



Advancing Generic Drug Development (AGDD): Modernizing Bioequivalence Approaches for Topical & Transdermal Products

September 10, 2026, 8:30am – 12:40pm EDT

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|-------------------------|---|
| 8:30 – 8:35 am | <u>Welcome and Overview</u>
Kori Adair, PharmD
<i>Pharmacist</i>
Small Business and Industry Assistance (SBIA)
Division of Drug Information (DDI)
Center for Drug Evaluation and Research (CDER) FDA |
| 8:35 – 8:40 am | <u>Introduction and Scope of Webinar</u>
Priyanka Ghosh, PhD
<i>Lead Pharmacologist</i>
Division of Therapeutic Performance I (DTP I)
Office of Research and Standards (ORS)
Office of Generic Drugs (OGD) CDER |
| <u>Session 1</u> | <u>Current Recommendations, Challenges and Opportunities for Topical Products</u> |
| 8:40 – 9:00 am | <u>Current Recommendations and ANDA Landscape for Topical Products</u>
Tannaz Ramezanli, PharmD, PhD
<i>Senior Pharmacologist</i>
DTP I ORS OGD CDER |
| 9:00 – 9:20 am | <u>ANDA Assessment Challenges – Bioequivalence Perspective</u>
Allison Schafer, PhD
<i>Senior Interdisciplinary Scientist</i>
Division of Bioequivalence II (DBII) Office of Bioequivalence (OB) OGD CDER |
| 9:20 – 9:40 am | <u>Mechanistic Modeling to Support the Approval of Generic Tazarotene Cream</u>
Eleftheria Tsakalozou, PhD
<i>Lead Pharmacologist</i>
Division of Quantitative Methods and Modeling (DQMM) ORS OGD CDER |

9:40 – 10:05 am Question and Answer Session

Moderator:

Priyanka Ghosh, PhD

Panelists:

Tannaz Ramezanli, PharmD, PhD

Allison Schafer, PhD

Eleftheria Tsakalozou, PhD

and joined by:

Robert Lionberger, PhD

Director

ORS | OGD | CDER

Partha Roy, PhD

Director

OB | OGD | CDER

Pahala Simamora, PhD

Director

Division of Product Quality Assessment IX (DPQA IX)

Office of Product Quality Assessment II (OPQA II)

Office of Pharmaceutical Quality (OPQ) | CDER

10:05 – 10:15 am Break

Session 2 **Using Research to Support and Streamline Product Specific Guidances (PSG) for Topical Products**

10:15 – 10:35 am Critical Formulation, Foam-Structure, and Performance Attributes of Topical Foams

Ahmed Zidan, PhD

Senior Research Pharmacologist

Division of Product Quality and Research V (DPQR V)

Office of Pharmaceutical Quality Research (OPQR)

OPQ | CDER

10:35 – 10:55 am IVPT Unplugged: From Challenges to Solutions in Topical Permeation Method Development.

Nahid Kamal, PhD

Pharmacologist

DPQR V | OPQR | OPQ | CDER

10:55 – 11:15 am Mechanistic Modelling to Streamline PSG Recommendations and Reduce Regulatory Burden

Eleftheria Tsakalozou, PhD

Lead Pharmacologist

DQMM | ORS | OGD | CDER

11:15 – 11:40 am

Question and Answer Session

Moderator:

Hiren Patel, PhD

Senior Staff Fellow

DBII | OB | OGD | CDER

Panelists:

Ahmed Zidan, PhD

Nahid Kamal, PhD

Eleftheria Tsakalozou, PhD

and joined by:

Sam Raney, PhD

Associate Director for Science and Chief Scientific Advisor

ORS | OGD | CDER

Xiaoming Xu, PhD

Director

DPQR V | OPQR | OPQ | CDER

Andrew Babiskin, PhD

Deputy Director

DQMM | ORS | OGD | CDER

11:40 – 11:50 am

Break

Session 3

Using Research to Streamline Recommendations for Topical and Transdermal Delivery Systems (TDS)

11:50 – 12:10 pm

Current Recommendations and ANDA Landscape for TDS

Ying Jiang, PhD

Chemist

DTP I | ORS | OGD | CDER

12:10 – 12:35 pm

Question and Answer Session

Moderator:

Megan Kelchen, PhD

Senior Pharmacologist

DTP I | ORS | OGD | CDER

Panelists:

Ying Jiang, PhD

Priyanka Ghosh, PhD

and joined by:

Markham C. Luke, MD, PhD

Director

DTP I | ORS | OGD | CDER

Robert Berendt, PhD

Supervisory Pharmaceutical Scientist

Division of Product Quality Assessment V (DPQA V)

Office of Product Quality Assessment I (OPQA I) | OPQ | CDER

Wanjie Sun, PhD

Master Mathematical Statistician

Division of Biometrics VIII (DB VIII) | Office of Biostatistics (OB)

Office of Translational Sciences (OTS) | CDER

Ying Fan, PhD

Lead Pharmacologist

Division of Clinical Review (DCR)

Office of Safety and Clinical Evaluation (OSCE) | OGD | CDER

12:35 – 12:40 pm

Closing Remarks

Robert Lionberger, PhD