AHPA

AMERICAN HERBAL PRODUCTS ASSOCIATION

2016 Fifth Annual AHPA Botanical Congress Agenda

SATURDAY, OCTOBER 8, 2016 • 7:30AM-5:00PM

SUPPLYSIDE WEST • LAS VEGAS, NV • MANDALAY BAY CONVENTION CENTER

SOUTH SEAS BALLROOM E (PLENARY) & PALM A (BREAKOUT)

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PLENARY SESSION SCHEDULE OF EVENTS

Time	Plenary Session: Mandalay Bay, South Seas Ballroom E	Presenter(s)
7:30-8am	**Registration and Continental Breakfast**	
8-8:15am	**Welcome and Introduction**	**Michael McGuffin**, AHPA
8:15-9am	**FDA Industry Update** A look at current topics affecting the industry, such as cannabis, and how other key topics might impact the industry and its method of conducting business.	Introduction: **Michael McGuffin**, AHPA Presenter: **Cara Welch, Ph.D.**, Food and Drug Administration
Transition to ALOE Breakout Session [See Separate Agenda]		
9-10:30am	**Money and the Marketplace** The marketplace is changing very rapidly. With transitions occurring in channels of trade via market segmentation, what is the potential impact on brands?	Moderator: **Rajiv Khatau**, LODAAT Pharma Presenters: **Brianna Peterson**, Euromonitor Int'l. **David T. Thibodeau**, Wellvest Capital
10:30-11am	**Break**	
11am-12:30pm	**Building Consumer Trust: The Medium and the Message** It's no secret that the national news media often reports the herbal supplements industry is unregulated and adulterated, yet the herbal supplements category has continued to dispel that message by showing a projection in sales growth. Despite the additional scrutiny of attorneys general, U.S. consumers still believe in the importance of consuming herbal dietary supplements. This session will provide a lively discussion on the noise that surrounds the industry, and savvy tips from media experts on what mediums you should explore to better control your message in an effort to avoid the pitfalls of negative media.	Moderator: **Haley Chitty**, AHPA Presenters: **Erin Gargan**, Socialite Agency **Josh Long, Esq.**, Informa **Rick Polito**, *Nutrition Business Journal*
12:30-1:45pm	**Lunch / Special Panel Discussion:** **FDA's Revised NDI Draft Guidance (August 2016)** With the 60-day comment period due to expire just a few days following this Botanical Congress, join a panel of legal and regulatory experts who will explore FDA's latest revision of draft guidance for new dietary ingredients (NDIs). Industry experts will draw on nearly two months of analysis to provide in-depth, substantive insights into the guidance and answer industry's questions.	Moderator: **Michael McGuffin**, AHPA Presenters: **Cara Welch, Ph.D.**, FDA **Ashish R. Talati, Esq.**, Amin Talati & Upadhye **Marc S. Ullman, Esq.**, Rivkin Radler LLP **Anthony L. Young, Esq.**, Kleinfeld, Kaplan and Becker, LLP
Transition to CANNABIS Breakout Session [See Separate Agenda]		

Time	Plenary Session: Mandalay Bay, South Seas Ballroom E	Presenter(s)
1:45-2:45pm	**Supply Chain Management – Stage 1: Good Agricultural and Collection Practices (GACP)** As a manufacturer, what should you know about the raw botanical material before it arrives at your facility? The first step is to ensure the raw material has been properly cultivated, collected, recorded and documented during its processing. As quality control directly impacts the safety and efficacy of your finished product, it's imperative that you – the manufacturer – control the quality of the raw botanical material throughout the entire process. This session will review the GACP from seed to post-harvest.	Moderator: **Antoine Bily, Ph.D.**, Naturex Presenters: **Edward Fletcher**, Herbal Ingenuity **Nicolas Jegouic**, Naturex
2:45-3pm	**Break**	
3-4pm	**Supply Chain Management – Stage 2: Appropriate Ingredient GMPs Under FSMA** Ingredient suppliers are not currently subject to the GMP rule (21 CFR 111), as it applies to supplement manufacturers only. The argument has been made that such oversight has created a gap in supply-chain integrity because it places all of the risk on the contract manufacturer rather than the ingredient supplier. Others argue that FDA's Food Safety Modernization Act (FSMA) includes two rules that will apply directly to ingredient suppliers once they're fully implemented. This session will include a lively discussion of FSMA's Preventive Controls for Human Food regulation and Foreign Supplier Verification Program, and whether full implementation of said regulations will positively impact the risk on ingredient suppliers.	Moderator: **Shaheen Majeed**, Sabinsa Corp. Presenters: **Gary Swanson**, Herbalife **Ashish R. Talati, Esq.**, Amin Talati & Upadhye
4-4:50pm	**Supply Chain Management – Stage 3: Application and Limitations of Various Analytical Methods** This session will provide an overview of the application and limitations of various scientifically valid analytical methods that are used to verify product authenticity and quality. The industry has a duty to select appropriate scientifically valid analytical methods because they do exist. This session will highlight the correct applications and limitations of a variety of scientifically valid analytical methods used to ensure identity.	Moderator: **Rajiv Khatau**, LODAAT Pharma Presenters: **Nandakumara D. Sarma, Ph.D.**, United States Pharmacopeia **Roy Upton, RH, DipAyu**, American Herbal Pharmacopoeia
4:50-5pm	**Closing Remarks / Overview**	**Michael McGuffin**, AHPA
5pm	**Adjournment**	

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BREAKOUT SESSIONS SCHEDULE OF EVENTS

Time	ALOE Breakout Session: Mandalay Bay, Palm Ballroom A	Presenter(s)
9:15-10:45am	**Regulatory-Focused Panel**	Moderator: **Jeff Barrie**, Aloecorp
	Proposition 65: Will Misconceptions Impact the *Aloe Vera* Market? A presentation regarding the potential impacts to the aloe products market because of the misconceptions about the Office of Environmental Health Hazard Assessment (OEHHA) adding non- decolorized whole leaf extract of *Aloe vera* to the Prop 65 list. As the one-year post-listing date approaches in December 2016, what are consumer perceptions; are private plaintiffs looking at this; are manufacturers eliminating aloe ingredients due to concerns?	Presenter: **Ann G. Grimaldi, Esq.**, Grimaldi Law Offices
	Regulatory Climate for *Aloe Vera* – Where are the Hot Spots? A presentation on regulatory issues that influence market access for aloe products – international in scope to address EU, South America, Asia, etc.; also acceptance of whole leaf vs. inner leaf products.	Presenter: **Andrew Shao, Ph.D.**, Herbalife
	Regulatory Climate for *Aloe Vera* As *Aloe vera* products come under increased regulatory scrutiny, the potential for civil class action litigation increases. Private plaintiff enforcers often use FDA warning letters, regulatory investigations, and other regulatory actions to generate ideas for class action lawsuits against all members of an industry event those that were not the direct subject of the regulatory action. This presentation will address ways to mitigate exposure to those types of claims.	Presenter: **Amy P. Lally, Esq.**, Sidley Austin LLP
10:45-11am	**Break**	

11am-12:30pm	**Scientific-Focused Panel** **Prevention of Azoxymethane / Dextran Sodium Sulfate-Induced Mouse Colon Carcinogenesis by Processed *Aloe Vera* Gel** The preventive effect of a processed *Aloe vera* gel (PAG) on colon carcinogenesis was examined using an azoxymethane (AOM)-initiated and dextran sodium sulfate (DSS)-promoted mouse colon carcinogenesis model. Oral administration of PAG significantly reduced the multiplicity of colonic neoplasms compared with the AOM / DSS only-treated mice. This presentation will address the findings. **Development of AOAC INTERNATIONAL'S Standards for the Determination of *Aloe Vera* Quality** AOAC INTERNATIONAL has developed a stakeholder based process to develop test standards that can help industry with quality testing. This process is based on the development of Standard Method Performance Requirements (SMPR). These SMPR's are then used as the basis for evaluation and approval of test standards. This process has been successfully applied to the identification and approval of quality standards for *Aloe vera*. This presentation will describe the AOAC process, and provide details on the SMPR's that were approved for *Aloe vera*, and the AOAC Official Test Methods that were approved for the determination of quality in *Aloe vera*. **Reduction of Fasting Blood Glucose and Hemoglobin A1c Using Oral *Aloe Vera*: A Meta-Analysis** A synthesis of the evidence behind the use of oral *Aloe vera* for diabetes, and dyslipidemia treatment will be provided. The strengths and limitations of existing data will be used to project prospects for future clinical trials and development.	Moderator: **Steven Dentali, Ph.D.**, Industry Consultant Presenter: **Professor Chong-Kil Lee**, Univera Presenter: **Darryl Sullivan**, Covance Laboratories Presenter: **Sachin A. Shah, Pharm.D.**, University of the Pacific
12:30pm	**Return to Plenary Session: South Seas Ballroom E**	

Time	CANNABIS Breakout Session: Mandalay Bay, Palm Ballroom A	Presenter(s)
2-3pm	**State of Cannabis Legal Review and Policy** This session will discuss trends toward legalization of cannabis and will provide an overview of federal challenges faced by the industry.	Moderator: **Christopher W. Shade, Ph.D.**, Quicksilver Scientific Presenters: **Geoffrey Kaiser, Esq.**, Rivkin Radler LLP **Amanda Reiman**, Drug Policy Alliance
3-3:15pm	**Break**	
3:15-5pm	**Channels of Trade for Consumption of Cannabis** With the steady expansion of medical cannabis programs and other markets for cannabis products, oral consumption methods for this botanical are being introduced to consumers. The development of oral forms of cannabis-derived products has broadened the interest in this plant among users interested in the nutritional benefits of the cannabis plant or who opt to avoid consumption of cannabis by inhalation. This panel will review the history and explore the emergence of the markets for cannabis-derived products for oral consumption: hemp seed oil, dietary supplements and oral medical cannabis. **Hemp Seed Oil** **Dietary Supplements** **Oral Medical Cannabis**	Moderator: **Josh Long, Esq.**, Informa Presenter: **Eric Steenstra**, Hemp Industries Association Presenter: **Marc S. Ullman, Esq.**, Rivkin Radler LLP Presenter: **Steph Sherer**, Americans for Safe Access
5pm	**Closing Remarks / Adjournment**	**Jane Wilson**, AHPA

Updated 10/3/16 -- Topics and speakers subject to change