

AHPA Regulatory Congress

November 14, 2023 | VIRTUAL



AGENDA

GENERAL SPONSOR:

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TIME	SESSION	SPEAKERS
9:00 AM PT 12:00 PM ET	Welcome & Introduction	Michael McGuffin AHPA
9:05 AM PT 12:05 PM ET	Updates from FDA Office of Dietary Supplement Programs This year, following recommendations from the Reagan-Udall Foundation evaluation of the agency's human foods program, the U.S. Food and Drug Administration (FDA) announced a proposed reorganization to strengthen its food regulatory role. Under the proposed organizational structure, the Office of Dietary Supplement Programs (ODSP) would move to the new Office of Food Chemical Safety, Dietary Supplements and Innovation. In this opening session, ODSP Director Cara Welch, Ph.D., and ODSP Deputy Director Hellen Oketch-Rabah, Ph.D., will share updates on the reorganization and how these changes may impact the dietary supplement industry. SESSION SPONSOR: 	Cara Welch FDA ODSP Hellen Oketch-Rabah FDA ODSP
10:00 AM PT 1:00 PM ET	The Makeup Shakeup: New cosmetic regulations under MoCRA The Modernization of Cosmetics Regulation Act of 2022 (MoCRA) is the most significant update to federal cosmetics law in over 80 years. Part of this law requires that the FDA develop good manufacturing practices (GMP) regulations for facilities that manufacture or process cosmetic products that are distributed in the United States. Recently, the standards-writing body NSF suggested that FDA adopt NSF/ANSI 455-3, the American National Standard for Good Manufacturing Processes for Cosmetics. In this session moderated by Katie Banaszewski (NOW Foods), Brandi Reinbold (NSF) will discuss the new requirements and existing standards. In addition, Rick Kingston, PharmD (SafetyCall International) will speak on cosmetic adverse events and safety substantiation, and Robert Marriott (AHPA), will break down the recent draft guidance on facility and product registration. SESSION SPONSOR: 	Katie Banaszewski – Moderator NOW Foods Rick Kingston SafetyCall International Robert Marriott AHPA Brandi Reinbold NSF
11:15 AM PT 2:15 PM ET	Seeds of Change: Strengthening Organic Enforcement In January, the United States Department of Agriculture's (USDA's) National Organic Program (NOP) announced the Strengthening Organic Enforcement (SOE) final rule. The most significant update to organic regulations in over 30 years, this rulemaking will strengthen the oversight of production, handling, and sale of organic products. This session will dive into USDA's perspective on these changes and feature discussion of effective organic fraud prevention plans, compliance practices, and practical application of the new regulations. Moderator Genevieve Albers (Traditional Medicinals) will be joined by speakers Jennifer Tucker, Ph.D. (USDA NOP), Gwendolyn Wyard (Strengthening Organic Systems), and Johanna Phillips (Ecocert USA). SESSION SPONSOR: 	Genevieve Albers – Moderator Traditional Medicinals Johanna Phillips Ecocert USA Jennifer Tucker USDA NOP Gwendolyn Wyard Strengthening Organic Systems
12:25 PM PT 3:25 PM ET	<i>Break</i>	
12:40 PM PT 3:40 PM ET	The claims they are a-changin' In the first update to dietary supplement advertising guidance since 1998, the Federal Trade Commission (FTC) issued its Health Products Compliance Guidance in December 2022. Then, in April 2023, FTC sent out a mass notice of penalty offenses to almost 700 companies that market dietary supplements, OTC drugs, homeopathic products, and functional foods, referring to the guidance and warning that the agency could pursue civil penalties for companies that did not substantiate their claims. Moderated by Asa Waldstein (Supplement Advisory Group), this session will feature discussion of the new guidance, the notices, and the impact of both, as well as adequate claim substantiation with expert input from Rend Al-Mondhiry (Amin Talati Wasserman), William Rowe (SGS Nutrasource), and Eric Unis (BBB National Programs - National Advertising Division). Ricardo Carvajal (Hyman, Phelps & McNamara) will also review current trends in litigation. SESSION SPONSOR: 	Asa Waldstein – Moderator Supplement Advisory Group Rend Al-Mondhiry Amin Talati Wasserman Ricardo Carvajal Hyman, Phelps & McNamara William Rowe Nutrasource Eric Unis BBB National Programs - National Advertising Division®
1:55 PM PT 4:55 PM ET	Keeping up with the “shroom boom” From coffee to burgers and dietary supplements to skincare, medicinal mushroom and functional fungi products are booming. The diversity of products available has prompted robust discussion around industry best practices. In this session, Scott Dicker (SPINS) will provide a financial update on this fast-growing sector, while Michael McGuffin (AHPA) will discuss product labeling. In addition, Anthony Fontana, Ph.D. (Alkemist Labs) will review proper analytical tools, while Andrew Kline (Perkins Coie), will present an update on psychedelics and how they are regulated globally. SESSION SPONSOR: 	Will Woodlee – Moderator Kleinfeld, Kaplan & Becker; AHPA General Counsel Scott Dicker SPINS Anthony Fontana Alkemist Labs Andrew Kline Perkins Coie Michael McGuffin AHPA
3:05 PM PT 6:05 PM ET	Closing & Adjournment	Michael McGuffin AHPA