GDUFA Reauthorization Stakeholder Meeting
May 25, 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	Stakeholders
Tiana Barnes - CDER	Jeffrey Anders – Color of Crohn's and Chronic Illness
Carter Beach - CDER	Karin Bolte – American Pharmacists Association
Jacqueline Corrigan-Curay - CDER	Marissa Brykman - U.S. Pharmacopeia
Dat Doan – CDER	Gavin Clingham - Alliance for Patient Access
Susan Rosencrance - CDER	Jeanette Contreras – National Consumers League
Edward (Ted) Sherwood – CDER	Sohail Mosaddegh - U.S. Pharmacopeia
Tawni Schwemer – CDER	Jenna Riemenschneider – Asthma and Allergy Foundation of America
	Andrew Scott – Global Liver Institute

Summary of Recent Negotiations
FDA provided a summary of negotiations between FDA and industry held on May 6, May 13, and May 20, 2021.

- FDA and Industry continued discussions around the proposals for setting a sound foundation for continued programmatic success.
- FDA and Industry have been discussing proposals regarding complex generics. The next public meeting is scheduled for June 30, 2021.

Stakeholder Questions
FDA addressed stakeholder questions and comments:

- FDA addressed how we seek to continue to implement process improvements in GDUFA.
- FDA discussed patient engagement opportunities regarding the generics program.

Next Meeting
The next stakeholder meeting is planned for June 30, 2021.