Over-the-Counter Monograph User Fees – FDA and Industry Meeting
October 26, 2016, 12:00 PM -2:00 PM
FDA White Oak Campus, Silver Spring, MD
Building 22, Room 1309

Purpose

- To discuss a timeline for implementation of each activity
- To discuss possible timelines for review of certain monograph submissions

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		

Timeline for Implementation of Each Activity

FDA and Industry discussed a timeline for when each activity could begin during each of the five years of the program based on when potential new employees would be on board and fully trained to do work. FDA noted there would be numerous implementation activities that would need to start in year 1 and continue through approximately year 3. FDA asked Industry its priorities for the order of activities that could be incrementally implemented after the baseline activities were considered. While some activities would begin in year 1, since it will take FDA several years to build the program to full review capacity, some activities would not begin until subsequent years.

Review Timelines of Certain Monograph Submissions

FDA proposed a possible review timeline for certain monograph submissions, including length of time for FDA review of submission, comment period, and FDA review time after the comment period closes. FDA and Industry discussed, and FDA will propose a revised review timeline at the next meeting.

Plan for Future Meeting

The goals for the next meeting on November 2, 2016 will be to continue discussing review timelines of certain monograph submissions, to discuss performance goal concepts and covered activities where fees can be spent (included activities), and to continue fee discussions.

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