FDA-Industry PDUFA VI Reauthorization Meeting
Finance Sub-Group
November 4, 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 fees-exceed-the-cost waiver, PDUFA standard cost model, and discussion of FDA's time reporting fact finding exercise.

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
Laurie Keating	BIO (Alnylam)
Robert Metcalf	PhRMA (Eli Lilly)
Lucy Vereshchagina	PhRMA

Fees-Exceed-the-Cost (FEC) waiver

FDA explained it must grant a partial or full fee waiver when the total amount of all PDUFA user fees paid by a company and its affiliates will exceed the total anticipated present and future costs incurred by the Agency in reviewing all of the human drug applications from the company and its affiliates. FDA stated it uses PDUFA standard costs in determining FEC waivers as allowed by statute. FDA explained the FEC waiver is outdated since PDUFA user fees are not intended to represent actual application review costs, but structured to provide stable funding for the program. FDA explained the process for adjudicating an FEC waiver can be cumbersome and lengthy, which adds to the program overhead costs. FDA stated that the waiver benefits very few companies (approximately $2 million dollars in refunds annually) and increases fees for other companies. FDA proposed removing the FEC waiver in PDUFA VI. Industry requested FDA provide level of effort estimates for adjudicating FEC waivers.

PDUFA standard cost model briefing

FDA explained it uses the PDUFA standard costs for FEC waiver determinations, priority review voucher user fee setting, and as weighting factors in the PDUFA workload adjuster. FDA explained the calculation of standard costs each year under FDA's current approach requires significant data collection and analysis, which adds to the program's administrative burden. FDA stated that the agency's current approach to PDUFA standard costs may no longer be needed if the FEC waiver is removed. FDA and Industry discussed alternative approaches to FDA's current approach to standard costs.

Time reporting fact finding exercise

FDA discussed its exercise to explore time-reporting enterprise and capacity planning systems.

Plan for future meetings

FDA and Industry plan to discuss the following items at the next meeting on November 18:

- PDUFA fully loaded full-time equivalent (FTE) cost models,
- Options for modifying financial reporting,
- Allocation of workload adjuster revenue,
- Industry's proposal to enhance the transparency of PDUFA FTE distribution,
- Update on the carryover balance.

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