

**Markham C Luke, M.D., PhD**  
**U.S. Food & Drug Administration (FDA)**



Markham C. Luke, MD, PhD serves as FDA Supervisory Physician (Dermatology) and Director of the Division of Therapeutic Performance (DTP) in the Office of Research and Standards, Office of Generic Drugs at FDA. DTP is responsible for facilitating pre-application development of generic drugs by conducting and promoting regulatory science research to establish standards to ensure therapeutic equivalence of new generic drug products. Markham has been at FDA since 1998 serving various roles, including as the Lead Medical Officer for dermatology drugs in the Office of New Drugs at CDER, Chief Medical Officer and Deputy Director for the Office of Device Evaluation in CDRH, and as Acting Director for Cosmetics in CFSAN. Markham has an MD degree and a PhD in Pharmacology from Johns Hopkins University, internal medicine training at Johns Hopkins Bayview Medical Center, and dermatology residency and fellowship at Washington University, St. Louis, MO and at NCI/NIH, Bethesda, MD. Markham is an Associate Professor in Dermatology at the Uniformed Services University of the Health Sciences, Bethesda, MD. Markham has research interests in dermato-pharmacology, clinical pharmacology, product innovation and design – especially for combination drug-device products, clinical study design and endpoints assessment (including patient-reported outcomes) for medical, surgical, and aesthetic products and serves as consultant dermatologist to various parts of FDA.

**PRESENTATION: The Role of FDA in Dermatology and Dermatological Products**

**Speaker:** Markham C. Luke, MD PhD

This presentation will focus on the basics of FDA as it relates to dermatology and the products that were discussed during the meeting, discussing what parts of FDA regulate different types of topical products for the benefit of U.S. public health. The talk will be based on the speaker's experience and regulatory knowledge from various roles within different parts of FDA, combined with his clinical understanding as a practicing dermatologist, as well as his work in clinical pharmacology. Dr. Luke will endeavor to convey FDA's role in assuring safe and effective drugs and devices, safety for cosmetics and personal care products, and access to good dermatology drugs.