GDUFA Reauthorization Stakeholder Meeting
April 27, 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	Karin Bolte – American Pharmacists Association
Carter Beach - CDER	Jeanette Contreras – National Consumers League
Ashley Boam - CDER	Dennis Cryer – Global Liver Institute
Jacqueline Corrigan-Curay-CDER	Sohail Mosaddegh - U.S. Pharmacopeia
Alonza Cruse - ORA	Andrew Scott – Global Liver Institute
Dat Doan - CDER	
Brian Hasselbalch - CDER	
Robert Lionberger - CDER	
Elizabeth Miller - ORA	
Edward (Ted) Sherwood – CDER	
Tawni Schwemer – CDER	
Maryll Toufanian – CDER	

Welcome and Stakeholder Questions
Following introductions, FDA addressed stakeholder questions:

- FDA summarized improvements to the generics program.
- FDA reiterated Acting FDA Commissioner Janet Woodcock's support and dedication toward the generics program.
- FDA provided methods utilized to help speed up reviews throughout the lifecycle of the abbreviated new drug application (ANDA) such as the prioritization scheme for ANDAs and supplements as well as pre-submission meeting opportunities.
- FDA provided a summary regarding the Imminent Approval process.
- FDA reiterated the agency and industry's collaborative interest in increasing first-cycle approvals.

FDA Presentation

- "Remote Interactive Evaluations of Drug Manufacturing and Bioresearch Monitoring Facilities During the COVID-19 Public Health Emergency" – **Guidance for Industry**
    - Brian Hasselbalch, Deputy Director, Office of Policy for Pharmaceutical Quality, Office of Pharmaceutical Quality, CDER, FDA

Summary of Recent Negotiations
FDA provided a summary of negotiations between FDA and industry held on March 25, April 1, April 8, April 15 and April 22, 2021.

- Inspections
- Continued to discuss proposals related to drug master files (DMFs) Streamlining reporting commitments while maintaining key and meaningful categories
- Discussions around the implementation of the Inactive Ingredient Database (IID).
- Discussions regarding setting a sound foundation for continued programmatic success.
- Noted that further discussions will occur regarding process improvements for review of complex products.

Next Meeting
The next stakeholder meeting is planned for Tuesday, May 25, 2021.