RESEARCH SEMINAR SERIES REMOTE

The Center for Dermal Research Welcomes

Dr. Robert Falcone, Prestige Consumer Healthcare

"Development and Application of a Consumer Reported Outcome Measure to Support Label Claims for Skin Care Products"

Monday, March 7 at 5:30pm EST

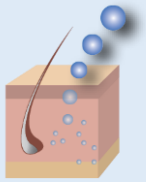
Robert received his B.S. in Physical Chemistry and Chemical Engineering from the U.S. Naval Academy. He received his M.S. in Chemical Engineering from Manhattan College and his Ph.D. in Material Science and Engineering from NJIT. From 1980 to 1987, he worked with the ONR as a Materials Scientist/Line officer. He worked at Zeneca (now known as Astra-Zeneca) as a Regulatory Scientist in Active Pharmaceutical Ingredients for Human and Animal Prescription Applications to FDA and EU. Program Regulatory Manager for the Hartz Mountain Corporation / Church and Dwight working with Veterinary and Human Drugs (Prescription and OTC) - FDA & EPA. Director of Regulatory Devices (Class I and II) and Combination Products – Nice Pak – FDA and Health Canada. Director of Regulatory Affairs for Prescription and OTC Dermatological Products – FDA, EMA and Health Canada – Peter Thomas Roth LLC. Sr. Global Regulatory Manager – API development and submissions to FDA, Health Canada, Mexico, Brazil, EU and China – Vantage Specialty Ingredients. Sr. Global Regulatory Affairs Manager for Finish Prescription and OTC products representing companies selling in the US, Canada and EU – Integris Biosolutions. Robert is presently working as a Sr. Regulatory Affairs Manager for Finish Prescription and OTC products sold in US and Canada – Prestige Consumer Healthcare. Robert is a fellow of the Regulatory Professional Society (RAPS) and The Organization for Professional in Regulatory Affairs (TOPRA).

Abstract: Unlike pharmaceuticals in the US, claims in personal care products are usually not reviewed nor require approvals before products are sold in the US market. However, it is not implied that regulators do not monitor the market for miss-representations on such products. Moreover, since label and advertising approvals are not required to sell cosmetic products in the US, other US agencies will conduct additional oversights. The one, in particular, is the Federal Trade Commission (FTC) under the auspices of the Fair Packaging and Labeling Act (FPLA). Because of this lack of clarity, personal care and cosmetics manufacturers have, on several occasions, trespassed the boundaries on the claims used, resulting in being cited for promoting unsafe/unadulterated products in the US market.

Continued on page 2

RUTGERS

Center for Dermal Research, 145 Bevier Road, Piscataway, NJ 08854
Tel: 848.445.3589 Fax: 732.445.5006 For more information: cdr_frontdesk@dls.rutgers.edu



RESEARCH SEMINAR SERIES REMOTE

One of the main reasons for this anomaly is the lack of methodologies for building / setting claims. Neither FDA nor FTC does indicate what to use leverage when considering building suitable cosmetic products claims, which is unlike what it is recommended for prescription products. Although no specific set is recommended for the Cosmetic / Personal Care Industries, FTC has also leveraged Truth in Advertising (TAFTC) to gauge the claims' veracity. Both, FDA and FTC, must use TAFTC very often because one of the major promotional sales significantly is the use of testimonials.

The question arises, how can testimonials be used/leveraged without infringing into the guidance set in TAFTC?

The presentation will share the research work on the DEVELOPMENT AND VALIDATION OF A CONSUMER-REPORTED OUTCOMES MEASURE TO SUPPORT LABEL CLAIMS

CONFERENCE LINK:

Meeting link:
https://rutgers.webex.com/rutgers/j.php?MTID=m5d08159cca660ed44e06e55fed8fc2c6

Link is also available on our website: https://sites.rutgers.edu/centerfordermalresearch/

under the Events menu.

Or send an email to cdr_frontdesk@dls.rutgers.edu to request a direct invite.

RUTGERS

Center for Dermal Research, 145 Bevier Road, Piscataway, NJ 08854
Tel: 848.445.3589 Fax: 732.445.5006 For more information: cdr_frontdesk@dls.rutgers.edu