GDUFA Reauthorization Stakeholder Meeting
March 23, 2021, 1:00 pm – 2:00 pm
Virtual Meeting

Purpose

The Federal Food, Drug, and Cosmetic Act (FD&C Act) 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

Tiana Barnes - CDER
Carter Beach - CDER
Ashley Boam - CDER
Jacqueline Corrigan-Curay-CDER
Alonza Cruse - CDER
Dat Doan - CDER
Robert Lionberger - CDER
Edward (Ted) Sherwood – CDER
Tawni Schwemer – CDER

Stakeholders

Karin Bolte – American Pharmacists Association
Gavin Clingham – Alliance for Patient Access
Jeanette Contreras – National Consumers League
Dennis Cryer – Global Liver Institute
Vadim Gurvich – National Institute for Pharmaceutical Technology and Education (NIPTE)
Jessica Kennedy – Mental Health America
Linda Mimms – Schizophrenia and Related Disorders Alliance of America (SARDAA)
Sohail Mosaddegh - U.S. Pharmacopeia
Jenna Riemenschneider – Asthma and Allergy Foundation of America
Andrew Scott – Global Liver Institute

Welcome and Summary of Recent Negotiations

Following introductions, FDA provided a summary of negotiations between FDA and industry held on February 25, March 11, and March 18, 2021. FDA summarized its discussions with industry regarding:

- Inspections
- Taking into account business days when setting certain goal dates for responses which are based on calendar days
- Drug Master Files (DMFs) and how to leverage that process to improve ANDA review efficiency
- Setting a sound foundation to start GDUFA III to account for fluctuations in workload such as supplements and controlled correspondences. FDA discussed how time reporting data are available to inform this activity .

Stakeholder Comments:

- Linda Mims provided a statement on behalf of SARDAA regarding the potential for complex generics, such as injectables, to improve medication adherence for patients with schizophrenia
- Discussion regarding methods of prioritization to improve access to high priority medications (MAPP 5240.3).
- Discussion regarding methods utilized to reduce Abbreviated New Drug Application (ANDA) review cycles.

Next Meeting

The next stakeholder meeting is planned for Tuesday, April 27, 2021.