

Over-the-Counter Monograph User Fees – FDA and Industry Meeting
October 12, 2016, 12:00 PM – 4:00 PM
FDA, White Oak Campus, Silver Spring, MD
Hillandale, Room 1210

Purpose:

- To continue discussing total program size of a potential user-fee program
- To discuss proposed plans for FDA’s growth of monograph review resources to desired steady state

Participants:

FDA:

Michelle Adams	OC (observer)
Amy Bertha	CDER
Christine Kearsley	OC
Karen Mahoney	CDER
Donal Parks	CDER
Chris Shreeve	CDER
Sherry Stewart	CDER (note-taker)

Industry:

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

Total Program Size and FDA’s Proposed Monograph Review Resources Growth Concept Scenarios

FDA presented a new proposed plan for total program size based on an accelerated growth scenario in which FDA would hire 75% of the additional employees through funding from user fees in year 1 and 25% in year 2. This proposed growth plan included hiring targets by quarter. FDA and Industry discussed all three growth scenerios proposed to date: 50% hiring in year 1/50% in year 2, hiring over first four years, and 75% hiring in year 1/25% in year 2, and coresponding total program costs. Industry favors a managed growth scenario with hiring over the first four years because it provides realistic hiring and training goals for new FDA staff. Both parties acknowledged that it will take FDA several years to build the program to full review capacity. FDA and Industry discussed what the total number of FTEs would be at steady state and what the ratio of non-user fee budget authority to user fees would be. After discussion, it was agreed FDA would update the growth scenario for hiring over the first four years. The updated plan would include spreading out the IT implementation costs over the 5-year period.

Fee Discussions

FDA and Industry continued to discuss possible fee types, such as facility, product/formula and application-type fees, including which entity would be responsible for paying a product fee and a facility fee. In regards to a possible application-type fee, FDA and Industry discussed the amount of this fee in relation to the amount of an application fee under the Prescription Drug User Fee Act program. FDA and Industry continued to discuss possible penalties for failure to pay user fees. Both parties also started discussing a possible staggered implementation for fee assessment for year 1 of the program. No final agreements on fee types have been reached.

Plan for Future Meeting

The goals for the next meeting on October 19, 2016, will be to discuss the revised plan for growth to steady state and corresponding total program costs.

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