

ABSTRACT

PRESENTER: Dr. Stanley Milstein

COMPANY: FDA - Center for Food Safety and Applied Nutrition

JOB TITLE: Retired - Acting Deputy Director

Podium Title: *Soaps, Syndets, and Hand Sanitizers: 'Cleaning Up' Our Knowledge About Their Regulation: COVID-19 Pandemic Edition*

Abstract

It has never been more important than during the current COVID-19 Pandemic to practice good hand hygiene. Frequent, thorough handwashing with 'soap' and water is essential, but when "water" is not available, FDA and CDC recommend the use of alcohol-based "hand sanitizers".

'Soap' is not included in the legal definition of "cosmetic" (FD&C Act (Sec 201(i)), but FDA has given further interpretation at 21 CFR 701.20. True "Soap" is regulated by the U.S. Consumer Product Safety Commission (CPSC). But soap-type products may be regulated by FDA as 'cosmetic' or 'drug', based on composition or labeling claims.

FDA recently published temporary Guidance for Industry, articulating Agency policy during the COVID-19 Pandemic for alcohol-based hand sanitizers. FDA and CDC have reported increased adverse event reports (AER), including acute oral poisonings and deaths, from "*economically adulterated*" alcohol-based hand sanitizers, most of them imports.



Stanley R. Milstein, Ph.D. retired as Acting Deputy Director in FDA's Office of Cosmetics and Colors at the FDA Center for Food Safety and Applied Nutrition (CFSAN) in Washington, D.C. in 2017 after 26 years of service with the Agency. Prior to joining the Agency in 1991, Dr. Milstein held several senior scientific and regulatory affairs positions for the preceding 12 years in the R&D Division of the Andrew Jergens Co. (now KAO USA), (Cincinnati, OH).

Dr. Milstein is a Fellow of the Society of Cosmetic Chemists (SCC) and has served the SCC over the past 40 years as Chapter Chair of the "Ohio Valley" and "Mid-Atlantic"

Chapters, as regional Area II and Area IV Director, and as President of the National Society (1992). He is also a 50+ Year Member of the American Chemical Society (ACS).

Dr. Milstein He has held visiting faculty appointments in general and organic chemistry in the Departments of Chemistry at Adelphi University (Garden City, NY) and the University of

Cincinnati, respectively. He recently joined the faculty of the UC College of Pharmacy as Adjunct Professor, Cosmetic Science. He has been an invited guest speaker at the Weidner University-Delaware School of Law Symposium, "All Matters FDA" (2018, 2019)

Dr. Milstein has addressed Cosmetic Industry Trade Association (CTFA/PCPC, ICMAD) audiences and has given presentations to foreign regulatory delegations to FDA-CFSAN and in FDA Office of Regulatory Affairs University (ORA U) courses on Import Operations and Entry Review (2005-2017). He is currently a member of the FDA Alumni Association (FDAAA) Activities Committee.

Dr. Milstein has published in the peer review literature of organic and medicinal chemistry, is principal co-author of two chapters on cosmetic regulation in the Handbook of Cosmetic Science and Technology (Marcel Dekker/ Taylor-Francis, 2001, 2006) and co-author of a chapter on the analysis and regulatory aspects of color additives in cosmetics in Analysis of Cosmetic Products (Elsevier, 2007, 2018). Most recently, he has published a 3-part "blog" for SCC ("Following the Yellow Brick Road: Introducing the QSAR Paradigm to the Cosmetic Sector") (2019).

See: <https://www.scconline.org/yellow-brick-road-p1/>;

<https://www.scconline.org/yellow-brick-road-p2/>;

<https://www.scconline.org/yellow-brick-road-p3/>

Dr. Milstein holds a B.S. degree in Biology from Rensselaer Polytechnic Institute (RPI), an M.S. degree in Pharmaceutical Sciences (Cosmetic Science) from the University of Cincinnati College of Pharmacy, and a Ph.D. in Organic Chemistry from Adelphi University (Garden City, NY). He also completed two post-doctoral research fellowships in medicinal chemistry and QSAR at Pomona College (Claremont, CA) and at the University of Cincinnati College of Pharmacy (Cincinnati, OH).