

**Over-the-Counter Monograph User Fees – FDA and Industry Meeting**  
**November 2, 2016, 1:30 PM – 5:00 PM**  
**FDA, White Oak Campus, Silver Spring, MD**  
**Building 22, Room 1311**

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**Purpose:**

- To continue discussing possible timelines for review of certain monograph submissions
- To discuss activities covered by a potential user-fee program and performance goals for a potential user-fee program

**Participants:**

FDA:

Amy Bertha	CDER
Patrick Frey	CDER
Karen Mahoney	CDER
Chris Shreeve	CDER
Sherry Stewart	CDER (note-taker)
Eva Temkin	OC

Industry:

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

**Review Timelines**

FDA proposed revised possible review timelines for certain types of monograph submissions, including lengths of time for FDA review of submission, comment period, and FDA review time after the comment period closes. Industry thought the timeline was long in a couple of places, and stated that they believe some types of submissions might require fewer review resources and thus less time. FDA asked Industry to define the exact types of submissions that Industry believes would require less FDA resources to review and therefore could possibly shorten the review time. FDA will propose review timelines for additional types of monograph submissions at the next meeting.

**Performance Goals**

FDA and Industry discussed performance goal concepts. Items and activities that might be appropriate for performance goals were discussed, such as review of application-type submissions. The discussion will continue at the next meeting.

**Covered User Fee Activities**

The group began discussing activities that could be covered by user fees by identifying activities that would be included and excluded. Based on the discussion, FDA will propose a list of covered activities at the next meeting.

**Plan for Future Meeting**

The goals for the next meeting on November 9, 2016, will be to continue discussing review timelines for certain types of monograph submissions, performance goals, and activities covered by user fees.

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