FDA-Industry PDUFA VI Reauthorization Meeting
Finance Sub-Group
October 28, 2015, 12:30pm-2:30pm
FDA White Oak Campus, Silver Spring, MD
Building 51, Room 5200

Purpose

To continue discussing financial enhancements for PDUFA VI reauthorization including cost allocation models and the 5-year offset provision.

Participants

FDA	
Joshua Barton	CDER
Yanming Chae	CBER
Amanda Edmonds	OCC
Patrick Frey	CDER
Azada Hafiz	CDER
John Johnson	OC
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

Cost allocation models

FDA briefed Industry on efforts to modify the Agency's cost allocation models for shared services. Industry expressed interest in moving to a full-time equivalent (FTE) cost allocation model that:

- differentiates between new and existing FTEs funded through PDUFA, and
- differentiates between FTEs directly involved in drug review process and indirect FTEs.

Industry stated that the PDUFA financial report does not provide sufficient financial information, including information on the allocation of revenue generated from the workload adjuster, and expressed concern that the report is frequently released after the statutory deadline (the deadline is 120 days after the end of the fiscal year). FDA and Industry agreed to identify areas of improvement for the financial report in a future meeting.

5-Year Offset Provision

FDA stated that one of its goals is to enhance flexibility in PDUFA VI with respect to the Agency's ability to allocate fees to bolster workforce capacity to keep pace with increases in review workload. FDA explained that one impediment to achieving this goal is the statute's 5-year offset provision. The 5-year offset provision requires that PDUFA fees collected in excess of the cumulative amount specified in appropriations acts during the first three fiscal years and estimated for the fourth fiscal year be offset in the fifth fiscal year. FDA explained that fees can exceed the amount specified in appropriations acts for

a fiscal year when fees (for applications, products, and establishments) received are greater than what FDA estimated would be paid for that fiscal year. As a consequence, when FDA receives additional fee revenue because FDA underestimated the number of fee-paying submissions in the first four years of the program-- which represents increased workload for the program during those years--FDA is unable to invest those funds in the program because the additional fee revenue must be offset in the fifth year. FDA stated it would like to discontinue the 5-year offset in PDUFA VI, so it can invest those funds in the program as they become available. Industry stated that any modifications to the offset provision should ensure that additional funding collected is allocated in a timely manner to the offices that manage the review workload.

Plan for Future Meetings

The goal for the next meeting on November 4 will be to discuss FDA's time reporting fact finding exercise, provide a briefing on standard costs, and to discuss the fees-exceed-the-cost waiver.

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