FDA-GDUFA Reauthorization Stakeholder Meeting
May 17, 2016, 10:00 am - 10:30 pm
FDA White Oak Campus, Silver Spring, MD
Building 52/72, Conference Room 4100

Purpose

The Generic Drug User Fee Amendments of 2012 (GDUFA) requires that FDA hold monthly discussions with representatives of patient and consumer advocacy groups on their views on the reauthorization of GDUFA and their suggestions for changes to the GDUFA program. These discussions are to take place at least once every month during the GDUFA reauthorization negotiations between FDA and the generic drug industry.

Participants

FDA		Stakeholders	
Mary Beth Clarke	CDER	Paul Brown	National Center for Health Research
Keith Flanagan	CDER	Marcia Horn	International Cancer Advocacy Network
Michael Jones	CDER	Sarah Sorscher	Public Citizen
Martha Nguyen	CDER		

FDA Supporting Staff
Derek Griffing, Katie Stronati, Tawni Schwemer, Trang Tran

Welcome & Overview

Following introductions, FDA gave an overview of the progress of the GDUFA negotiation meetings.

Summary of Recent Negotiation Sessions

FDA provided a summary of the GDUFA negotiation meetings between FDA and Industry held on April 14, 20, 27, 28, and May 12. FDA explained that FDA and Industry have reached tentative, conceptual alignment on Abbreviated New Drug Application (ANDA) review goals and program enhancements, Drug Master File (DMF) program enhancements and a pre-ANDA process, subject to ratification of a satisfactory overall agreement with adequate resourcing, and are in continued discussions on the GDUFA II Commitment Letter.

Next Meeting

The date of the next stakeholder meeting is under discussion.