The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER)
Office of Generic Drugs, Office of Research and Standards, Division of Therapeutic Performance

FDA Public Workshop

Topical Dermatological Generic Drug Products:
Overcoming Barriers to Development and Improving Patient Access

October 20th, 2017
FDA White Oak Campus, 10903 New Hampshire Avenue, Silver Spring, MD 20993
Building 31, Room 1503 Section A

Agenda

7:30 – 8:00 am **Registration**

SESSION I

Chair: Sam Raney, PhD

8:00 – 8:05 am

Welcome
Sam Raney, PhD
Scientific Lead, Division of Therapeutic Performance (DTP)
DTP/ORS/OGD/CDER/FDA

8:05 – 8:20 am

Opening Remarks: Evolving Perspectives on Generic Drugs in the 21st Century
John Peters, M.D.
Deputy Director, Office of Generic Drugs (OGD)
OGD/CDER/FDA

8:20 – 8:40 am

Overcoming Barriers and Improving Patient Access to Topical Dermatological Drugs
Markham Luke, M.D., PhD
Director, Division of Therapeutic Performance (DTP)
DTP/Office of Research and Standards (ORS)/OGD/CDER/FDA

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SESSION II

Chair: Priyanka Ghosh, PhD

8:40 – 9:20 pm

In Vivo Dermal Open Flow Microperfusion: A Novel Approach to Evaluating Topical Bioavailability and Bioequivalence

Frank Sinner, PhD
Director, Joanneum Research (Austria)

9:20 – 10:00 am

Correlation of Physicochemical Characteristics and In Vitro Permeation Test Results for Acyclovir and Metronidazole Topical Products

Michael Roberts, PhD
Professor and Research Chair: Therapeutics and Pharmaceutical Science
University of South Australia

10:00 – 10:20 am Refreshment Break

SESSION II *continued*

Chair: Priyanka Ghosh, PhD

10:20 – 11:00 am

Characterizing the Critical Quality Attributes and In Vitro Bioavailability of Acyclovir and Metronidazole Topical Products

S. Narasimha Murthy, PhD
Professor of Pharmaceutics
University of Mississippi

11:00 – 11:40 am

Characterizing In Vitro Bioavailability of Acyclovir and Metronidazole Topical Products, and In Vitro – In Vivo Correlation Results with Transdermal Systems

Audra Stinchcomb, PhD
Professor of Pharmaceutical Science
University of Maryland

11:40 – 12:40 pm Lunch Break

SESSION III

Chair: Yi Zhang, PhD

12:40 pm – 1:30 pm

Prepared Public Comments

Multiple Presenters

1:30 – 1:45 pm Refreshment Break

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SESSION IV

Chair: Priyanka Ghosh, PhD

1:45 – 2:15 pm

From Developing the Research Studies to Drafting a New Regulatory Standard

Sam Raney, PhD
Scientific Lead, Division of Therapeutic Performance (DTP)
DTP/ORS/OGD/CDER/FDA

2:15 – 2:45 pm

In Vitro Bioequivalence Data for a Topical Product: Chemistry Review Perspective

Pahala Simamora, PhD
Branch Chief, Division of Liquid-Based Products (DLBP)
DLBP/OLDP/OPQ/CDER/FDA

2:45 – 3:15 pm

In Vitro Bioequivalence Data for a Topical Product: Bioequivalence Review Perspective

Suman Dandamudi, PhD
Acting Team Lead, Division of Bioequivalence III (DBIII)
DBIII/Office of Bioequivalence (OB)/OGD/CDER/FDA

3:15 – 3:30 pm Refreshment Break

SESSION V

Moderator: Howard Maibach, MD

3:30 – 4:00 pm

Panel Discussion and Open Public Comment

1.	Howard Maibach, MD	Moderator	University of California, San Francisco
2.	John Peters, MD	Panelist	OGD/CDER/FDA
3.	Markham Luke, MD, PhD	Panelist	DTP/ORS/OGD/CDER/FDA
4.	Frank Sinner, PhD	Panelist	Joanneum Research
5.	Michael Roberts, PhD	Panelist	University of South Australia
6.	Narasimha Murthy, PhD	Panelist	University of Mississippi
7.	Audra Stinchcomb, PhD	Panelist	University of Maryland
8.	Sam Raney, PhD	Panelist	DTP/ORS/OGD/CDER/FDA
9.	Pahala Simamora, PhD	Panelist	DLBP/OLDP/OPQ/CDER/FDA
10.	Bing Cai, PhD	Panelist	DLBP/OLDP/OPQ/CDER/FDA
11.	Suman Dandamudi, PhD	Panelist	DBIII/OB/OGD/CDER/FDA
12.	Robert Lionberger, PhD	Panelist	ORS/OGD/CDER/FDA
13.	E. Dennis Bashaw, PharmD	Panelist	DCPIII/OCP/OTS/CDER/FDA
14.	Jill Lindstrom, MD	Panelist	DDDP/ODEIII/OND/CDER/FDA
15.	Elena Rantou, PhD	Panelist	DBVIII/DB/OTS/CDER/FDA
16.	Stella Grosser, PhD	Panelist	DBVIII/DB/OTS/CDER/FDA

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SESSION VI

Chair: Sam Raney, PhD

4:00 – 4:15 pm

Patient Access to Topical Dermatological Drugs: A Research Dermatologist's Perspective
Howard Maibach, M.D.
Professor of Dermatology
University of California, San Francisco

4:15 – 4:30 pm

Closing Remarks: GDUFA Regulatory Science Research and the Future of Generic Drugs
Robert Lionberger, PhD
Director, Office of Research and Standards (ORS)
ORS/OGD/CDER/FDA