elements related to potential commitments for Patient-Focused Drug Development. In addition, the group planned on further discussing proposals related to the Benefit-Risk Framework in their next meeting.

Information Technology Group Report & Next Steps
FDA noted that they had received draft proposed IT-relevant commitment language from Industry and had develop red-line edits and made comments for discussion at the next meeting.

Post-Market Group Progress Report & Next Steps
The Post-Market group said they planned on discussing resource allocation and staffing for a mini-Sentinel enhancement proposal, as well as discussing in greater detail proposals related to the use of real world evidence in regulatory decision making in their next meeting.

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