## Center for Dermal Research Innovations in Dermatological Sciences Conference 2023



## Carl D'Ruiz

Carl is currently the Senior Manager of Regulatory and Scientific Affairs at DSM Personal Care. He has over 30 years of experience in providing strategic scientific, regulatory and pre-market approval advice and direction for the commercialization and marketing of OTC drug, cosmetic and personal care products, ingredients, and brands.

Prior to joining DSM, Carl held key R&D, business, policy, regulatory, advocacy, quality, safety, clinical and scientific affairs

positions at the US Environmental Protection Agency, Ciba, Dial, Henkel Consumer Goods, Lorillard Tobacco, Blu Electronic cigarettes, Kemira and Newell Rubbermaid. He is widely regarded as a thought leader in tobacco harm reduction and photoprotection and is currently Chair of PCPC's Sunscreen Consortium, championing industry's efforts to substantiate the safety and efficacy of existing sunscreens and paving the innovation path for the inclusion of PARSOL® Shield (Bemotrizinol) under FDA's sunscreen monograph.

Carl holds a Master's Degree in Public Health from Yale University and a bachelor's in political science and biology from Fordham University. He has executive business certifications in negotiations, bargaining and marketing from The Darden and Wharton Business Schools and is a full member of the Society of Toxicology, board member of the Photodermatology Society and frequent speaker at the Society for Cosmetic Chemists. He also is an avid road cyclist and certified rescue diver.

## "Status and outlook for new US Sunscreens - are we there yet?"

## Abstract:

Sunscreens are topically applied drug products regulated by the U.S. FDA under its OTC sunscreen drug monograph. They are indicated to help prevent sunburn and decrease the risk of skin cancer and early skin aging, caused by exposure to the sun's ultraviolet radiation.

Compared to other countries, which have 30 or more UV filters approved for use in sunscreen products, the US has 16 UV filters currently listed on FDA's OTC sunscreen

monograph. Of these, only about nine are currently viewed as technically suitable for formulating sunscreen products that provide adequate, effective, and broad-spectrum UV protection as prescribed by the OTC sunscreen drug monograph.

This small number of approved UV filters reduces the options to provide American consumers a variety of innovative, broad spectrum and effective sun protection products that help protect them against skin cancer and skin damage associated with overexposure to the sun. This situation is further complicated by an absence of new UV filters added to the sunscreen monograph in over 20 years and by the FDA's 2021 deemed final order and proposed order for OTC sunscreens request that additional clinical and preclinical safety data be generated for twelve of the sixteen sunscreen actives listed on the sunscreen monograph.

An overview of the status of current UV-filters, new UV-filters on the horizon, and the required clinical pharmacokinetic (PK), human dermal safety, nonclinical and efficacy studies needed to bring new UV-filters to market for sunscreen use in the US will be discussed.