

# S E M I N A R P R O G R A M

Discussion of current legislative calls for mandatory AER for dietary supplements, methods for proper implementation and risk management.

## Register Today!

Attendance restricted to first **300** registered individuals

**February 20, 2004**

Huntsman Cancer Institute  
Salt Lake City, Utah

# Adverse Event Reporting (AER) and Dietary Supplements:

## Challenges & Opportunities



**SPONSORED BY:**



American Botanical Council

Utah Natural Products Alliance

**UNPA**

# S U M M A R Y

## Adverse Event Reporting (AER) and Dietary Supplements:

### Challenges & Opportunities

**February 20, 2004**

Huntsman Cancer Institute  
Salt Lake City, Utah

**T**he safety of herbs and other dietary supplements is front-page news. While most popular herbs have a wide margin of safety, there is growing pressure to adopt a mandatory adverse event reporting (AER) system to track and confirm safety. When HHS Secretary Thompson announced the proposed ephedra ban, he repeatedly stated his intention to mandate an AER system and several trade associations have promoted and supported this idea as well. Industry can take the initiative to proactively deal with this issue. This seminar will provide a forum to discuss the complex issues related to understanding AER, provide a framework for AER documentation, and highlight existing and emerging safety information programs designed to help companies promote responsible use of supplements and help prevent AERs.

### In this one-day seminar, participants will:

- Analyze the current legislative calls for mandatory AERs for dietary supplements.
- Examine the AER system laid out in the Food & Drug Administration's proposed GMP regulation for dietary supplements.
- Compare AER systems now in use for supplements.
- Learn how poison control centers receive and manage AERs for dietary supplements.
- Learn about the American Botanical Council's Safety Labeling Program and how providing more safety information can prevent AERs and reduce legal risks.
- Discuss the budgeting and costs to implement an effective AER system.

### Who should attend?

- Senior-level management
- In-house counsel & regulatory managers
- Insurance and risk managers
- Quality assurance (QA) and quality control (QC) staff
- Marketing and sales staff

# P R O G R A M

8:00 – 8:30 am	<b>Registration / Morning Coffee &amp; Tea</b>	
8:30 – 8:45 am	<b>Welcome and introduction</b>	Introduction: Loren Israelsen Executive Director <i>Utah Natural Products Alliance</i>
8:45 – 9:45 am	<b>Legislative and Regulatory Initiatives for Dietary Supplement AERs.</b>	Presenter: Loren Israelsen Executive Director <i>Utah Natural Products Alliance</i>
9:45 – 10:45 am	<b>What is an AER and How Do You Manage Them? A Look at the PROSAR System.</b>	Presenter: Rick Kingston, Pharm.D, President <i>PROSAR</i>
10:45 – 11:00 am	<b>BREAK</b>	
11:00 – 12:15 am	<b>Inside Perspective on FDA's AER System for Dietary Supplements.</b>	Presenter: Joseph Kelly, M.D. (invited) Former Deputy Director <i>CARES (CFSSAN Adverse Event Reporting System)</i>
12:15 – 1:15 pm	<b>LUNCH</b>	
1:15 – 2:15 pm	<b>How We Manage AERs.</b>	Presenter: Susan Trimbo, PhD Senior Vice President, Scientific Affairs <i>General Nutrition Center (GNC)</i>  Presenter: Thomas Truszkowski Section Leader Technical Regulatory Affairs <i>Access Business Group</i>
2:15 – 3:15 pm	<b>ABC's Safety Labeling Program: Managing Risk and Adverse Events through Increased Safety Information.</b>	Presenters: Mark Blumenthal Founder and Executive Director Wayne Silverman, PhD Chief Administrative Officer <i>American Botanical Council</i>
3:15 – 3:30 pm	<b>BREAK</b>	
3:30 – 4:30 pm	<b>Industry Reaction Panel</b>	All Presenters
4:30 – 5:00 pm	<b>Summary Comments &amp; Wrap-up</b>	

# R E G I S T R A T I O N

## Adverse Event Reporting (AER) and Dietary Supplements: Challenges & Opportunities

### Registration Info:

Attn: Lindsay Wright, Utah Natural Products Alliance (UNPA)  
1075 Hollywood Avenue, Salt Lake City, UT 84105  
Tel: (801) 474-2572 / Fax: (801) 474-2571 / e-mail: lindsay@unpa.us

### Registration Fees:

	# of Attendees	Fees
<b>All UNPA Members / ABC Sponsor Members:</b>		
\$295 first person	1	x \$295 = _____
\$95 each additional from same company	_____	x \$95 = _____
<b>All Others:</b>		
\$495 per person:	_____	x \$495 = _____
	<b>Total Fees</b>	_____

### Registration Form: (No On-Site Registrations Accepted)

NAME (LAST, FIRST) \_\_\_\_\_

POSITION \_\_\_\_\_

ORGANIZATION \_\_\_\_\_

ADDRESS \_\_\_\_\_

CITY \_\_\_\_\_ STATE \_\_\_\_\_ ZIP \_\_\_\_\_

PHONE \_\_\_\_\_ FAX \_\_\_\_\_

E-MAIL \_\_\_\_\_

### Payment Method:

Check: Payable to "UNPA". Please note "February 20 Seminar" on the check. Send payment to the UNPA address listed above.

Credit Card:  Visa  MasterCard

CREDIT CARD NUMBER \_\_\_\_\_ EXPIRATION DATE \_\_\_\_\_

SIGNATURE OF CARDHOLDER \_\_\_\_\_

February 20, 2004

Huntsman Cancer Institute  
Salt Lake City, Utah

### Suggested Hotel:

Marriott Salt Lake City  
University Park

480 Wakara Way  
Salt Lake City, UT 84108  
Call 1-800-228-9292

Ask for the UNPA room block rate of \$89.00 per night. Must reserve by January 31st for discount.

### About the Sponsors:

**American Botanical Council**  
(ABC) is the leading nonprofit education and research organization disseminating science-based information regarding the safe and effective use of medicinal plants and phytomedicines. Founded in 1988, ABC works to educate the public, healthcare practitioners, media, and government agencies. Our vision is an educated public that makes responsible choices about herbal medicine as an accepted part of healthcare.

**Utah Natural Products Alliance**  
(UNPA) represents the leading dietary supplement companies in the state of Utah. Our members are some of the world's most respected natural healthcare companies. Utah is the largest dietary supplement manufacturing center in the world, with annual sales of Utah-based companies exceeding \$2.5 billion. World class production and quality control systems are a basic segment of UNPA membership, as are rigorous raw materials specifications, in-process controls, and analytical testing methods.