FDA-GDUFA Reauthorization Stakeholder Meeting
March 23, 2016, 10:00 am - 11:00 pm
FDA White Oak Campus, Silver Spring, MD
Building 52/72, Conference Room 1100

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, Trang Tran

Welcome & Overview

Following introductions, FDA provided an overview of the process of GDUFA negotiations moving forward.

Summary of Recent Negotiation Sessions

FDA provided an overview of the GDUFA negotiation meeting between FDA and Industry held on March 16, 2016. FDA explained that negotiators split into two groups based on the topics to be covered. One group discussed review goals, program enhancements, and the pre-Abbreviated New Drug Application (ANDA) process while the other group discussed Drug Master File (DMF) review, inspection parity, communications, and DMF/finished dosage form (FDF) characterizations. FDA reiterated two primary objectives for GDUFA II: (1) simpler review goals that align with stakeholder expectations; and (2) improving submission quality via a robust pre-ANDA process.

Public Citizen requested additional information about the complexity of performance goals in GDUFA I. FDA gave a brief overview of all the different review goals/timelines and factors involved in calculating goal dates. 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 Tuesday, April 12, 2016.