FDA-Industry PDUFA VI Reauthorization Meeting
Finance Sub-Group
December 2, 2015, 12:30pm-2:30pm
FDA White Oak Campus, Silver Spring, MD
Building 51, Room 6197

Purpose

To continue discussing financial enhancements for PDUFA VI reauthorization, including a discussion of the financial transparency and capacity planning options, and options for modifying the workload adjuster.

Participants

FDA		Industry	
Joshua Barton	CDER	Jennifer Boyer	BIO (Alkermes)
Yanming Chae	CBER	Sascha Haverfield	PhRMA
Amanda Edmonds	OC	Deborah Henderson	PhRMA (Merck)
Patrick Frey	CDER	Kay Holcombe	BIO
Azada Hafiz	CDER	Laurie Keating	BIO (Alnylam)
Andrew Kish	CDER	Robert Metcalf	PhRMA (Eli Lilly)
Robert Marcarelli	OC	Lucy Vereshchagina	PhRMA

Financial transparency and capacity planning options

In previous meetings, Industry expressed the need to ensure that PDUFA user fee resources are administered, allocated, and reported in an efficient and transparent manner. Industry also expressed the need for FDA to develop a capacity planning function and expand time reporting to enhance PDUFA resource management. FDA and Industry discussed options to develop a capacity planning function and expand time reporting in PDUFA VI with the assistance of a 3rd party organization. FDA and Industry discussed engaging a 3rd party to evaluate the financial administration of the PDUFA program to help identify areas to enhance efficiency and transparency.

FDA and Industry discussed publishing a PDUFA 5-year financial plan in PDUFA VI and making annual updates, along with convening public meetings to discuss the plan and the Agency's progress in implementing expanded time reporting and capacity planning. Industry agreed to provide additional feedback on the financial transparency and capacity planning options at a future meeting.

Workload adjuster

In the October 14 meeting, Industry expressed concern about how the workload adjuster is applied. FDA explained that revenue produced from the workload adjuster can be unpredictable from year to year, which makes financial planning challenging. FDA also stated an ideal workload adjuster would account for sustained increases in workload and be predictable from year to year. FDA and Industry discussed options to modify the workload adjuster weighting methodology to help meet these goals.

Industry and FDA discussed additional workload elements, such as formal meetings, that could be incorporated in the model and options for making the revenue generated from the workload adjuster more predictable from year to year. Industry agreed to provide feedback on the updated workload adjuster model options at a future meeting.

Plan for future meetings

The goal for the next meeting on December 16 will be to discuss Industry's feedback on the financial transparency and capacity planning options and the updated workload adjuster options.

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