**FDA-GDUFA Reauthorization Stakeholder Meeting**
**February 24, 2016, 10:00 am - 11:00 pm**
**FDA White Oak Campus, Silver Spring, MD**
**Building 52/72, Conference Room 1100**

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**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 | |
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| Mary Beth Clarke | CDER | Paul Brown | National Center for Health Research |
| Keith Flanagan | CDER | Marcia Horn | International Cancer Advocacy Network |
| Michael Jones | CDER | Andrea Lowe | Society for Women's Health |
| Martha Nguyen | CDER | Sarah Sorscher | Public Citizen |

FDA Supporting Staff
Derek Griffing, Tawni Schwemer, 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 held on February 3, 2016, and February 17, 2016. FDA summarized its discussions with Industry on the following issues: regulatory science priorities, metric review goals and review timelines, complex products, the pre-Abbreviated New Drug Application (pre-ANDA) process, controlled correspondence, facility evaluations and inspection parity, and transparency and communication. FDA also explained that it is discussing a number of Drug Master File (DMF) program enhancements with Industry.

The Society for Women's Health expressed its support for the regulatory science program, particularly with respect to demonstrating generic sameness and using such research to educate health care providers and consumers on generic drugs. Public Citizen noted that it would like to see speedy approvals and high quality, but not at the price of lower standards.

**Next Meeting**

The next stakeholder meeting is planned for Wednesday, March 23, 2016.