FDA-Industry PDUFA VI Reauthorization Steering Committee Meeting
January 27, 2016, 10:00am-2:00pm
FDA White Oak Campus, Silver Spring, MD
Building 2, Room 2046

Purpose
To provide progress updates for remaining working groups, review resources, and discuss next steps for the reauthorization process.

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	Sascha Haverfield	PhRMA
Joe Franklin	OC	Kay Holcombe	BIO
Patrick Frey	CDER	Laurie Keating	BIO (Alnylam)
John Jenkins	CDER	Robert Metcalf	PhRMA (Eli Lilly)
Chris Joneckis	CBER	Sandra Milligan	PhRMA (Merck)
Andrew Kish	CDER	Paula Rinaldi	PhRMA (Novartis)
Theresa Mullin	CDER	Michelle Rohrer	BIO (Roche Genentech)
Mary Parks	CDER	Mark Taisey	PhRMA (Amgen)
Grail Sipes	CDER		
Terry Toigo	CDER		
Brad Wintermute	OIMT		

Pre-Market Group Progress Report
The Pre-Market group reported that they had completed discussions on draft commitment letter language for an enhancement proposal related to the review of combination products, and had drafted updated language pertaining to the rare disease program. The Pre-Market group indicated that its discussions were now complete.

Post-Market Group Progress Report
The Post-Market group reported that they had completed discussions on draft commitment letter language for all proposal enhancements within their purview.

Review Resources
FDA and Industry agreed to add additional detail to the draft commitment letter regarding the activities under the patient-focused drug development proposal.

FDA and Industry reached broad, tentative agreement at the negotiating team level to recommend to their respective ratifiers to fund a package of enhancement proposals.

The enhancement proposals within this package include ensuring sustained success of the Breakthrough Therapy program, enhancing the incorporation of patient's voice in drug development and decision-making, advancing development of drug-device and biologic-device combination products regulated by CBER and CDER, enhancing drug development tools qualification pathway for biomarkers, promoting innovation through enhanced communication between FDA and sponsors during drug development, early consultation on the use of new surrogate endpoints, enhancing use of real world evidence for use in regulatory-decision making, updates to the NME Review Program to enhance flexibility and codify best practices, updates to meeting management processes, enhancing benefit-risk assessment in regulatory decision making, advancing model-informed drug development, enhancing capacity to review complex innovative trial designs, enhancing capacity to support analysis data standards for product development and review, advancing postmarketing drug safety evaluation through expansion of the Sentinel System and integration into FDA pharmacovigilance activities, timely and effective evaluation and communication of postmarketing safety findings related to human drugs, enhancing management of user fee resources, improving FDA hiring and retention of review staff, and updates to information technology goals to enhance electronic submission processes and data standards activities.

The group agreed to reconvene on January 29th to provide time for the Financial group to complete discussions on draft commitment letter language regarding management of user fee resources, to discuss edits to proposed statutory language to incorporate the tentatively agreed upon funding levels, and to complete the draft Justification for Proposed Statutory Changes document.

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