Over-the-Counter Monograph User Fees – FDA and Industry Meeting
July 19, 2016; 12:00 PM to 4:00 PM
FDA White Oak Campus, Silver Spring, MD
Building 22, Room 1421

Purpose

- To discuss, at a high level, user fee statutory framework elements.
- To continue discussion of program costs, specifically resource estimates for certain monograph review activities.

Participants

FDA:		Industry:	
Michelle Adams	OC (observer)	Linda Bowen	CHPA (Sanofi)
Amy Bertha	CDER	Jethro Ekuta	CHPA (J&J)
Patrick Frey	CDER	Barbara Kochanowski	CHPA
Karen Mahoney	CDER	Alison Maloney	CHPA (Bayer)
Donal Parks	CDER	Richard Stec	CHPA (Perrigo)
Chris Shreeve	CDER	David Spangler	CHPA
Sherry Stewart	CDER (note-taker)		
Eva Temkin	OC		

Ground Rules
Ground rules for the discussions were finalized.

User-Fee Statutory Framework Elements
The elements of a user fee statutory framework were discussed. Those elements include defining applicable terms; types of fees; fee revenue amounts; adjustments; fee waivers/reductions, if applicable; effect of failure to pay fees; and clarification on the circumstances under which FDA can use the fees.

Program Costs
FDA and industry continued discussions on program costs, specifically full-time-equivalent (FTE) cost estimates for certain monograph review activities and workload forecasts.

Plan for Future Meetings
The goals for the next meeting on July 26 will be to continue discussion of program costs, including informatics cost estimates, and begin discussions about fee structure.

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