Over-the-Counter Monograph User Fees – FDA and Industry Meeting
December 6-8, 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	OL (observer)	Linda Bowen	CHPA (Sanofi)
Amy Bertha	CDER	Greg Collier	CHPA (P&GC)
Matt DeFina	CDER (note-taker) (Dec 7&8)	Jethro Ekuta	CHPA (J&J)
		Elizabeth Guo	Covington & Burling
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		
Sherry Stewart	CDER (note-taker) (Dec 6)		
Eva Temkin	OC		

Performance Goals
FDA and Industry discussed review timelines and performance goals for administrative order requests that would enable industry to initiate innovation under the monograph. There was also discussion of industry's ability to submit "major amendments" to monograph submissions, and discussion of "in-review" meetings during the FDA review time of a submission. Meeting management goals, such as timelines for responding to meeting requests and for scheduling meetings, and meeting types were discussed. The applicability of a "written response only" meeting was also discussed.

Guidances
FDA and Industry discussed possible guidance development that could be part of a user fee program.

Hiring Models
FDA and Industry discussed the rate of FDA's building of effective review capacity each year under a user fee program. FDA stressed that it takes time for a newly-hired FTE to gain needed skills and knowledge in order to be effective, which can only be obtained after onboarding.

Electronic Submissions
FDA and Industry agreed in principle that OTC monograph-related industry application–type submissions would be submitted electronically.

Plan for Future Meetings
The goals for the next meetings on December 12 - 14, 2016 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.