**GDUFA Reauthorization Stakeholder Meeting**
**June 30, 2021, 2:00 pm – 3:00 pm**
**Virtual Meeting**

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**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 |
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| Tiana Barnes - CDER | Jeffrey Anders – Color of Crohn's and Chronic Illness |
| Carter Beach - CDER | Karin Bolte – American Pharmacists Association |
| Ashley Boam – CDER | Marissa Brykman - U.S. Pharmacopeia |
| Jacqueline Corrigan-Curay - CDER | Dennis Cryer – Global Liver Institute |
| Alonza Cruse – ORA | Jenna Riemenschneider – Asthma and Allergy Foundation of America |
| Dat Doan – CDER | |
| Edward (Ted) Sherwood – CDER | |
| Tawni Schwemer – CDER | |
| Maryll Toufanian - CDER | |

**Summary of Recent Negotiations**
FDA provided a summary of negotiations between FDA and industry held on June 3, June 10, and June 24, 2021.

- Continued discussion regarding proposals for setting a sound foundation for continued programmatic success. What this primarily entailed was the discussion of a CPA to be in alignment with PDUFA.
- Discussions around a proposal for suitability petitions.

**Stakeholder Questions**
FDA addressed stakeholder questions and comments:

- FDA discussed the importance of and opportunities for patient advocacy regarding the generics program going forward.
- FDA discussed the Commitment Letter ratification process, the posting of the Federal Register notice, and the public meeting that will occur in the Fall.

**Next Meeting**
The next stakeholder meeting is planned for July 28, 2021.