Over-the-Counter Monograph User Fees – FDA and Industry Meetings
August 22, 2016, 9:00 AM – 12:30 PM and August 23, 2016, 9:00 AM – 1:00 PM
FDA White Oak Campus, Silver Spring, MD
Building 21, Room 1539 and Hillandale, Room 1210

Purpose

- To discuss electronic monograph submissions in the future
- To continue fee discussions
- To discuss an outline for a potential commitment letter

Participants

FDA:

Michelle Adams	CDER (observer)
Amy Bertha	CDER
Patrick Frey	CDER
Amelia Li	CDER (note-taker)
Karen Mahoney	CDER
Donal Parks	CDER
Chris Shreeve	CDER
Eva Temkin	OC

Industry:

Linda Bowen	CHPA (Sanofi)
Greg Collier	CHPA (P&GC)
Jethro Ekuta	CHPA (J&J)
Barbara Kochanowski	CHPA
Alison Maloney (Aug 22nd only)	CHPA (Bayer)
David Spangler	CHPA
Richard Stec (Aug 23rd only)	CHPA (Perrigo)

Electronic Submission Requirements
In order to align with other CDER programs (e.g., new drugs and generic drugs), FDA proposed that OTC monograph related industry application-type submissions be submitted electronically, preferably in electronic Common Technical Document (eCTD) format. This approach is also in line with a Presidential directive that requires federal agencies to eliminate paper and use electronic recordkeeping to the fullest extent possible. Industry will consider this proposal.

Increased Capacity for OTC Monograph Work
FDA is increasing its capacity for monograph review work. This increased capacity will be captured in future CDER time reporting activities, once the new staff has been hired.

Fee Discussions
FDA and industry continued to explore possible fee types, such as facility, product/formula, and application-type fees. FDA's preference is to have a low number of fee types in order to keep the administration costs as low as possible. Industry's position is to not yet rule out any particular fee type, in order to spread out costs among users. Industry is continuing to consider the options, brainstorm possible additional options to consider, and gain alignment.

FDA and industry discussed a possible small business waiver, a time-table for assessing and collecting fees, the effects of failure to pay fees, an inflation adjustor, a capacity planning adjustor, and instances where refunds might be applicable.

FDA is working to understand the feasibility of relying on the Drug Registration and Listing System (DRLS) as a basis for assessing fees. Accurate and up-to-date drug listing and facility

registration information is critical to setting annual fee amounts. FDA and industry are discussing whether a self-identification and annual certification process should be required to confirm the accuracy of facility and drug listing information.

Workload Forecast Estimates
Industry revised its original workload estimates of certain industry-initiated (i.e., application-type) monograph review activities. FDA explained that accurate workload forecasts of both industry- and FDA-initiated activities are important for ensuring the monograph program is adequately funded. If the workload forecasts underestimate the number of review activities, FDA would be challenged to meet committed-to review performance goals.

Outline for Potential Commitment Letter
FDA presented examples of topics for a potential commitment letter and possible statutory language for comments and questions.

Plan for Future Meetings
The goals for the next meeting on September 8th are to continue discussion of program costs and topics for a potential commitment letter.

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