FDA-GDUFA Reauthorization Stakeholder Meeting
July 28, 2016, 11:00 am - 11:30 pm
FDA White Oak Campus, Silver Spring, MD
Building 75, Conference Room 3600

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
Michael Jones	CDER	Marcia Horn	International Cancer Advocacy Network
Martha Nguyen	CDER	Sarah Sorscher	Public Citizen

FDA Supporting Staff
Derek Griffing, Katie Stronati, 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 an overview of the GDUFA negotiation meetings between FDA and Industry, since the last stakeholder meeting. FDA explained that FDA and Industry have tentatively agreed on the GDUFA II Commitment Letter language. FDA noted fiscal year 2017 fee estimates had been published and that there are still ongoing discussions regarding the fee structure for GDUFA II.

Next Meeting
The next stakeholder meeting is planned for Wednesday, August 31, 2016.