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/Office of Bioequivalence (OB)/OGD/CDER/FDA
12. Robert Lionberger, PhD  Panelist  ORS/OGD/CDER/FDA
13. E. Dennis Bashaw, PharmD  Panelist  DCPIII/OC/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