

GDUFA Reauthorization Stakeholder Meeting
November 17, 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

Tiana Barnes	CDER	Karin Bolte - American Pharmacists Association
Carter Beach	CDER	Marissa Brykman – U.S. Pharmacopeia
Ashley Boam	CDER	Rutesh Dave - NIPTE
Alonza Cruse	ORA/FDA	Vadim Gurvich - NIPTE
Jacqueline Corrigan-Curay	CDER	Sohail Mosaddegh – U.S. Pharmacopeia
Dat Doan	CDER	Hemant Patel – Temple University
Sau (Larry) Lee	CDER	Rick White - NORD
Robert Lionberger	CDER	
Tawni Schwemer	CDER	
Edward (Ted) Sherwood	CDER	
Maryll Toufanian	CDER	
Lei Zhang	CDER	

Welcome and Overview

Following introductions, FDA provided an overview of the role of regulatory science in generic drug development and application assessment.

Summary of Recent Negotiations

FDA provided an overview of the GDUFA negotiation meetings between FDA and industry held on October 22, October 29, and November 12, 2020. FDA summarized its discussions with industry:

1. Continue to make progress on proposals focused on advancing earlier approvals. FDA and Industry discussed how to optimize the tools that are currently used such as imminent approvals, discipline review letters and information requests.
2. Discussions on when a deficiency should be categorized as Major or Minor.
3. Ongoing discussion regarding transparency around the few applications for which FDA is unable to complete the reviews by the goal date.
4. Ongoing discussions regarding the Pre-Submission Facility Correspondence (PFC) program.

Stakeholder Comments

No stakeholder comments.

Next Meeting

The next negotiation meeting is planned for Tuesday, December 15, 2020.