Over-the-Counter Monograph User Fees – FDA and Industry Meetings
January 17, 2017, 9:30 AM – 4:00 PM and January 18, 2017, 9:30 AM – 12:00 PM
FDA White Oak Campus, Silver Spring, MD
Building 32, Room 1215 and Hillandale, Room 1210

Purpose

- To continue discussing facility identification
- To discuss performance goals for potential user fee program

Participants

FDA:		Industry (via telecon):	
Patrick Frey	CDER	Linda Bowen	CHPA (Sanofi)
Christine Kearsley	OC	Greg Collier	CHPA (P&GC)
Amelia Li	CDER (note-taker)	Jethro Ekuta	CHPA (J&J)
Karen Mahoney	CDER	Barbara Kochanowski	CHPA
Donal Parks	CDER	Alison Maloney	CHPA (Bayer)
Chris Shreeve	CDER	David Spangler	CHPA
Sherry Stewart	CDER	Richard Stec	CHPA (Perrigo)
Eva Temkin	OC		

Facility Identification

FDA provided Industry an update on potentially using the electronic Drug Registration and Listing System for the collection of facility-related information for the purposes of fee assessment. FDA explained at a high level how the eDRLS system might work, the savings from not creating a new system, and the low costs associated with using this system for this purpose. FDA and Industry agreed in principle that they would like to use the eDRLS system for facility identification, if eDRLS can be adapted for this purpose.

Performance Goals

FDA and Industry continued to discuss items and activities that might be appropriate for performance goals, such as developing and implementing an information technology platform, guidance development, hiring goals, meeting management goals, and review of application-type submissions. FDA and Industry also discussed when certain performance goals would start. While some performance goals would likely not start until several years into the program, both parties agreed that having some goals early in the program was important. Certain activities that would be performed as part of developing and implementing an information technology platform were also discussed.

Tiering of Monograph Submissions

FDA and Industry continued discussing the possibility of having "tiers" of OTC monograph application-type submissions, based on the type of the change proposed. In order to flesh out the concept more fully, both parties discussed possible examples of application-type submissions and which possible tier would be appropriate for each example. Review timelines for possible tiers were also discussed.

Operating Reserve

FDA and Industry continued discussing the concept of an operating reserve and how such a reserve would function throughout the program.

Plan for Future Meetings
The goals of the next meeting (yet to be scheduled) will be to discuss performance goals and to discuss review timelines.

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