Public Stakeholder Meeting on Biosimilars User Fee Program
July 29, 2011, 3:00 – 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 and further discuss implementation of the Biologics Price Competition and Innovation (BPCI) Act.

Participants

FDA

Sunanda Bahl	CDER	Patricia Kuntze	OER
Sandra Benton	OMP	Heidi Marchand	OSHI
Dominic Cirincione	OSHI	Theresa Mullin	CDER
Leah Christl	CDER	Jay Sitliani	ORP
Amanda Edmonds	OCC	Andrea Tan	CDER
Steven Kozlowski	CDER	Ann Wion	OCC
Brian Kehoe	OL	Robert Yetter	CBER

Public Stakeholders

David Bernstein	American Society of Clinical Oncology
Shein-Chung Chow	University of Toronto
Dustin Trong Nguyen	Academy of Managed Care Pharmacy
Elizabeth Sampsel	Academy of Managed Care Pharmacy

FDA provided information on the agency's implementation of the BPCI Act, including the development of a user fee program for biosimilar biological products. FDA described three committees that ensure consistency in FDA's regulatory approach and guidance to applicants regarding development programs for proposed biosimilar biological products. These include the following: the Center for Drug Evaluation and Research (CDER) Biosimilar Review Committee, the Center for Biologics Evaluation and Research (CBER) Biosimilar Review Committee, and the CDER/CBER Biosimilar Implementation Committee (BIC). FDA stated that the CDER/CBER BIC is the forum to discuss policy issues, while the review committees focus on product-specific and scientific issues related to applicants' requests for advice concerning proposed biosimilar development programs. FDA also described its current workload, noting that development programs have included prospective and retrospective development programs. FDA also stated that based on priorities identified by public stakeholders, it is working towards issuing initial draft guidance this year to clarify expectations and provide predictability to applicants initiating biosimilar development programs. Public stakeholders asked clarifying questions about the roles and responsibilities of each of the committees.