Over-the-Counter Monograph User Fees – FDA and Industry Meeting
April 19, 2017, 9:30 AM to 3:30 PM
FDA, White Oak Campus, Silver Spring, MD
Hillandale, Room 1210

Purpose

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

Participants

FDA:		Industry:	
Amy Bertha	CDER	Linda Bowen	CHPA (Sanofi)
Patrick Frey	CDER	Greg Collier	CHPA (P&GC)
Christine Kearsley	OC	Barbara Kochanowski	CHPA
Yasemin Luebke	OC (observer)	Richard Stec	CHPA (Perrigo)
Karen Mahoney	CDER	David Spangler	CHPA
Donal Parks	CDER		
Chris Shreeve	CDER		
Sherry Stewart	CDER (note-taker)		
Eva Temkin	OC		

Tiering of Monograph Submissions

FDA and Industry continued to discuss tiering of OTC monograph application-type submissions. Under a tiered structure, certain types of submissions could qualify for shorter timelines and lower fees, based on the type of change proposed. The tiers would need to be defined clearly, and be easily identifiable upon initial review. FDA and Industry agreed to pursue a two-tier structure and agreed in principle on the default tier and the types of submissions that would fall into each of the two tiers.

Review Timelines

FDA and Industry discussed review timelines for OTC monograph application-type submissions. Extensions to the review clock were discussed, including extensions that could result from amendments submitted by Industry and extensions that could result from FDA's review of substantive or numerous comments submitted to the docket during the comment period.

Resubmissions

FDA and Industry discussed how resubmissions could be handled if Industry were to resubmit after FDA had issued a Final Order that did not make the requested change to the monograph. Both parties discussed different "classes" for resubmissions. The class would depend on the content of the resubmission and different timelines would be associated with each class.

Performance Goals

Both parties discussed the reporting of performance goals and the adding of additional goals related to the public web interface and information technology platform development.

Plan for Future Meetings

No future meetings between FDA and Industry were planned.

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