FDA-Industry PDUFA VI Reauthorization Meeting
Finance Sub-Group
November 18, 2015, 12:30pm-2:30pm
FDA White Oak Campus, Silver Spring, MD
Building 51, Room 5300

Purpose

To continue discussing financial enhancements for PDUFA VI reauthorization, including options for modifying the financial report, and an update on the carryover balance.

Participants

FDA	
Joshua Barton	CDER
Yanming Chae	CBER
Patrick Frey	CDER
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

Financial reporting

FDA explained the content of the PDUFA financial report and the process for developing and clearing the report. Industry stated that it's difficult to interpret the annual financial reports without information on FDA's financial plan for a given PDUFA 5-year authorization. Industry expressed the need for a financial report that is based on the Agency's long term financial and capacity plan for the PDUFA program. Industry stated the report should track how the Agency is progressing against its planned goals to ensure resources are allocated appropriately to support the program. Industry stated that the report should show how the Agency plans for and spends revenue generated from the PDUFA workload adjuster.

Carry over balance

FDA provided fiscal year (FY) 2015 carry over level and estimates for FY 2016 and FY 2017.

Plan for future meetings

The goal for the next meeting on December 2 will be to discuss options for modifying the workload adjuster.

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