FDA-Industry PDUFA VI Reauthorization Meeting
Finance Sub-Group

Day 1: September 29, 2015, 11:00 am – 2:15 pm	**Day 2: September 30, 2015, 12:30 pm – 2:30 pm**
FDA White Oak campus, Silver Spring, MD Building 71, Room 5064	FDA White Oak Campus, Silver Spring, MD Building 51, Room 5200

Purpose

To initiate discussion on FDA and Industry interests in 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)

FDA perspectives on financial enhancements

FDA began the meeting by stating its financial goals for PDUFA VI are to enhance funding predictability, simplify the administration of user fees, and enhance flexibility in managing program funding. FDA discussed the factors that contribute to funding uncertainty and how that uncertainty impacts the management of the program. FDA described the challenges associated with administering the establishment fee and fees-exceed-the cost waiver, along with the impact of the 5-year offset provision. FDA and Industry discussed options for increasing funding predictability.

Industry perspectives on financial enhancements

Industry stated its financial goals for PDUFA VI are to enhance the sustainability, transparency, efficiency, and accountability of the PDUFA program. Industry expressed concern over the annual growth of the program and the need to develop a better understanding of how PDUFA resources are allocated. Industry discussed augmenting PDUFA time reporting and data collection, exploring FTE cost allocation models, and developing FTE distribution reporting to address some of their identified goals.

Industry and FDA agreed to discuss financial enhancement in greater detail in future meetings.

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