Over-the-Counter Monograph User Fees – FDA and Industry Meeting
July 13, 2016, 12:00 PM -4:00 PM
FDA Hillandale Building, Silver Spring, MD
Room 1210

Purpose

- To finalize the ground rules.
- To develop an action plan, discuss how user fees are separate from activities, and begin discussions on resource estimates for certain monograph review activities.

Participants

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

Ground Rules for Discussions
Both parties continued to discuss the ground rules around communications with external parties. Based on the discussions, some further revisions will be made and discussed at the next meeting.

Action Plan
FDA and Industry drafted an action plan for topics that would need discussion at future meetings.

Explanation of how user fees are separate from review activities
FDA explained that there is no direct correlation between user fees paid to FDA, and any discrete review activity. Funds collected from different fee types are aggregated and used, along with budget authority funds, to cover the full range of activities that fall within the scope of the process for review activities. This principle applies to all user fee programs.

Resource Requirement Estimates
FDA and Industry began discussions on resource estimates for certain monograph review activities.

Plan for Future Meetings
The goals for the next meeting on July 19 will be to finalize the ground rules, continue discussions on resource requirement estimates, and discuss at a high-level user-fee statutory framework elements.

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