GDUFA Reauthorization Stakeholder Meeting
February 22, 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	Karin Bolte – American Pharmacists Association
Carter Beach - CDER	Marissa Brykman – US Pharmacopeia
Ashley Boam - CDER	Jeanette Contreras – National Consumers League
Jacqueline Corrigan-Curay – CDER	Vadim Gurvich – National Institute for Pharmaceutical Technology and Education (NIPTE)
Alonza Cruse – CDER	
Dat Doan – CDER	Richard White – National Organization for Rare Disorders (NORD)
Robert Lionberger – CDER	
Maryll Toufanian - CDER	

Welcome and Summary of Recent Negotiations
Following introductions, FDA provided a summary of negotiations between FDA and industry held on January 28, February 4, and February 18, 2021. FDA summarized its discussions with industry regarding:

- Resource needs for continued programmatic success:
  - Inspections
  - Revisiting Controlled Correspondences types and timelines
  - Possible areas for GDUFA to be in alignment with the other user fee programs (BsUFA, PDUFA)
  - Other potential challenges to appropriately resource the program, including the potential impact of changes to FDARA Section 905

- FDA also informed meeting participants of the Office of Generic Drugs (OGD) 2020 Annual Report and the Office of Pharmaceutical Quality (OPQ) 2020 Annual Report.

Next Meeting
The next stakeholder meeting is planned for Monday, March 23, 2021.