

Public Stakeholder Meeting on Biosimilars User Fee Program
June 24, 2011, 3:30 – 5:00 PM
FDA White Oak Campus, Silver Spring, MD
Building 32, Room 2162

Purpose

To consult with public stakeholders to obtain their input on the development of recommendations for a biosimilars user fee program for fiscal years 2013-2017.

Participants:

FDA

Sunanda Bahl	CDER	Julia Lippman	OL
Daniel Brounstein	CDER	Theresa Mullin	CDER
Kristina Das	OL	Donal Parks	CDER
Amanda Edmonds	OCC	Lisa Rovin	OC
John Jenkins	CDER	Rokhsana Safaai-Jazi	CDER
Chris Joneckis	CBER	Andrea Tan	CDER
Steven Kozlowski	CDER	James Valentine	OSHI
Heidi Marchand	OSHI	Ann Wion	OCC
		Robert Yetter	CBER

Public Stakeholders

David Bernstein	American Society of Clinical Oncology
Laszlo Endrenyi	University of Toronto
Jeanie Kennedy	American Academy of Orthopedic Surgeons
Thair Phillips	RetireSafe
David Rubin	Crohn's and Colitis Foundation of America
Elizabeth Sampsel	Academy of Managed Care Pharmacy

FDA presented an overview of the Biologics Price Competition and Innovation (BPCI) Act and discussed the information published in the May 9, 2011 *Federal Register*, <http://www.gpo.gov/fdsys/pkg/FR-2011-05-10/pdf/2011-11348.pdf>, including identified principles for development of a 351(k) user fee program, the proposed structure for a 351(k) user fee program that would adhere to these principles, and proposed performance goals for this program.

FDA noted that in the May 9, 2011, *Federal Register* publication, the agency proposed that the biosimilars user fee program would include a biosimilar biological product development (BPD) fee. FDA explained that the BPD fee is under consideration because it would shift a portion of payment for FDA review activities to the earlier stage of biosimilar biological product development, where FDA activities are currently in greatest demand and increased review capacity is needed. FDA explained that the FY 2011 appropriation included a total of \$1.8 million with 4 Full Time Equivalent staff for biosimilar biological product review. FDA stated that it will need additional resources in order to review biosimilar biological product applications in a timely way.

Following the FDA presentation, some stakeholders expressed interest in industry's reaction to the BPD fee. FDA stated that a number of comments were filed to the public docket. Some industry commenters highlighted the importance of ensuring user fee resources are not diverted from innovator review activities to biosimilar review activities. FDA explained that based on the current resources available for the program, a BPD fee is a reasonable approach to provide additional resources for biosimilar review activities in the near-term. Public stakeholders also expressed interest in the issuance of guidance concerning biosimilar products. FDA stated that it plans to issue guidance in 2011.