

FDA-GDUFA Reauthorization Stakeholder Meeting
June 30, 2016, 9:00 am - 9:30 pm
FDA White Oak Campus, Silver Spring, MD
Building 75, Conference Room 5600

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

Mary Beth Clarke CDER
Keith Flanagan CDER
Michael Jones CDER
Martha Nguyen CDER

Stakeholders

Paul Brown National Center for Health Research
Marcia Horn International Cancer Advocacy Network
Sarah Sorscher Public Citizen

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 an overview of the GDUFA negotiation meeting between FDA and Industry (held on June 28, 2016), since the last stakeholder meeting. FDA explained discussions continue on specific features to be included in the GDUFA II Commitment Letter. Topics covered included review goals, communications, facility evaluations, reporting, scientific research and pre ANDA meetings. FDA also noted that a subgroup was formed to discuss modeling of fees. The subgroup also met on June 28, 2016, and discussed principles and positions.

Next Meeting

The next stakeholder meeting is planned for Thursday, July 28, 2016.