

Over-the-Counter Monograph User Fees – FDA and Industry Meeting

July 6, 2016, 2:00 PM – 4:00 PM

FDA Hillandale Building, Silver Spring, MD

Room 1210

Purpose

- To lay the groundwork for FDA-Industry discussions regarding development of a potential OTC monograph user fee program.
- To discuss ground rules, proposed meeting schedule, current FDA resources dedicated to OTC monograph work, and the federal budgeting process.

Participants

FDA:

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

Industry:

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

Ground Rules for Discussions

The ground rules governing the OTC monograph user fee discussions were discussed. FDA and Industry agreed that high-level meeting minutes would be generated from each FDA and Industry meeting and posted on FDA's website. As another means to keep external stakeholders informed, the FDA also plans to hold a public WebEx meeting, or similar type of information session, at some point during discussions. Both parties discussed how communications with external parties would be handled. Based on the discussions, FDA will propose some revisions to be discussed at the next meeting.

Meeting Schedule

FDA and Industry agreed to schedule meetings over the next couple of months, see how progress is going, and then possibly schedule additional meetings.

Explanation of Current FDA Resources and Federal Budgeting Process

FDA explained the current FDA resources dedicated to OTC monograph work. FDA also described at a high level the federal budgeting process.

Plan for Future Meetings

The goals for the next meeting on July 13 will be to finalize the ground rules and to start discussing resource estimates for certain monograph review activities.

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