FDA-GDUFA Reauthorization Stakeholder Meeting
August 31, 2016, 1:00 pm - 1:30 pm
FDA White Oak Campus, Silver Spring, MD
Building 75, Conference Room 2600

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		
Martha Nguyen	CDER		

FDA Supporting Staff
Carter Beach, Derek Griffing, Katie Stronati

Discussion

Following introductions, FDA noted that FDA and Industry agreed on the terms of a GDUFA II reauthorization package on August 24, 2016. FDA explained that the package will go through official clearance prior to being formally transmitted to Congress as per the statute. In addition, FDA will hold a public meeting per the statute in the fall at which the public may present its views and comments on the GDUFA II reauthorization package.

Next Meeting

GDUFA II negotiations have concluded. No further meetings are scheduled.