Over-the-Counter Monograph User Fees – FDA and Industry Meeting
October 19, 2016, 12:00 PM -4:00 PM
FDA White Oak Campus, Silver Spring, MD
Building 22, Room 1309

Purpose

- To continue discussing total program size of a potential user-fee program
- To continue fee discussions

Participants

FDA:		Industry:	
Michelle Adams	OC (observer)	Greg Collier	CHPA (P&GC)
Amy Bertha	CDER	Jethro Ekuta	CHPA (J&J)
Patrick Frey	CDER	Barbara Kochanowski	CHPA
Amelia Li	CDER (note-taker)	Alison Maloney	CHPA (Bayer)
Karen Mahoney	CDER	David Spangler	CHPA
Donal Parks	CDER	Richard Stec	CHPA (Perrigo)
Chris Shreeve	CDER		
Eva Temkin	OC		

Total Program Size and FDA's Proposed Monograph Review Resources Growth Concept Scenarios
FDA presented an updated plan for total program size based on a managed growth scenario in which FDA would hire additional employees through funding from user fees at a steady rate in years 1, 2, 3, 4 and the beginning part of year 5. This updated plan also included spreading out the IT implementation costs over the 5-year period, and additional funding from non-user-fee budget authority that CDER would reallocate to monograph review work. FDA and Industry also discussed the corresponding total program costs, including total number of additional FTE. FDA and Industry are not in agreement on a total program size. FDA went back to the list of review activities that Industry and FDA had previously proposed, and at Industry's request, FDA presented a smaller list of activities and fewer program enhancements that would result from a program size that was not large enough for the full list of envisioned activities. Industry will consider the updated managed growth scenario and truncated program size information.

Resources Needed Per Review Activity
In principle FDA and Industry are in agreement on the number of FDA FTE resources needed to perform most monograph review activities, except for one review activity. Industry thought the resource estimate was high. FDA is concerned about overcommitting and not being able to meet possible performance goals for this activity.

Fee Discussions
FDA and Industry discussed possible percentages of each possible fee type, such as application-type, product/formula, and facility fees. FDA noted that a product fee could result in tens of thousands of transactions, and such a high number of transactions and entities paying fees would result in higher administration costs. FDA and Industry also continued discussing the definitions of entities that would pay a product and facility fee.

Plan for Future Meetings
The goals for the next meeting on October 26, 2016, will be to discuss a timeline for implementation of each activity based on when resources would be onboard and trained to do work and timelines for review of certain monograph activities.

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