

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

A discussion of current initiatives for mandatory or voluntary system for supplements, approaches for proper implementation and management.

UPDATE:
News about the Hatch/Durbin AER Legislative Agreement!

Adverse Event Reporting (AER) and Dietary Supplements II: Towards a National System of Surveillance



June 30, 2004

8:00 am - 5:00 pm
Hubert H. Humphrey Room
Radisson Metrodome

SPONSORED BY:

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Utah Natural Products Alliance
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The 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 dietary supplement postmarket surveillance, and promote a better understanding of the practical implications in adopting, implementing and managing an effective AER system for your company.

In this one-day seminar, participants will:

- Analyze the current legislative calls for mandatory AERs for dietary supplements.
- Examine the “anatomy” of adverse event reports, its investigation, management and resolution.
- Compare multiple AER systems now in use for both supplements and other consumer products.
- Learn how poison control centers receive and manage AERs for dietary supplements and other products.
- Discuss uses, and misuses, of information obtained from various AER systems.
- Discuss the budgeting and costs to implement an effective AER system.
- Learn about alternative approaches toward establishing a national system for dietary supplement adverse event monitoring.

Who should attend?

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

M O R N I N G P R O G R A M

8:00 – 8:30 am	Registration / Morning Coffee & Tea	
8:30 – 8:45 am	Welcome and introduction	Introduction: Dr. Marilyn Speedie Dean - <i>University of Minnesota School of Pharmacy</i>
8:45 – 9:00 am	Legislative and Regulatory Initiatives for Dietary Supplement AERs— An Overview.	Presenter: Loren Israelsen Executive Director <i>Utah Natural Products Alliance</i>
9:00 – 9:30 am	“CAERS” - The CFSAN Adverse Event Reporting System: Where FDA is Today.	Presenter: Kenneth Falci, PhD Director <i>Office of Scientific Analysis and Support, Food & Drug Administration - Center of Food Safety and Applied Nutrition</i>
9:30 – 10:45 am	Anatomy of AER Reporting: - Available Systems and Options for Surveillance - Practical Considerations in Collecting, Analyzing and Sharing of Incident Data - Compare/Contrast Mandatory vs. Voluntary Approaches to Surveillance - Implications for Companies - Sample Framework for a National System	Presenter: Rick Kingston, Pharm.D, CSPI Professor - <i>Department of Experimental & Clinical Pharmacology, and the “Center for Dietary Supplement Safety” Development Initiative, College of Pharmacy, University of Minnesota</i>
10:45 – 11:00 am	BREAK	
11:00 – 12:15 am	Collaborative Science Initiatives and Clinical Practice Perspectives Regarding Dietary Supplement PostMarket Surveillance.	University of Minnesota Panel Tim Tracy, PhD Professor & Chair, <i>Department of Experimental & Clinical Pharmacology, University of Minnesota</i> Theodore P. Labuza, PhD Morse Alumni Distinguished Professor of Food Science and Engineering, <i>Department of Food Science & Nutrition, University of Minnesota</i> Linda Halcón, PhD, MPH, RN Associate Professor, <i>School of Nursing, and Division of Epidemiology, School of Public Health, University of Minnesota</i>

AFTERNOON PROGRAM

12:15 – 1:15 pm

LUNCH

1:15 – 3:00 pm

Current Perspectives of the Dietary Supplement Industry — Trade Associations

Moderator: Dr. Rick Kingston
University of Minnesota

Michael McGuffin
President
American Herbal Products Association (AHPA)

Douglas Bierer, PhD
Vice President
Regulatory and Scientific Affairs
Consumer Healthcare Products Association (CHPA)

Annette Dickinson, PhD
President
Council for Responsible Nutrition (CRN)

Current Perspectives of Allied Organizations: ABC & USP

Mark Blumenthal
Executive Director
American Botanical Council (ABC)

Shawn Becker, BSN, RN
Director, Patient Safety Initiatives
USP Center for the Advancement of Patient Safety

3:00 – 3:15 pm

BREAK

3:15 – 4:45 pm

Audience Reaction / Q & A Session

All Panelists

4:45 – 5:00 pm

Summary Comments & Wrap-up

Marilyn Speedie, PhD
Dean & Professor
College of Pharmacy, Univ. of Minnesota

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

Adverse Event Reporting (AER) and Dietary Supplements II: Towards a National System of Surveillance

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

All UNPA, AHPA, CHPA, CRN and/or NNFA Members:

\$395 first person 1 x \$395 = _____
\$145 each additional from same company _____ x \$145 = _____

Non-Member Companies:

\$595 first person 1 x \$595 = _____
\$295 each additional from same company _____ x \$295 = _____

Total Fees _____

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 "June 30 Seminar"
on the check. Send payment to the UNPA address listed above.

Credit Card: Visa MasterCard American Express

CREDIT CARD NUMBER

EXPIRATION DATE

SIGNATURE OF CARDHOLDER

June 30, 2004

8:00 am - 5:00 pm

Hubert H. Humphrey Room
Radisson Metrodome

Suggested Hotel:

RADISSON METRODOME

615 Washington Avenue
Minneapolis, MN 55414
(612) 379-8888

Ask for the UNPA room block rate
of \$94.00 per night.

About the Sponsors:

THE COLLEGE OF PHARMACY

of the University of Minnesota is the only school of pharmacy in Minnesota. The college offers its program on the Twin Cities and Duluth campuses. Founded in 1892, the College of Pharmacy educates pharmacists and scientists and engages in research and practice to improve the health of people of Minnesota and society. The college is part of the Academic Health Center, which is home to the University of Minnesota's seven health professional schools and colleges as well as several health-related centers and institutes.

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 health-care 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.