Human Dermal (Skin) Safety Testing For Topical Drug Products:
Regulatory Utility and Evaluation

7:45 AM – 8:30 AM  Registration

8:30 AM – 8:35 AM  Opening Remarks  
**Speaker:** Kendall Marcus, MD, Director, DDDP, ODE3, OND, CDER, FDA

Session I. FDA Presentations on the Status Quo
**Moderator:** Kendall Marcus, MD, Director, DDDP, ODE3, OND, CDER, FDA

**Speaker:** Hon-Sum Ko, MD, Medical Officer, DDDP, ODE3, OND, CDER, FDA

8:50 AM – 9:20 AM  Presentation: Nonclinical Aspects of Dermal Safety Testing  
**Speaker:** Barbara Hill, PhD, Supervisory Pharmacologist/Toxicologist, DDDP, ODE3, OND, CDER, FDA

9:20 AM – 9:35 AM  Presentation: Labeling and Human Dermal Safety Testing  
**Speaker:** Jill Lindstrom, MD, Deputy Director, DDDP, OND, CDER, FDA

9:35 AM – 9:45 AM  Questions and Answers

9:45 AM – 9:55 AM  Break

Session II. Basic and Applied Science on Human Dermal Safety Testing
**Moderator:** Hon-Sum Ko, MD, Medical Officer, DDDP, ODE3, OND, CDER, FDA

9:55 AM – 10:25 AM  Presentation: Mechanisms of Foreign Antigen Recognition in Skin  
**Speaker:** Keisuke Nagao, MD, PhD, Earl Stadtman Investigator, Dermatology Branch, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institutes of Health

10:25 AM – 10:55 AM  Presentation: Dermal Safety Studies in Development: Sponsor’s Perspective  
**Speaker:** Michael Graeber, MD, Senior Medical Advisor, Galderma R&D, Inc.

**Speaker:** Derek Grimes, BS, MBA, Vice President, Clinical Operations, TKL Research, Inc. and John Lyssikatos, BS, Senior Director, Business Operations, TKL Research, Inc.
11:25 AM – 11:35 AM  Break

11:35 AM – 12:05 AM  Presentation: Rethinking Pre-marketing Risk Assessment for Contact Dermatitis  
**Speaker:** Jonathan Wilkin, MD, Former Director, DDDP, ODE3, OND, CDER, FDA

12:05 PM – 12:35 PM  Presentation: In Vitro Methodologies for Assessing Cutaneous Irritation, Sensitization and Photosensitivity  
**Speaker:** Donald Belsito, MD, Leonard C. Harber Professor of Dermatology, Columbia University

12:35 PM – 12:45 PM  Questions and Answers

12:45 PM – 1:30 PM  Lunch Break

1:30 PM – 2:00 PM  Session III. Public Input  
**Moderator:** Jill Lindstrom, MD, Deputy Director, DDDP, ODE3, OND, CDER, FDA

2:00 PM – 2:45 PM  Open Public Hearing  
**Session IV. Panel and Audience Discussion**  
**Moderator:** Jill Lindstrom, MD, Deputy Director, DDDP, ODE3, OND, CDER, FDA

2:45 PM – 3:00 PM  Break

3:00 PM – 3:45 PM  Questions to the Panel with Audience Participation (Continued)  
**Panelists:** Donald Belsito, MD, Michael Graeber, MD, Derek Grimes, BS, MBA, John Lyssikatos, BS, Keisuke Nagao, MD, PhD, and Jonathan Wilkin, MD

3:45 PM – 4:00 PM  Presentation: Wrap-up from Workshop  
**Speaker:** Kendall Marcus, MD, Director, DDDP, ODE3, OND, CDER, FDA

4:00 PM  Adjourn