Over-the-Counter Monograph User Fees – FDA and Industry Meeting
September 8, 2016, 12:00 PM -4:00 PM
FDA White Oak Campus, Silver Spring, MD
Building 22, Room 1309

Purpose

- To discuss meeting management and types of OTC monograph meetings
- To continue fee discussions

Participants

FDA:		Industry:	
Michelle Adams	OC (observer)	Linda Bowen	CHPA (Sanofi)
Amy Bertha	CDER	Greg Collier	CHPA (P&GC)
Karen Mahoney	CDER	Jethro Ekuta	CHPA (J&J)
Donal Parks	CDER	Barbara Kochanowski	CHPA
Khushboo Sharma	CDER (note-taker)	Alison Maloney	CHPA (Bayer)
Chris Shreeve	CDER	Richard Stec	CHPA (Perrigo)
Eva Temkin	OC		

Meeting Management

FDA and industry discussed potential topics of monograph related meetings between the FDA and industry, such as discussing data requirements for a new dosage form or new indication or new combination, reviewing safety data, and discussing alternative test methods. In order to align with other FDA user fee programs, FDA proposed that the general principles for meeting management for OTC monograph meetings parallel those for new drugs from Prescription Drug User Fee Act VI (PDUFA VI). In principle, industry agreed. For example, there could be Type A (for critical path issues), Type B (for milestones), and Type C (for advice) meetings. FDA and industry discussed what milestone meetings might look like in the monograph space. Other meeting related topics such as FDA responses to meeting requests, when meetings would be scheduled, the option of written response instead of a meeting, the timing of the submission of background packages by sponsors, how preliminary responses would be handled, and meeting minutes. FDA and industry agreed to think about what was discussed. No final agreements have been reached at this time.

Fee Discussions

FDA and industry continued to discuss possible fees types, such as facility, product/formula and application-type fees. FDA has continued to work internally on exploring the feasibility of relying on the Drug Registration and Listing System (DRLS) as a basis for assessing fees. FDA and industry continued discussion of a time-table for assessing and collecting fees and the effects of failure to pay fees.

Plan for Future Meetings

The goals for the next meeting on October 4 will be to discuss a total program size and topics for a potential commitment letter.

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