

FDA-GDUFA Reauthorization Stakeholder Meeting
January 27, 2016, 10:00 am - 11:00 am
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

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

Stakeholders

Paul Brown National Center for Health Research
Kenyon Farrow Treatment Action Group
Sarah Sorscher Public Citizen

FDA Supporting Staff

Derek Griffing, Tawni Schwemer, Katie Stronati, Trang Tran, Connie Wisner

Welcome & Overview

Following introductions, FDA gave a broad overview of the progress of the GDUFA reauthorization negotiation meetings.

Summary of Recent Negotiation Sessions

FDA provided an overview of the GDUFA negotiation meetings between FDA and Industry held on January 6, 2016, and January 20, 2016. FDA summarized its discussions with Industry on three important issues: (1) metric review goals and the review timeframe; (2) GDUFA program enhancements for communications and transparency; and (3) the pre-Abbreviated New Drug Application (pre-ANDA) process.

FDA then discussed a number of topics related to the preceding three issues, including: product-specific recommendations, pre-ANDA meetings, controlled correspondence, first generics, and regulatory science priorities.

Next Meeting

The next stakeholder meeting is planned for Wednesday, February 24, 2016.