Over-the-Counter Monograph User Fees – FDA and Industry Meeting
August 2, 2016, 1:00 PM – 4:00 PM
FDA White Oak Campus, Silver Spring, MD
Bldg 32, Room 1215

Purpose

- To continue discussions of a fee structure
- To better understand FDA's drug registration and listing system (DRLS)

Participants

FDA:		Industry:	
Amy Bertha	CDER	Linda Bowen	CHPA (Sanofi)
Patrick Frey	CDER	Greg Collier	CHPA (P&GC)
Amelia Li	CDER (note-taker)	Jethro Ekuta	CHPA (J&J)
Paul Loebach	CDER (DRLS presenter)	Barbara Kochanowski	CHPA
Yasemin Luebke	CDER (observer)	Alison Maloney	CHPA (Bayer)
Donal Parks	CDER	Richard Stec	CHPA (Perrigo)
Eva Temkin	OC	David Spangler	CHPA

Fee Types
Industry provided an overview of the OTC market for background. FDA and industry brainstormed on several different fee type options and discussed the pros and cons of each. Industry suggested that they be allowed to consider the options for two weeks, and FDA agreed. No fee types have been selected.

DRLS
FDA provided an overview of the DRLS and how it currently functions. Industry and FDA discussed the possible use of the system to track relevant OTC information for the purpose of collecting fees.

Plan for Future Meetings
The goals for the next meeting on August 9 will be to continue discussions of a fee structure, discuss docket comments from the June 10th public meeting, and provide an overview of structured product labeling for drug establishment registration and drug listing.

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