Over-the-Counter Monograph User Fees – FDA and Industry Meeting
July 26, 2016, 9:00AM- 1:00PM
FDA White Oak Campus, Silver Spring, MD
Bldg 22, Room 1419

Purpose

- To continue discussion of program costs, specifically OTC monograph informatics cost estimates.
- To begin discussions of a fee structure.

Participants

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

Program Costs

FDA and industry continued discussions on program cost, specifically OTC monograph informatics cost estimates. FDA provided an overview of an informatics platform for monograph work that would cover such areas as review work, the collection of user fees, reporting, and a public-facing database and planning tool. The proposal involves expanding the existing IT platform that is used for abbreviated new drug review, and is planned to be used for new drug review, to include monograph work. Industry asked FDA to investigate other possible options for informatics solutions; FDA agreed to do so. Additionally, FDA and industry continued discussions on workload estimates of certain monograph review activities. FDA and industry agreed that further discussion of program costs is needed and no agreements have been reached at this time.

Fee Structure

FDA provided a high level comparison of fee types across various existing CDER user fee programs.

Plan for Future Meetings

The goal for the next meeting on Aug 2 will be to continue discussing options for a fee structure.

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