

Association for Official and Analytical Chemists (AOAC)  
Southern California Section (SCS)



&

United States Pharmacopeia (USP)  
Western Compendial Discussion Group (WCDG)



U.S. PHARMACOPEIA

**"Discussion Day" for all Testing Labs Supporting  
the Dietary Supplement Industry,  
Friday, November 7, 2008**

**Location: US FDA at Irvine,  
19701 Fairchild, Irvine, CA 92612**

**Purpose:** To allow people from independent & in-house testing labs that support the dietary supplement industry to discuss the analytical challenges in meeting the new GMP regulations with emphasis on issues specific to the testing labs.

**Goal:** To define current analytical challenges and draft common / practical approaches to these challenges.  
To open communication routes between testing labs in order to improve quality & clarity of analytical data.  
To increase customer's confidence & satisfaction in analytical data provided.

**Agenda**

- 7:00 A.M. Registration  
8:30 A.M. Welcome Remarks by  
William Martin, Ph.D., Director, PRL-SW, US FDA, Irvine, CA  
Alonza Cruse, M.S., *Director*, Los Angeles District, US FDA, Irvine, CA  
Sumit Sen, Ph.D., US FDA, Irvine, CA *President*, AOAC SCS
- 9:00 A.M. How Good Lab Management System helps to address Critical Dietary Supplements Industry Issues  
Speaker: Jane Weitzel,  
*Associate Director Laboratory Operations*, Watson Pharmaceuticals, Corona, CA & *Meeting Host*
- 9:30 A.M. Analysis of Dietary Supplements for Toxic Heavy Metals – Some Challenges and Solutions  
Speaker: William Mindak,  
*Chemist*, CFSAN, College Park, MD
- 10:00 A.M. Refreshment Break  
10:15 A.M. How Other Industries have Addressed the Challenges Dietary Supplement Industries are Facing  
Speaker: Wesley Johnson, Ph.D.  
*Principal Consultant*, Quality Analysis Consultants, Victoria, BC
- 10:45 A.M. Challenges Of A Lab Supporting The Dietary Supplement Industry And The Actions They Are Taking To Address These Issues  
Sidney Sudberg, Alkemists Pharmaceuticals, Costa Mesa, CA

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- 11:15 A.M. "Industry Concerns and Challenges to cGMP Compliance"  
Speaker: Joy Joseph.,  
President, Joys Quality Management Systems  
& Chair, USP Expert Committee, Dietary Supplements Non Botanical
- 12:00 P.M. Sponsor Presentations
- 12:30 P.M. Lunch Break
- 1:30 P.M. Speakers Panel Discussion Session  
Moderator: Jane Weitzel
- 3:00 P.M. Adjourn

### Registration Information

*Please note:*

**Pre-registration is REQUIRED.** NO REGISTRATIONS will be taken at the event. FDA Security requires at least 24 hours notice. Registration fees paid by mail with a postmark on or before Nov. 3 are: (payable by cash or check only) **Current students** - \$10 for the day, [first 5 students to register receive free registration]; **FDA employees** – free; **AOAC members** - \$150 for the day; **Non-members** \$200 for the day.

Make checks payable to AOAC- Southern California Section. Yearly dues of \$20 for AOAC local section membership can also be paid at this time.

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### Address Information for Meeting Registration

The e-mail address for the Southern California Section Treasurer, Dr. Gina Zhang, is [gina.zhang@medtronic.com](mailto:gina.zhang@medtronic.com) Please send your reservation for the November 7 2008 AOAC Meeting and address all further treasury business to Gina at this address. You can also mail your reservation to Dr. Gina Zhang, AOAC Southern California Section Treasurer, 4397 Park Monte Nord, Calabasas, CA 91302.

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### General Directions to the FDA

From the north, take the 405 freeway to Tollroad CA- 73 heading south. Exit at Jamboree. Turn left on Jamboree, then right onto Fairchild. From the south, take the 405 or 5 north to CA-73. Exit at Bison, turning left onto Bison. Turn right on MacArthur continuing on to Fairchild and turn right. Turn right into FDA entrance at the guard house. Identify yourself to the guard as a participant in the AOAC Meeting. You will need to pass through security once inside the building. As at the airport, knives, scissors etc can be confiscated.

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**Background to the Discussion Day**

**Reason for the discussion**

The dietary supplement industry must meet stricter and more rigorous requirements than in the past. The lack of well defined reference standards, published analytical methods and proficiency testing programs compromises a lab's ability to adequately meet these requirements. There is a real need to create uniformity / consistency / clarity of data analysis & results between testing labs. This challenge hurts not only the individual testing labs, but harms the industry in general. Without adequate control in testing labs, the industry is open to criticism from its customers & also contributes to increased costs from additional testing as well as slowing the production process down.

**Reference Standards and Reference Materials**

Consistency issues between labs when reference standards are available through different vendors (USP, Chromadex, Phytolab, Sigma...). Need to address different lab practices across US & world in handling these standards (ex: correction for hplc purity only vs adjusted purity (when available) vs drying of the standard).

Limitation of reference standard availability in some cases. Quantitative assay of markers not always an option.

Limitation of reference botanicals (plant voucher not easily available) – Identity testing, differentiation between species become problematic.

Limitations of reference materials (SRM) to address matrix issues in complex finished products.

Impact of variability in available reference standards/materials on analysis & on customer confidence in analytical testing

**Test Sample Matrix**

Impact of test sample matrix in analytical testing. Novel / complex formulation. Merging of dietary supplement industry (vitamins & herbs pills) with food industry: fortified foods & juices. Need for more elaborate & tailored sample preparation techniques. How to address this needs while still conducting routine & profitable testing?

**Proficiency Testing & Collaborative Studies**

How to participate. Programs already in place. Current AOAC & NIST role. What's next?

Schemes of program: testing lab competency vs helping develop much needed reference materials vs validating specific analytical method

How to use program to first map existing results variability between testing labs in the industry & second reduce it? (mining industry good example)

Usefulness to labs versus Costs (money & time) to the lab.

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**Abstracts**

**Jane Weitzel**

Introduction. Describe lab management systems and how a good management system helps address some of the issues the dietary supplement industry is facing. For example, measurement uncertainty, setting specifications, compliance assessment.

**William Mindak**

Describe some of the challenges faced in the analyses of toxic heavy metals in dietary supplements and the solutions.

**Dr. Wesley Johnson**

Describe how other industries have faced similar challenges and have successfully addressed them. The dietary supplement industry can learn from other industries, so they do not have to “reinvent the wheel”. For example, how have other industries implemented proficiency testing when there is no material with which to make test samples.

**Sidney Sudberg**

Present the challenges of a lab supporting the dietary supplement industry and the actions they are taking to address these issues.

**Joy Joseph**

Promote an understanding of Testing requirements for Raw materials and Finished Products.

Who and How to establish specifications.

What to do about supporting data for expiration dating when used.

What is subset testing?

How USP monographs can help?

**Speaker Biographies**

**Jane Weitzel**

Jane Weitzel has worked in analytical chemistry and Quality Assurance for over 30 years. Jane is Associate Director of Laboratory Operations in a large pharmaceutical company, responsible for test method development, validation, transfer and for supporting laboratory investigations.

Previously Jane has held positions in Quality Assurance at different pharmaceutical companies. In these positions Jane was responsible for all Quality functions, including Quality oversight of manufacturing and testing labs at facilities all over North America. In the last 20 years, Jane has been active in many organizations such as AOAC International and the Standards Council of Canada, where she has developed guides for meeting Quality requirements in the lab. In AOAC, Jane is Chair of ALACC (Analytical Laboratory Accreditation Criteria Committee) that wrote the *AOAC INTERNATIONAL Accreditation*

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*Guidelines for Laboratories* and developed a guide on Method Verification. Jane is also Vice-Chair for AOAC International's Technical Division for Laboratory Management.

Jane is active as an educator and consultant on laboratory accreditation to ISO/IEC 17025:2005 including the estimation and use of Measurement Uncertainty. She is a technical assessor for Standard Council of Canada. Jane is experienced in implementing, maintaining, and improving compliance with cGMP regulations of many regulatory bodies including US FDA, Health Canada, UK MHRA and others in a drug and biologic manufacturing facility. Implementing and maintaining ISO 9001:2000 Quality Systems in a manufacturing facility has also been part of Jane's responsibility.

**William Mindak**

B.S. in chemistry from George Mason University.

Worked at Versar Laboratories, a contract environmental laboratory, from 1980 to 1991 analyzing water, soil and various hazardous waste samples for trace elements using atomic absorption (AA), and atomic emission spectroscopy (ICP-AES). Started at FDA/CFR in 1991 in the Elemental Research Branch. Have been involved in method development and analysis of foods and dietary supplements for trace elements using AA, ICP-AES and ICP-MS. Been involved with plasma spectroscopy since 1980. ICP-MS research has included both high resolution and quadrupole based instruments.

**Dr. Wesley Johnson**

Dr. Johnson has had many years of experience in commercial, industrial and government laboratories as an analyst, manager and Quality Control/Quality Assurance officer. He is retired from teaching Analytical and Environmental Chemistry at Okanagan University College. He has developed and presented, in co-operation with Ms. Weitzel, numerous workshops on Quality Control/Quality Assurance, Method Validation, the Estimation of Measurement Uncertainty, Basic Statistics for Validation and Traceability as well as aspects of classical and instrumental analysis for industrial clients in Canada and abroad. He was involved in the development of CAN-P-1579 as a member of the Mineral Analysis Working Group set up by the SCC to establish a Standard 17025 accreditation program for laboratories in that industry. Dr. Johnson drafted the CAEAL Policy for the Estimation of Measurement Uncertainty. He has served as an auditor for private industry and for SCC and CAEAL accreditation visits to numerous laboratories and is an NQI Certified Auditor as well as a BC Certified Assayer

**Sidney Sudberg, D.C., L.Ac. RH (AHG)**

Sidney began his career in chemistry in at the City University of NY where he was involved in drug discovery for cancer research. Graduate studies continued at SUNY at Stonybrook and then at New York University for 2 years until he left chemistry to study acupuncture and western herbal medicine in the UK. He earned his doctorate of chiropractic from the Los Angeles College of Chiropractic and practiced alternative medicine for several years.

Sidney is the founder and director of Alkemists Pharmaceuticals, Inc., an independent contract, research & development laboratory dedicated to and specializing in the analysis, identification and authentication of

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botanicals with microscopy, HPTLC and HPLC as well as method development and method validation. Characterization, identification and isolation of phytochemical marker compounds for further study and botanical 'fingerprint' analysis using chemometrics and multivariate data analysis are projects currently under development.

**Joy Joseph**

President: Joys Quality Management Systems (Industry Consultant on GMPs and Science based Product Formulations)

Chair: USP Expert Committee , Dietary Supplements Non Botanical  
Former Vice President , Science and Technology -24 years ;Pharmavite  
LLC,Makers of Nature Made Vitamins

Experienced Quality Professional in Pharmaceutical and Dietary  
Supplement Industries

Member of Council for Responsible Nutrition Regulatory Affairs  
Committee,Member of USC andTablet and Capsule Trade Journal Advisory  
Boards

Contributing Author: "Regulations of Functional Foods and  
Nutraceuticals" and Pharmaceutical Dosage Forms:Tablets,Third Edition.