

## **Closing Remarks – May 1, 2019 Generic Drug Research Public Workshop**

I'd like to express my appreciation to everyone in the audience, whether you're attending in person or by webcast. We are very appreciative of your interest in this topic and for your attention to the presentations and discussions at today's workshop.

I'd like to thank the speakers from industry and academia, as well as those from FDA. Thank you for providing a very informative overview of the regulatory science landscape for generic drugs. I'd also like to thank the panel members who participated in each of the sessions. Thank you for providing your perspectives on provocative questions – the discussions that were held today will help ORS create a strong regulatory science program for generic drugs.

I'd also like to thank all of the ORS staff for volunteering to help in various aspects of this workshop to ensure that everything ran smoothly. They did an excellent job of ensuring that we had all the necessary volunteers, worked extensively with the Great Room staff to go over logistics, and coordinated much of the work behind-the-scenes. I'd also like to thank the OGD Communications staff for their support in promoting this workshop both internally and externally.

The GDUFA Regulatory Science Program is a platform that allows for collaboration between the FDA and our external stakeholders to provide tools to efficiently evaluate and develop generic drugs in all product categories. FDA and OGD will carefully consider all the comments received today as well as submissions to the docket as we develop the fiscal year 2020 regulatory science initiatives under GDUFA. Once approved by the CDER center director, Dr. Janet Woodcock, the priorities list will be posted publicly on the GDUFA regulatory science webpage.

The docket will remain open until June, 2019, and we strongly encourage all interested parties – those attending in person, those by webcast, and those you know who may have an interest in this field who were not able to attend – to submit comments to the docket. It is your external input that makes this research program robust.

I would like to thank everyone for their participation and today's meeting is now concluded.

Thank you