GDUFA Reauthorization Stakeholder Meeting
October 20, 2020, 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
Jacqueline Corrigan-Curay	CDER	Charmayne Anderson - Allergy & Asthma Network
Maryll Toufanian	CDER	Karin Bolte - American Pharmacists Association
Carter Beach	CDER	Tammy Boyd - Black Women's Health Imperative
Ashley Boam	CDER	Marissa Brykman – U.S. Pharmacopeia
Tawni Schwemer	CDER	Sohail Mosaddegh – U.S. Pharmacopeia
Tiana Barnes	CDER	Jeanette Contreras - National Consumers League
Dat Doan	CDER	Nissa Shaffi - National Consumers League
Sally Choe	CDER	Rick White - National Organization for Rare Disorders (NORD)
Robert Lionberger	CDER	Rachel Sher - NORD
Alonza Cruse	ORA/FDA	Rutesh Dave – National Institute for Pharmaceutical Technology and Education (NIPTE)
		Vadim Gurvich - NIPTE
		Xiuling Lu - NIPTE
		Fernando Muzzio - NIPTE
		Rex Reklaitis - NIPTE

Welcome and Overview
Following introductions, FDA provided a broad overview of the User Fee programs. In addition, FDA described major GDUFA II accomplishments.

Summary of Recent Negotiations
FDA provided an overview of the GDUFA negotiation meetings between FDA and Industry. FDA summarized its discussions with Industry on the following three issues:

1. Advancing earlier ANDA approvals
2. Pre-Submission Facility Correspondence
3. Improving transparency and communication

Stakeholder Comments
Representatives from stakeholder organizations offered an introduction and highlighted their group's primary topics pertaining to GDUFA III. Some of the themes frequently cited by stakeholders included reducing cost of medications to consumers, ensuring safety and quality of generic drug products, reducing drug shortages, advanced manufacturing, and development of complex products.

Next Meeting
The next stakeholder meeting is planned for Thursday, November 17, 2020.