FDA-Industry PDUFA VI Reauthorization Meeting
Finance Sub-Group
December 15, 2015, 3:00pm-5:00pm
FDA White Oak Campus, Silver Spring, MD
Building 51, Room 6300

Purpose

To continue discussing financial enhancements for PDUFA VI reauthorization, including Industry's feedback on the financial transparency and capacity planning options and the billing model.

Participants

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

Financial transparency and capacity planning options

In the previous meeting, FDA and industry discussed options to modernize time reporting and develop a capacity planning function during PDUFA VI, with the assistance of a 3rd party organization. Industry emphasized the need for timely implementation of modernized time reporting and a capacity planning function during PDUFA VI.

Billing model

In previous meetings, FDA and Industry had discussed options for modifying the target revenue allocation among application, establishment, and product fee types. Industry expressed concern about the impact of the modification on product fees for products with multiple presentations. FDA agreed to explore product fee options for products that have multiple presentations.

Plan for future meetings

The goal for the next meeting on January 12 will be to continue discussing financial enhancements for PDUFA VI reauthorization and to discuss changes to statutory language and the commitment letter for financial enhancements.

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