

Are You Ready to Comply with New EU Draft Regulations for Claims Testing? Are You Familiar with Advertising Self-Regulation?

SEPTEMBER 15th 2014

Life Sciences Building Auditorium, 145 Bevier Road, Piscataway NJ 08854
Claim Substantiation for Topical Products - Comprehensive and Updated

Dr. Nava Dayan L.L.C and Guest Speaker Annie Ugurlayan; Senior Staff Attorney, National Advertising Division

COURSE DESCRIPTION

The EU Commission issued a draft guideline for claims substantiation in July of 2013. The FDA and the FTC are carefully watching cosmetic products for non-substantiated misleading claims. Ethical issues are raised by misleading claims as the product will not deliver the promised results. With the skin care industry striving to produce safer products, it should also improve its testing methods to better evaluate products activity on the skin and to clearly and accurately communicate the results in product claims. Common criteria for justification of claims are a challenging aspect in product development since they need to be customized for the purpose of use and nature of the product developed. This course is tailored to provide key aspects in the establishment of best practices to be applied in experimental design and tie it into the regulatory framework rationale.

OUTLINE

9:00am - 10:30am

- Cosmetic vs. physiological claims
- FDA requirement for "substantial evidence"
- Translation of data into fair claims
- The stratum corneum structure
- Structural changes

10:30am - 10:45am Break

10:45am - 12:00pm

The function premise - translation of data into claims:

- In vitro studies:
- Enzymatic studies
- Cell cultures
- Genomics and proteomics
- Ex vivo studies
- Skin penetration
- Skin metabolism
- Stability
- Identifying site of activity
- The therapeutic index concept

12:00pm - 1:00pm - Lunch

1:00pm - 2:30pm

"Advertising Self-Regulation - A Review of Cosmetics Claims" by guest speaker Annie Ugurlayan, Senior Staff Attorney at the National Advertising Division

2:30pm - 2:45pm Break

2:45pm - 4:00pm

Clinical study design:

- Panel size and statistical significance
- Validity of pilot runs
- Subjective vs. quantitative evaluation
- Consumer feedback and questionnaire
- Activity of raw materials vs. finished formulation
- Duration of activity
- Ethical and scientific consideration
- Review and summary

Cost: \$475 - non member, \$395 - member

Registration link: <http://tinyurl.com/NavaDayan>

COURSE DIRECTOR



Nava Dayan, PhD, is founder and president of a skin science and research consultancy serving the pharmaceutical, cosmetic, and personal care industries. Dr. Dayan's 24 years of experience in the greater skin care segment, have yielded more than 150 publication credits in numerous industry-respected journals four books, as well as an In-Cosmetics Gold Award for innovation and commensurate recognition from the NYSCC and the CRS for excellence.

GUEST SPEAKER



Annie Ugurlayan is a Senior Staff Attorney at the National Advertising Division. Since 2003, she has handled over 150 cases, particularly in the areas of cosmetics, food and oral care products, and has successfully argued appeals before the National Advertising Review Board. Annie is also a frequent lecturer at conferences nationwide and abroad.