

FDA-Industry PDUFA VI Reauthorization Meeting
Finance Sub-Group
January 19, 2016, 12:30pm - 2:30pm
FDA White Oak Campus, Silver Spring, MD
Building 71, Room 1206

Purpose

To continue discussing financial enhancements for PDUFA VI reauthorization, including a briefing on the fully-loaded full-time equivalent (FTE) cost methodology, technical changes to the PDUFA fee provisions of the FD&C Act, and options for the commitment letter.

Participants

FDA

Joshua Barton	CDER
Yanming Chae	CBER
Amanda Edmonds	OC
Azada Hafiz	CDER
Andrew Kish	CDER
Robert Marcarelli	OC
David Miller	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

Fully-loaded full-time equivalent (FTE) cost methodology

In previous meetings, Industry requested information on FDA's practice for costing a fully-loaded FTE. FDA explained the fully-loaded FTE cost is made up of center specific pay costs, non-pay costs, and rent costs.

Statutory Language

FDA and Industry continued discussing potential technical revisions to the fee provisions in Sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) that would codify modifications to the current fee structure to enhance financial predictability, transparency, and stability. FDA and Industry agreed to continue discussing these revisions to the statutory fee provisions at future meetings.

Commitment Letter

FDA and Industry discussed potential options for the PDUFA Reauthorization Performance Goals and Procedures, also known as the commitment letter, that would reflect related proposed changes to the fee provisions in the FD&C Act and other financial enhancements to ensure financial predictability, transparency, and stability.

Plan for future meetings

The goal for the next meeting on January 27 will be to continue discussing technical changes to the PDUFA fee provisions of the FD&C Act and continue discussing related changes to the commitment letter.

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