FDA-Industry PDUFA VI Reauthorization Meeting
Finance Sub-Group
October 21, 2015, 12:30pm-2:30pm
FDA White Oak Campus, Silver Spring, MD
Building 51, Room 6200

Purpose

To continue discussing financial enhancements for PDUFA VI reauthorization including a discussion of the billing model and the workload adjuster.

Participants

FDA	
Joshua Barton	CDER
Yanming Chae	CBER
Amanda Edmonds	OCC
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
Robert Metcalf	PhRMA (Eli Lilly)
Lucy Vereshchagina	PhRMA

Billing model

In the October 7th meeting, Industry requested FDA add more years of data to the billing model to help assess the multi-year impact of modifying the target revenue allocation among application, establishment, and product fee types. FDA shared the updated billing model with three year average data from fiscal years 2013 through 2015. Industry asked FDA's goal for modifying the target revenue allocation. FDA stated its goal is to improve funding predictability while minimizing impact on sponsors. FDA stated it will show the impact of target allocation scenarios on funding predictability using historical data during a future meeting.

Workload adjuster

FDA explained revenue produced from the workload adjuster can be unpredictable from year to year, which makes financial planning challenging. FDA stated an ideal workload adjuster would account for sustained increases in workload and be predictable from year to year. Industry acknowledged FDA's challenges in relying on the current workload adjuster model for predictable funding. Industry expressed concern about funding generated from the workload adjuster going to the carry over balance and asked how funding generated from the workload adjuster is allocated to the offices that manage the workload represented in the adjuster. Industry also noted that the workload adjuster appears to compound; FDA explained that it does not. FDA and Industry agreed to discuss options to enhance transparency of the allocation of workload adjuster generated revenue in a future meeting.

Plan for Future Meetings

The goal for the next meeting on October 28 will be for FDA and Industry to discuss full time equivalent (FTE) cost allocation models and the 5-year offset provision.

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