FDA-Industry PDUFA VI Reauthorization Meeting
Finance Sub-Group
October 7, 2015, 12:30pm-2:30pm
FDA White Oak Campus, Silver Spring, MD
Building 51, Room 6200

Purpose

To agree on a schedule to discuss financial topics and to continue discussing financial enhancements for PDUFA VI reauthorization.

Participants

FDA	
Joshua Barton	CDER
Yanming Chae	CBER
Amanda Edmonds	OCC
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
Laurie Keating	BIO (Alnylam)

At the previous meeting on September 30th, Industry and FDA discussed financial enhancements for PDUFA VI. Industry and FDA agreed to continue reviewing enhancement topics.

Meeting calendar

FDA proposed a meeting calendar for the finance sub-group. FDA and Industry discussed and agreed to a calendar of topics for subsequent finance sub-group meetings.

Discuss billing model

FDA stated one of its financial goals for PDUFA VI is to achieve more predictable funding. FDA shared a model that shows the impact of modifying the target revenue allocation among application, establishment, and product fee types on anonymized sponsor bills. Industry requested the FDA to include additional years of data in the model to help assess the potential multi-year impact of allocation shifts on sponsors. FDA agreed to look into adding data to the model.

Review PDUFA target revenue components

In the previous meeting, Industry asked for more information on the elements that drive cost growth in the PDUFA program. FDA shared data from 2009 through 2016 on the components of the annual target revenue published in the annual Federal Register notices that establish the fee rates each year. The components included the statutory base, drug safety funding in PDUFA IV, inflation adjustment,

workload adjustment, offset for excess collections, final year adjustment, and the PDUFA V negotiated addition to the statutory base funding.

Workload adjuster

The discussion of workload adjuster began with Industry stating they want to ensure that the PDUFA program is sufficiently resourced to meet review performance and commitment letter goals. Industry expressed concern that based on the findings of the Eastern Research Group's report entitled "PDUFA V Workload Adjuster Evaluation, the workload adjuster may not function optimally. Industry stated that it's unclear if the additional revenue generated from the workload adjuster is allocated to the offices that manage the workload represented in the adjuster. Industry expressed concern over the size of the PDUFA carry over balance and additional revenue the workload adjuster generates each year. FDA explained the carry over balance, in part, is a result the challenges associated with operating under continuing resolutions, sequestration, and also challenges with recruiting, hiring, and retaining highly specialized scientific and medical expertise.

Plan for Future Meetings

The goal for the next meeting on October 14 will be for FDA to provide a briefing on time reporting and to discuss the PDUFA workload adjuster with emphasis on the Eastern Research Group report.

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