Over-the-Counter Monograph User Fees – FDA and Industry Meeting
November 9, 2016, 12:00 PM – 3:30 PM
FDA White Oak Campus, Silver Spring, MD
Building 22, Room 1309

Purpose

- To continue discussing possible timelines for review of certain monograph submissions
- To continue discussing activities covered by a potential user-fee program and performance goals

Participants

FDA:		Industry:	
Michelle Adams	OC (observer)	Linda Bowen	CHPA (Sanofi)
Amy Bertha	CDER	Greg Collier	CHPA (P&GC)
Matt DeFina	CDER (note-taker)	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)
Chris Shreeve	CDER		

Review Timelines

FDA proposed review timelines for certain types of monograph submissions. FDA and Industry discussed the factors that would affect how long each review would take, including the amount and type of data that would be in submissions and public comments. Both parties also discussed the possibility of such things as FDA and sponsor meetings, major amendments, and FDA communications during the review period. Discussions will continue.

Performance Goals

FDA and Industry continued to discuss items and activities that might be appropriate for performance goals, such as review of application-type submissions and meeting management. FDA and Industry discussed when certain performance goals would start, what would be considered in certain cohorts, and the potential size of certain cohorts. FDA and Industry agreed that some performance goals would likely not start until several years into the program because of numerous initial review infrastructure development and implementation activities, and to allow for time to build the program to full review capacity. Both parties discussed possible ways to mitigate a potential backlog situation drawing on best practices from the other user fee programs.

Covered User Fee Activities

Based on the discussion at the last meeting, FDA proposed a list of activities that could be covered by user fees, including activities such as review work and FDA and Industry meetings. The discussion also included potential activities that would not be covered by user fees. FDA and Industry are not in agreement on a couple of possible included activities. Additional information will be obtained regarding some covered activities from other user fee programs to gain a deeper understanding for context.

Plan for Future Meetings
The goals for the next meeting on November 16, 2016, will be to continue discussing review timelines for certain types of monograph submissions, activities covered by user fees, and fees.

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