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.