Over-the-Counter Monograph User Fees – FDA and Industry Meeting
November 16, 2016, 12:00 PM -4:00 PM
FDA White Oak Campus, Silver Spring, MD
Building 22, Room 1309

Purpose

- To continue discussion of activities covered by a potential user-fee program
- To continue fee discussions

Participants

FDA:		Industry:	
Michelle Adams	OC (observer)	Linda Bowen	CHPA (Sanofi)
Amy Bertha	CDER	Greg Collier	CHPA (P&GC)
Patrick Frey	CDER	Jethro Ekuta	CHPA (J&J)
Karen Mahoney	CDER	Barbara Kochanowski	CHPA
Donal Parks	CDER	Alison Maloney	CHPA (Bayer)
Khushboo Sharma	CDER (note-taker)	David Spangler	CHPA
Chris Shreeve	CDER	Richard Stec	CHPA (Perrigo)
Eva Temkin	OC		

Resource Estimates Per Monograph Review Activity

FDA and Industry agreed in principle on the FDA resource estimates needed to perform monograph review activities under consideration. Both parties also agreed in principle on a managed growth scenario in which FDA would hire additional employees, through funding from user fees, at a steady rate over several years, and on a plan to implement an informatics platform. FDA and Industry acknowledge that all agreements in principle are contingent on Congressional action.

Covered User Fee Activities

FDA and Industry continued to discuss certain activities that could be covered by user fees.

Fee Discussions

FDA and Industry are leaning towards facility fees and an application-type fee with the majority of the program being funded by facility fees. FDA and Industry discussed whether a possible tiering of facility fees would be appropriate and discussed the definition of entitities that would pay a facility fee. FDA and Industry explored whether self-identification would be required to capture certain facility information, as not all data needed are currently captured by DRLS (Drug Registration and Listing System). FDA will explore the cost of implementing a self-identification system. FDA and Industry also discussed possibly staggering implementation of fee assessment in year 1 of the program.

Plan for Future Meetings

The goals for the next meetings on December 6, 7, and 8, 2016, will be to discuss possible performance goals and review timelines.

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