FDA-Industry PDUFA VI Reauthorization Steering Committee Meeting
September 29, 2015, 10:00am-11:00am; 2:15pm-3:00pm
FDA White Oak Campus, Silver Spring, MD
Building 71, Room 1208/1210

Purpose

To discuss topics for working group meetings, provide an overview of PDUFA financial background information, and discuss the schedule of meetings moving forward.

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	Deborah Henderson	PhRMA (Merck)
Andrew Kish	CDER	Laurie Keating	BIO (Alnylam)
Theresa Mullin	CDER	Robert Kowalski	PhRMA (Novartis)
Mary Parks	CDER	Robert Metcalf	PhRMA (Eli Lilly)
Grail Sipes	CDER	Sandra Milligan	PhRMA (Merck)
Melissa Segal	OC	Michelle Rohrer	BIO (Roche Genentech)
Graham Thompson	CDER	Mark Taisey	PhRMA (Amgen)
Terry Toigo	CDER	Lucy Vereshchagina	PhRMA
Brad Wintermute	OIMT		

Topics for Working Group Meetings

FDA and Industry discussed the assignment of proposal topics to the designated working groups. It was noted by both parties that some proposal topics would require discussion across multiple working groups. A tentative list of working group assignments was made with an agreement to further discuss the logistics of proposal topics requiring input across multiple working groups.

PDUFA Financial Briefing

FDA presented an overview of financial background information relevant to the PDUFA program. This included an overview of: the PDUFA fee structure and the annual fee setting process, the impact of volatility on collections, the role of waivers and exemptions, the challenges administering the establishment fee, the uses and status of the carryover balance, the impact of the 5-year offset provision, and the Fees-Exceed-Cost (FEC) waiver and standard cost model.

Working Group Meetings

The Steering Committee adjourned at 11:00am to allow time for the Pre-Market and Financial working groups to meet. The Steering Committee resumed at 2:15pm.

Working Group Report-Out & Future Meeting Schedule
The Financial and Pre-Market working group representatives provided a brief summary of their discussions.

The Financial working group stated that they discussed each FDA proposal at a summary level and would discuss Industry proposals in their next meeting.

The Pre-Market working group stated that they had discussed at a summary level approximately half of the FDA and Industry proposals. Given the relatively large number of proposal topics assigned to the Pre-Market working group, FDA and Industry agreed to reapportion time from the October 6th Steering Committee meeting to allow the Pre-Market working group to continue discussions of their proposal topics.

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