FDA-Industry PDUFA VI Reauthorization Meeting
Finance Sub-Group

Day 1: January 27, 2016, 3:00 pm - 6:00 pm	**Day 2: January 28, 2016, 3:00 pm - 6:00 pm**
FDA White Oak campus, Silver Spring, MD Building 32, Room 1211	FDA White Oak Campus, Silver Spring, MD Building 51, Room 4200

Purpose

To review the draft financial components of the PDUFA VI commitment letter, draft proposed statutory changes to the PDUFA fee provisions of the FD&C Act to reflect financial enhancements, and associated draft language to provide justifications for the proposed statutory changes.

Participants

FDA	
Joshua Barton	CDER
Yanming Chae	CBER
Amanda Edmonds	OC
Azada Hafiz	CDER
Andrew Kish	CDER
Robert Marcarelli	OC

Industry	
Jennifer Boyer	BIO (Alkermes)
Sascha Haverfield	PhRMA
Deborah Henderson	PhRMA (Merck)
Kay Holcombe	BIO
Laurie Keating	BIO (Alnylam)
Robert Metcalf	PhRMA (Eli Lilly)
Lucy Vereshchagina	PhRMA

FDA and Industry continued discussion of additional edits to the draft technical revisions to the fee provisions in Sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), the financial components of the PDUFA VI commitment letter, and the justifications for the proposed statutory changes.

FDA and Industry identified a small number of minor technical edits to the documents to enhance clarity. Contingent on these further edits, FDA and Industry agreed the draft documents that reflect the proposed PDUFA VI changes to the current fee structure to enhance financial predictability, transparency, and stability were ready for review by the Steering Committee.

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