

**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
- 8:35 AM – 8:50 AM      **Presentation: Status of Human Dermal Safety Testing in Topical Drug Product Development and Potential for Change: Charge for Workshop Participants**  
**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.
- 10:55 AM – 11:25 AM      **Presentation: Human Dermal Safety Testing for Topical Drug Products**  
**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**

**Session III. Public Input**  
**Moderator:** Jill Lindstrom, MD, Deputy Director, DDDP, ODE3, OND, CDER, FDA

1:30 PM – 2:00 PM **Open Public Hearing**

**Session IV. Panel and Audience Discussion**  
**Moderator:** Jill Lindstrom, MD, Deputy Director, DDDP, ODE3, OND, CDER, FDA

2:00 PM – 2:45 PM **Questions to the Panel with Audience Participation**  
**Panelists:** Donald Belsito, MD, Michael Graeber, MD, Derek Grimes, BS, MBA, John Lyssikatos, BS, Keisuke Nagao, MD, PhD, and Jonathan Wilkin, MD

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

**Session V. Summary and Moving Forward**

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**