FDA-Industry PDUFA VI Reauthorization Meeting
Finance Sub-Group
January 12, 2016, 3:00pm-5:00pm
FDA White Oak Campus, Silver Spring, MD
Building 51, Room 3200

Purpose

To continue discussing financial enhancements for PDUFA VI reauthorization, including the billing model and changes to statutory language.

Participants

FDA	
Joshua Barton	CDER
Amanda Edmonds	OC
Azada Hafiz	CDER
Andrew Kish	CDER
Robert Marcarelli	OC
Angela Moy	CBER

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

Billing model

In previous meetings, Industry had expressed concern about the impact of the modification on product fees for products with multiple presentations. FDA and Industry discussed not charging fees beyond a certain number of presentations per product. Industry agreed to provide feedback on the number of presentations per product at a future meeting.

Statutory Language

FDA and Industry discussed potential technical revisions to the fee provisions in Sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to codify modifications to the current fee structure to enhance financial predictability, transparency, and stability. FDA and Industry agreed to continue discussing these revisions to the statutory fee provisions at future meetings.

Plan for future meetings

The goal for the next meeting on January 19 will be to continue discussing technical changes to the PDUFA fee provisions of the FD&C Act, continue discussing related changes to the commitment letter, and for FDA to provide a briefing on the fully-loaded full-time equivalent (FTE) cost methodology.

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