

**Over-the-Counter Monograph User Fees – FDA and Industry Meeting**  
**August 9, 2016, 9:00 AM – 12:30 PM**  
**FDA White Oak Campus, Silver Spring, MD**  
**Building 22, Room 1421**

---

**Purpose**

- To provide an overview of Structured Product Labeling (SPL) for establishment registration and drug listing
- To discuss docket comments from the June 10, 2016 public meeting
- To continue discussion of possible fee types and structure

**Participants**

FDA:

Amy Bertha	CDER
Patrick Frey	CDER
Paul Loebach	CDER (DRLS presenter)
Donal Parks	CDER
Lonnie Smith	CDER (SPL presenter)
Sherry Stewart	CDER (note-taker)
Eva Temkin	OC

Industry:

Linda Bowen	CHPA (Sanofi)
Greg Collier	CHPA (P&GC)
Jethro Ekuta	CHPA (J&J)
Marcia Howard	CHPA (SPL advisor)
Barbara Kochanowski	CHPA
Alison Maloney	CHPA (Bayer)
David Spangler	CHPA

**SPL and DRLS (Drug Registration and Listing System)**

FDA provided an overview of SPL with a focus on nonprescription products and explained the relationship to DRLS, along with the capabilities and limitations of the current system. Industry and FDA continued to discuss the possible use of SPL and DRLS to track relevant OTC information for the purpose of collecting fees.

**Fee Structure**

Industry led a discussion of the various different ways OTC drug companies manage the workload associated with OTC monograph submissions for background. The potential benefits and demands user fees may have on industry were discussed. FDA and industry continued the exploration of fee types and fee structure.

**Docket Comments**

FDA and industry discussed the docket comments from the June 10, 2016 public meeting on a potential OTC monograph user fee program. The comments made by various stakeholder groups at the public meeting were also discussed.

**Plan for Future Meetings**

The goals for the next meetings on August 22 & 23 will be to continue fee discussions and discuss outlines for possible statutory language and a potential commitment letter.

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