

**FINAL  
PROGRAM**

**DIETARY SUPPLEMENTS**

# Analytical Methods WORKSHOP

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*An interactive workshop  
on why it is important  
to appropriately select  
and validate methods*

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## ORGANIZERS



AOAC INTERNATIONAL



Consumer Healthcare  
Products Association



Office of Dietary Supplements,  
National Institutes of Health

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**Thursday, April 18, 2002**

Natcher Center, Balcony (A)  
NIH Campus, Bethesda, MD

**Register Today!**  
Attendance restricted to  
first **95** registered  
individuals

# An interactive workshop designed to:

*Raise the level of understanding of the importance of appropriately selecting, validating, and documenting analytical methods for industrial, basic and clinical research, safety, compliance, and enforcement purposes, with the ultimate aim of creating a compendium/database of reference analytical methods.*

## PROGRAM

8:00 - 8:30 am	<b>Registration</b>	
8:30 - 8:45 am	<b>Welcome and Purpose of Workshop Walk Through Program</b>	<b>Paul Coates Leila Saldanha</b>
8:45 - 9:15 am	<b>Keynote Presentation</b> Speaker sets tone of workshop on the vision and value of appropriate selection, validation, and documentation of methods for industrial, research, safety, compliance, and enforcement purposes; including the need for creating a compendium of reference analytical methods for these purposes.	Introduction: <b>James Bradford</b> Speaker: <b>Bernard Schwetz</b> <i>Acting Principal Deputy Commissioner, FDA</i>
9:15 - 10:30 am	<b>Research &amp; Government Panel Session</b> This session provides FDA perspectives on level of validation and documentation appropriate for research, compliance (GMP) and enforcement purposes. Also on botanical product selection for NCCAM clinical trials.	Moderator: <b>Elizabeth Yetley</b> Speakers: <b>Marguerite Evans (NIH); Norman Farnsworth (U of Illinois); Agnes NguyenPho (FDA); Mike Olson (FDA); Jeanne Rader (FDA)</b>
10:30 - 11:00 am	<b>BREAK</b>	
11:00 am - 12:15 pm	<b>AOAC/NIST Panel Session</b> Presentations on how to validate and document methods that meet AOAC requirements, and on development of standard reference materials	Moderator: <b>Daryl Sullivan</b> Speakers: <b>Ikhlas Khan (U of Mississippi); Kathy Sharpless (NIST); Anita Mishra-Szymanski (AOAC)</b>

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## Analytical Methods WORKSHOP

## WHO SHOULD ATTEND?

*Individuals in industry, government, and academia involved in the management and development of analytical methods for dietary supplements.*

*An interactive workshop on why  
it is important to appropriately  
select and validate methods*

DIETARY SUPPLEMENTS

**Analytical  
Methods  
WORKSHOP**

12:15 - 1:00 pm

**LUNCH**

1:00-2:00 pm

**Industry Panel Session**

Presentations on how methods are selected, validated and documented by ConsumerLab.com, NSF, and USP for their certification programs/ monographs, by a contract lab for certificates of analyses, and by industry for excipients.

Moderator: **Leila Saldanha**

Speakers: **James Frazer** (*Whitehall-Robbins Healthcare*); **Libby Harvey** (*Alpha Labs*); **William Obermeyer** (*ConsumerLab.com*); **Srini Srinivason** (*USP*); **John Travis** (*NSF*)

2:00 - 3:00 pm

**Breakout Sessions**

Participants will be divided into four groups – each group will be assigned a rapporteur. The purpose of this session is to identify concerns and raise questions, which the speakers will be asked to address in the general Q&A session.

Rapporteurs: **John Cardellina** (*CRN*); **Edward Croom** (*Indena*); **Michael McGuffin** (*AHPA*); **Paul Schiff** (*U of Pittsburgh*)

3:00 - 3:30 pm

**BREAK**

3:30 - 4:45 pm

**Q&A Panel Session**

Rapporteurs will be asked to present their groups' concerns and questions for the panel to address.

Moderator: **Joseph Betz**

Panelists: **Selected speakers from the morning and afternoon sessions.**

4:45 - 5:00 pm

**Summary and Closing Remarks**

**Joseph Betz**

5:00 pm

**Adjourn**

**PLANNING COMMITTEE:**

**Leila G Saldanha, PhD, RD**, Consumer Healthcare Products Association (Chair)

**Joseph M Betz, PhD**, Office of Dietary Supplements, NIH

**E James Bradford, PhD**, AOAC INTERNATIONAL

**Paul M Coates, PhD**, Office of Dietary Supplements, NIH

**James Frazer**, Whitehall-Robbins Healthcare

**Agnes NguyenPho, PhD**, Center for Drug Evaluation and Research, FDA

**Douglas L Park, PhD**, Center for Food Safety and Applied Nutrition, FDA

**Jeanne I Rader, PhD**, Center for Food Safety and Applied Nutrition, FDA

**Daryl Sullivan**, Covance Laboratories, Inc

**Anita L Mishra-Szymanski**, AOAC INTERNATIONAL

**Elizabeth A Yetley, PhD**, Center for Food Safety and Applied Nutrition, FDA

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## HOTELS:

*(For room reservations, contact hotels directly)*

**Hyatt Regency Bethesda**  
One Bethesda Metro  
Bethesda, MD 20814  
Tel: (301) 657-1234

*Additional hotels:*

**The Sheraton**  
Tel: (301) 654-1000  
**Pooks Hill Marriott**  
Tel: (301) 897-9400

## REGISTRATION MAILING ADDRESS:

RSJ Associates  
P.O. Box 12023  
Silver Spring, MD 20908  
e-mail: [rsj@incomnet.net](mailto:rsj@incomnet.net)  
Tel: (301) 774-3038  
Fax: (301) 774-2926

## REGISTRATION FEES:

NIH employees: no charge  
Other government: \$95.00  
All others: \$150.00

Affiliation:  NIH Employee  Other government  All others  Media

## REGISTRATION FORM: *(No On-Site Registrations Accepted)*

NAME (LAST, FIRST)

POSITION

ORGANIZATION

ADDRESS

CITY

STATE

ZIP

TEL

FAX

EMAIL

## PAYMENT METHOD:

- Check – If paying by check, make checks payable to “RSJ Associates” please note event “April 18 Workshop” on check.  
 Credit card –  Visa  MasterCard

CREDIT CARD NUMBER

EXPIRATION DATE

SIGNATURE OF CARDHOLDER

Accepting checks through **March 19th** and credit cards through **April 12th**.  
Registration fees are not refundable, but they are transferrable for this meeting only.

**REGISTER EARLY!**  
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