Over-the-Counter Monograph User Fees – FDA and Industry Meeting
October 4, 2016, 12:00 PM – 4:00 PM
FDA White Oak Campus, Silver Spring, MD
Building 22, Room 1311

Purpose:

- To discuss total program size of a potential user-fee program
- To discuss FDA's proposed plans for growth to desired steady state

Participants:

FDA:		Industry:	
Michelle Adams	OC (observer)	Linda Bowen	CHPA (Sanofi)
Amy Bertha	CDER	Greg Collier	CHPA (P&GC)
Patrick Frey	CDER	Jethro Ekuta	CHPA (J&J)
Karen Mahoney	CDER	Barbara Kochanowski	CHPA
Donal Parks	CDER	Alison Maloney	CHPA (Bayer)
Chris Shreeve	CDER	David Spangler	CHPA
Sherry Stewart	CDER (note-taker)	Richard Stec	CHPA (Perrigo)
Eva Temkin	OC		

Total Program Size and FDA's Proposed Growth Concept Scenarios

Based on FDA and Industry discussions in recent meetings, FDA developed and presented a proposed plan for a total program size. The proposed plan included an estimate of the total FTE needed to achieve steady state for future monograph activities and the number of activity units estimated to occur during a 5-year cycle. FDA's plan included two possible scenarios that would grow its monograph review capacity to desired steady state over the five-year period. One plan outlined a scenario in which FDA would hire 50% of the additional employees through funding from user-fees in year 1 and 50% in year 2. The second plan outlined a scenario in which FDA would hire employees over years 1, 2, 3, and 4. Using these FTE cost estimates and some non-FTE cost estimates (primarily from information technology system implementation), FDA proposed two scenarios for total user-fee resources needed each fiscal year over the 5-year period. FDA and Industry were not in agreement on the total user fee resources. After discussion, it was agreed FDA would prepare a new scenario in which FDA would hire 75% of additional user-fee funded resources in year 1 and 25% in year 2 , as a more accelerated growth rate. Industry also asked FDA to explore spreading out the IT implementation costs over the 5-year period. Industry agreed to consider alternate scenarios and present them at the next meeting.

Timing of Implementation of Commitments

FDA and Industry began discussions on the timing of implementation of commitments for each of the two growth plans. FDA asked Industry to state which activities it would want to see implemented earliest, considering the projected FTE capacity under different proposed growth scenarios.

Plan for Future Meeting

The goals for the next meeting on October 12, 2016, will be to discuss alternative plans for growth to steady state and associated alternative total program costs.

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