FDA-GDUFA Reauthorization Stakeholder Meeting
April 12, 2016, 10:00 am - 11:00 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	Andrea Lowe	Society for Women's Health Research
Michael Jones	CDER	Sarah Sorscher	Public Citizen
Martha Nguyen	CDER		

FDA Supporting Staff
Derek Griffing, Katie Stronati

Welcome and Overview

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

Summary of Recent Negotiation Sessions

FDA provided an overview of the GDUFA negotiation meetings between FDA and Industry held on March 30, March 31, April 5, and April 6, 2016. FDA explained that the first three meetings were generally focused on metric review goals and/or program enhancements for submissions in GDUFA II, including Abbreviated New Drug Applications (ANDAs), Prior Approval Supplements (PASs), and Drug Master Files (DMFs). FDA stated that the last meeting (April 6 session) continued discussions on the development of a pre-ANDA process in GDUFA II. FDA explained that a robust pre-ANDA process could include the following: controlled correspondence, product-specific guidance, and pre-ANDA meetings.

FDA encouraged stakeholders' participation at the May 20, 2016, GDUFA Regulatory Science Initiatives Public Hearing**.** FDA also encouraged stakeholders to visit www.regulations.gov and submit their suggestions on topics for discussion at future stakeholder meetings to the following docket number: FDA-2012-N-0882.

Next Meeting

The next stakeholder meeting is planned for Thursday, May 12, 2016.