

FDA-Industry PDUFA VI Reauthorization Steering Committee Meeting
January 29, 2016, 12:30pm-3:00pm
FDA White Oak Campus, Silver Spring, MD
Building 2, Room 2046

Purpose

To reach agreement at the negotiation team level on commitment letter language describing a package of enhancement proposals for PDUFA VI.

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 (AInylam)
John Jenkins	CDER	Robert Metcalf	PhRMA (Eli Lilly)
Chris Joneckis	CDER	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		

Financial Group Report

The Financial group reported that they completed discussion on draft commitment letter language describing proposals to enhance the management of user fee resources. The group also reported that the proposed draft of the statutory changes document was ready for legal review. The group noted it had completed a first draft of the Justifications of Proposed Statutory Changes document and would be refining this draft in early February.

Commitment Letter Review

The Steering Committee reviewed the entire draft commitment letter to identify the need for clarifying edits or for any further corrections.

It was considered that progress on review program performance would be reported on in the annual Performance Report and progress on the proposed hiring goals would be reported on in the annual Financial Report.

The group agreed to restructure the table of contents of the draft commitment letter.

The group agreed to recommend the draft commitment letter and proposed statutory changes to their respective senior management for ratification.

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