

# Best Practices for Topical Generic Product Development and ANDA Submission

## Virtual Public Webinar

August 11, 2022

### Agenda

9:30 AM – 9:35 AM	<b>Opening Remarks</b> Nora Lim, PharmD	Pharmacist, CDER SBIA Program, FDA
9:35 AM – 9:40 AM	<b>Introduction to the Webinar</b> Priyanka Ghosh, PhD	Acting Team Lead, DTP-I/ORS/OGD/FDA
<b>Session 1: Q3 Characterization of Topical Products</b>		
9:40 AM – 10:00 AM	<b>Scientific and Regulatory Considerations for Q3 Characterization of Topical Products</b> Sam Raney, PhD	Associate Director for Science, ORS/OGD/FDA
10:00 AM – 10:30 AM	<b>Q&amp;A Panel on Q3 Characterization of Topical Products</b> <i>Moderator</i> Priyanka Ghosh, PhD <i>Panelists</i> Rob Lionberger, PhD Markham Luke, MD, PhD Sam Raney, PhD Pahala Simamora, PhD	Acting Team Lead, DTP-I/ORS/OGD/FDA Director, ORS/OGD/FDA Director, DTP-I/ORS/OGD/FDA Associate Director for Science, ORS/OGD/FDA Director, DLBP-II/OLDP/OPQ/FDA
<b>Session 2: IVRT Studies with Topical Products</b>		
10:30 AM – 10:55 AM	<b>Practical Considerations for IVRT Studies with Topical Products Submitted in ANDAs</b> Tannaz Ramezanli, PharmD, PhD	Pharmacologist, DTP-I/ORS/OGD/FDA
10:55 AM – 11:00 AM	<b>Break</b>	
11:00 AM – 11:30 AM	<b>Q&amp;A Panel on IVRT Studies with Topical Products</b> <i>Moderator</i> Priyanka Ghosh, PhD <i>Panelists</i> Xinran Li, PhD Anil Nair, PhD Hiren Patel, PhD Tannaz Ramezanli, PharmD, PhD Sam Raney, PhD	Acting Team Lead, DTP-I/ORS/OGD/FDA Staff Fellow, DB-II/OB/OGD/FDA Team Leader, DB-II/OB/OGD/FDA Staff Fellow, DB-II/OB/OGD/FDA Pharmacologist, DTP-I/ORS/OGD/FDA Associate Director for Science, ORS/OGD/FDA
<b>Session 3: IVPT Studies with Topical Products</b>		
11:30 AM – 11:55 AM	<b>Practical Considerations Related to IVPT Studies for Topical Products Submitted in ANDAs</b> Hiren Patel, PhD	Staff Fellow, DB-II/OB/OGD/FDA
11:55 AM – 12:25 PM	<b>Q&amp;A Panel on IVPT Studies with Topical Products</b> <i>Moderator</i> Priyanka Ghosh, PhD <i>Panelists</i> Usha Katragadda, PhD Archana Manerikar, MS, PharmD Hiren Patel, PhD Sam Raney, PhD Elena Rantou, PhD	Acting Team Lead, DTP-I/ORS/OGD/FDA Staff Fellow, DB-III/OB/OGD/FDA Pharmacologist, DB-I/OB/OGD/FDA Staff Fellow, DB-II/OB/OGD/FDA Associate Director for Science, ORS/OGD/FDA Lead Mathematical Statistician, DB-VIII/OB*/OTS/FDA
12:25 PM – 12:30 PM	<b>Closing Comments</b> Priyanka Ghosh, PhD	Acting Team Lead, DTP-I/ORS/OGD/FDA

## Appendix of Abbreviations

ANDAs	Abbreviated New Drug Submissions
DB-I	Division of Bioequivalence I
DB-II	Division of Bioequivalence II
DB-III	Division of Bioequivalence III
DB-VIII	Division of Biostatistics VIII
DLBP-II	Division of Liquid Based Products II
DTP-I	Division of Therapeutic Performance I
FDA	United States Food and Drug Administration
IVRT	In Vitro Release Test
IVPT	In Vitro Permeation Test
OB	Office of Bioequivalence
OB*	Office of Biostatistics
OGD	Office of Generic Drugs
OLDP	Office of Lifecycle Drug Products
OPQ	Office of Pharmaceutical Quality
ORS	Office of Research and Standards
OTS	Office of Translational Sciences
Q3	Physicochemical and Structural