Over-the-Counter Monograph User Fees – FDA and Industry Meeting
December 12-14, 2016
FDA, White Oak Campus, Silver Spring, MD
Hillandale, Room 1210

Purpose:

- To continue discussing possible timelines for review of certain monograph submissions
- To discuss performance goals for a potential user fee program

Participants:

FDA:		Industry:	
Michelle Adams	OC (observer)	Linda Bowen	CHPA (Sanofi)
Amy Bertha	CDER	Greg Collier	CHPA (P&GC)
Matt Defina	CDER (note-taker) (Dec 13&14)	Jethro Ekuta	CHPA (J&J)
		Barbara Kochanowski	CHPA
Patrick Frey	CDER	Alison Maloney	CHPA (Bayer)
Christine Kearsley	OC	David Spangler	CHPA
Karen Mahoney	CDER	Richard Stec	CHPA (Perrigo)
Donal Parks	CDER		
Chris Shreeve	CDER		
Sherry Stewart	CDER (note-taker) (Dec 12)		
Eva Temkin	OC		

Facility Identification
FDA and Industry discussed possible methods for facilities to identify themselves as manufacturers of monograph drug products. FDA and Industry discussed options for how best to collect reliable and accurate information, while at the same time keeping the burden and cost of information collection as low as possible. FDA will internally vet options and determine estimated associated costs.

Tiering of Monograph Submissions
FDA and Industry discussed the possibility of having "tiers" of OTC monograph submissions, based on the expected complexity of the proposed change. Both parties will continue to explore a possible tiering system and further develop the concept. Review timelines for OTC monograph submissions were also discussed.

Operating Reserve and Workload Adjuster
FDA and Industry discussed the concept of an operating reserve, the amount an operating reserve would contain for each year of the program, and at what rate the reserve would be built. FDA and Industry also discussed how a workload adjustment and/or capacity planning adjustment might work and whether they would be relevant to an OTC monograph user fee program.

Plan for Future Meetings
Discussions will resume in January 2017.

Post-meeting note – The next meetings were scheduled for January 17 & 18, 2017. The goals 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.