PQRI Workshop on the

Evaluation of New and Generic Topical Drug Products - Current Challenges in Bioequivalence, Quality, and Novel Assessment Technologies

Co-sponsored with AAPS, FIP and USP

U.S. Pharmacopeia Meeting Center

Rockville, Maryland

March 11-13, 2013

Goals and Objectives:

1. Develop a science based regulatory approach for development and evaluation of topical drug products – product quality, performance and bioequivalence (BE) determination.
2. Review the current approaches and novel technologies for determining bioequivalence of topical drug products.
3. Identify and suggest the methodology(ies) that may be used by the regulatory agencies to assess bioequivalence as part of registration dossiers.
4. Evaluation of product uniformity and stability and impact on bioequivalence of commercial products.
5. Determine the value of in-vitro drug release in semisolid dosage forms development and in assessment of product quality and BE.
6. Develop a summary report of the workshop discussions and recommendations.

Planning Committee members:

Avraham (Avi) Yacobi, Ph.D., DOLE Pharma LLC, Co-Chair
Vinod P. Shah, Ph.D., Pharmaceutical Consultant, Co-Chair
Derek Ganes, Ph.D., Independent Consultant
Isadore Kanfer, Ph.D., Rhodes University
Majella E. Lane, Ph.D., University College London School of Pharmacy
Robert Lionberger, U.S. Food and Drug Administration
Guang Wei Lu, Ph.D., Allergan
Russell J. Rackley, Ph.D., Mylan Pharmaceuticals Inc.
Chinmay G. Shukla, Ph.D., U.S. Food and Drug Administration
March 11, 2013

7:30 am – 5:00 pm
Registration

8:30 am – 12:30 pm
Session I: Regulatory Approaches

8:30 am
Welcome and Introduction
Moderators
Vinod P. Shah, Ph.D.
Pharmaceutical Consultant
Avraham Yacobi, Ph.D.
DOLE Pharma LLC

8:45 am
Regulatory Challenges and Standards for BE Evaluation of Topical Drug Products
Vinod P. Shah, Ph.D.
Pharmaceutical Consultant

9:15 am
Current Approaches and Guidelines for BE of Topical Drug Products in the U.S. and Canada
Derek A. Ganes, Ph.D.
Independent Consultant

9:45 am
Clinical Studies in BE Evaluation: FDA Perspective
Susan Walker, M.D., Invited
U.S. Food and Drug Administration

10:15 am – 10:30 am
Coffee Break

10:30 am
Clinical Studies in BE Evaluation of Generic Products
Brenda Gierhart, M.D.
U.S. Food and Drug Administration

11:00 am
Challenges with Clinical Endpoints in Designing BE Studies
Howard Maibach, M.D.
University of California-San Francisco
11:30 am
Role of Pharmacometrics in Evaluation of Topical Drugs (PBPK Dermal Modeling; Drug Transport Across the Skin)
Gerald B. Kasting
University of Cincinnati

12:00 noon
Present Experience and Challenges with the Use of Pharmacodynamics Evaluation of BE of Glucocorticoids – Industry Perspective
Lindsey Katz
Biostudy Solutions LLC

12:30 pm
Question and Answer Session

1:00 pm
Lunch Break

2:00 pm – 3:30 pm
Session 2: Dermatopharmacokinetics

Moderators
Kailas Thakker, Ph.D.
Tergus Pharma, LLC
Majella E. Lane, Ph.D.
University College London School of Pharmacy

2:00 pm
Experience with the Use of DPK
Lynn Kennard Pershing, Ph.D.
Consultant, Akesis

2:30 pm
FDA’s Experience and Concern in Evaluation of DPK Data
Dennis Bashaw, Pharm.D.
U.S. Food and Drug Administration

3:00 pm
Dermatopharmacokinetics (DPK) in BE Determination of Topical Products – Potential and Limitations
Majella E. Lane, Ph.D.
University College London School of Pharmacy

3:30 pm - 3:45 pm
Coffee Break

3:45 pm – 5:30 pm
Session 3: Quality of Topical Drug Products
Moderators
Kailas Thakker, Ph.D.
Tergus Pharma, LLC
Majella E. Lane, Ph.D.
University College London School of Pharmacy

3:45 pm
Scientific Approaches to Assess Quality and Performance of Topical Products
Avi Yacobi, Ph.D.
Dole Pharma LLC

4:15 pm
Evaluation of In-vitro Release Methodologies in Product Development of Topical Products
Kailas Thakker, Ph.D.
Tergus Pharma, LLC

4:45 pm
Quality by Design (QbD) for Topical Dermatologic Products
Andre Raw, Ph.D.
U.S. Food and Drug Administration

5:15 pm
Question and Answer Session

6:00 pm – 7:00 pm
Networking Reception

March 12, 2013

8:30 am – 1:00 pm
Session 4: New Methodologies to Evaluate Topical Products

Moderators
Robert Lionberger, Ph.D.
U.S. Food and Drug Administration
Russell J. Rackley, Ph.D.
Mylan Pharmaceuticals Inc.

8:30 am  
**Regulatory Approaches for New Drugs: BA/ BE of Topical Drug Products**  
Dennis Bashaw, Pharm.D.  
U.S. Food and Drug Administration

9:00 am  
**Approaches in Evaluation of BE of Topical Products: FDA’s Perspective**  
Robert Lionberger, Ph.D.  
U.S. Food and Drug Administration

9:30 am  
**New Approaches and Optimization of Methods for BE Assessment of Topical Drug Products**  
Isadore Kanfer, Ph.D.  
Rhodes University

10:00 am – 10:15 am  
Coffee Break

10:15 am  
**Potential of Microdialysis in Evaluation of Topical Drug Products – An Opportunity for Bioequivalence Determination of Topical Products**  
Eva M. Benfeldt, Ph.D., M.D.  
University of Copenhagen

11:00 am  
**Development of Pilosebaceous Gland-targeted Drug Products and Potential Impact on BE Testing**  
Guang Wei Lu, Ph.D.  
Allergan

11:30 am  
**Generic Industry Perspectives on BE Testing of Topical Drug Products**  
Russell J. Rackley, Ph.D.  
Mylan Pharmaceuticals Inc.

12:00 noon  
Question and Answer Session

12:30 pm – 1:30 pm  
Lunch Break
1:30 pm – 5:15 pm
Breakout Sessions
(Each breakout session will last 45 minutes and will be repeated 5 times)

Please Note: The afternoon break will be set up for you to help yourself throughout the afternoon any time after 3:00 pm

A. Clinical endpoint BE studies (variability, CR products)
   Moderators: Derek Ganes, Brenda Gierhart
B. BE Studies Using Pharmacodynamics and Pharmacokinetic Methodologies (Data processing)
   Moderators: Majella Lane and Barbara Davit
C. In-vitro Release Methodologies – Applications
   Moderators: Tapash Ghosh and Kailas Thakker
D. Alternative New Techniques to Assess BE Including In vitro Method
   Moderators: Robert Lionberger and Russ Rackley
E. Modeling and Simulations, Pharmacometrics
   Moderators: Chinmay Shukla and Gerald Kasting

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8:30 am – 12:30 pm
Session 5: Regulatory Approaches

Moderators
Barbara Davit, Ph.D.
U.S. Food and Drug Administration
Derek Ganes, Ph.D.
Independent Consultant

8:30 am
Summary of Break-out Sessions
  8:30 am- Breakout Session A
  8:45 am- Breakout Session B
  9:00 am- Breakout Session C
  9:15 am- Breakout Session D
  9:30 am- Breakout Session E

9:45 am
An Investigator’s Perspective on Practical Issues and Challenges in Conducting Clinical Endpoint Studies
Elizabeta Zovko, M.D.
Forest Research Institute

10:15 am
Regulatory Approaches for Generic Drugs: BE of Topical Drug Products
Barbara Davit, Ph.D.
U.S. Food and Drug Administration

10:45 am
Coffee Break

11:00 am
Practical Applications to Evaluate Topical Drug Products in Patients
Nathalie Wagner, M. Sc.
Galderma R & D

11:30 am
Challenges of Assessing Bioequivalence of Topical Pharmaceutical Products
Robert Lionberger, Ph.D.
OGD Science Staff

12:00 pm
Combination Techniques That Can Assure BE of Topical Drug Products
Avraham Yacobi, Ph.D.
DOLE Pharma LLC

12:30 pm
Question and Answer Session

12:45 pm
Conclusions –
Vinod P. Shah, Ph.D.
Pharmaceutical Consultant
Avraham Yacobi, Ph.D.
DOLE Pharma LLC

March 13, 2013 in the afternoon

1:30 pm – 4:30 pm
Planning Committee/Faculty Members ONLY– Summary Report