GDUFA Reauthorization Stakeholder Meeting
January 26, 2021, 12:00 pm – 1:00 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	Charmayne Anderson - Allergy & Asthma Network
Carter Beach	CDER	Karin Bolte - American Pharmacists Association
Ashley Boam	CDER	Tammy Boyd - Black Women's Health Imperative
Jacqueline Corrigan-Curay	CDER	Rutesh Dave – National Institute for Pharmaceutical Technology and Education (NIPTE)
Alonza Cruse	CDER	Vadim Gurvich - NIPTE
Dat Doan	CDER	Carrie Monks – Academy of Managed Care Pharmacy
Susan Rosencrance	CDER	Ken Morris - NIPTE
Tawni Schwemer	CDER	Sohail Mosaddegh – U.S. Pharmacopeia
Maryll Toufanian	CDER	Rick White - National Organization for Rare Disorders (NORD)

Welcome
Following introductions, FDA provided 2 presentations.

Presentations
Representatives from FDA provided the following presentations:

1. "Information Technology Improvements to Enhance Regulatory Assessment," Susan Rosencrance, Ph.D., Director, Office of Lifecycle Drug Products, Office of Pharmaceutical Quality

2. "Office of Generic Drugs Reorganization," Tawni Schwemer, Senior Advisor and Acting Associate Director for Regulatory Affairs, Office of Generic Drugs

Meeting Summary
FDA provided a summary of negotiations between FDA and industry held on the following dates:

- December 17, 2020
- January 14, 2021
- January 21, 2021

Next Meeting
The next stakeholder meeting is planned for Monday, February 22, 2021, 12:00 pm – 1:00 pm ET.