

FDA-Industry PDUFA VI Reauthorization Meeting
Finance Sub-Group
October 14, 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 briefing on time reporting practices and to discuss the PDUFA workload adjuster with emphasis on the Eastern Research Group (ERG) report.

Participants

FDA

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

Industry

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

Time reporting

In the previous meeting, Industry asked for more information on FDA's time reporting practices. FDA described the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research's (CDER) time reporting practices. FDA explained the time reporting frequency, provided a high-level overview of the categories, and explained the staffing requirements to report time for CBER and CDER. FDA explained CDER's time reporting system transition in 2013, including reasons for changing the time reporting system, changes in the new system, and implementation time frame.

Workload adjuster

In the previous meeting, Industry asked to discuss the PDUFA workload adjuster with an emphasis on the ERG report. FDA explained the components of the workload adjuster and how it is applied to the target revenue on an annual basis. FDA emphasized the uncertainty with how much funding the workload adjuster will produce during a 5-year period and its goal of predictable funding in PDUFA VI. FDA explained obstacles to hiring new staff when funding for subsequent years is not guaranteed. Industry expressed concern about how the workload adjuster is applied and how funding generated from the workload adjuster does not appear to be allocated to the offices that manage the workload represented in the adjuster.

Plan for Future Meetings

The goal for the next meeting on October 21 will be to continue discussing the workload adjuster and review the updated billing model with additional years of data.

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