



U.S. Pharmacopeia  
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## USP Annual Scientific Meeting 2006 *Dietary Supplements*

### Track Managers:

Gabriel I. Giancaspro, Ph.D., Director, Dietary Supplements, USP  
Lawrence Evans III, Ph.D., Scientist, Dietary Supplements, USP  
Dandapantula N. Sarma, Ph.D., Senior Scientist, Dietary Supplements, USP  
Maged H. Sharaf, Ph.D., Senior Scientist, Dietary Supplements, USP

**Track Description:** This track provides a forum for scientists to discuss four important aspects of the dietary supplement industry: 1) the science behind increasingly popular dietary supplements, 2) public standards for dietary supplements, 3) the global regulatory framework for dietary supplements, natural products, and traditional medicinal products, and 4) dietary supplements adverse event reporting systems. Session I examines the factors that contribute to the current fast growth in sales of some dietary supplements. Examples will be discussed. Session II will include discussions on the need for public standards and how they are developed by USP. In Session III, the issues around globalization of the dietary supplement industry will be addressed. As manufacturers expand into new markets, they are finding that not all botanicals, vitamins, and minerals are recognized as dietary supplements, resulting in additional regulatory obstacles. Session IV will analyze the current state of dietary supplements adverse event reporting systems and their implications.

### Planning Committee:

- Steven J. Dentali, Ph.D., Vice President, American Herbal Products Association
- Lawrence Evans III, Ph.D., Scientist, Dietary Supplements, USP
- Gabriel I. Giancaspro, Ph.D., Director, Dietary Supplements, USP
- Mahabir Prashad Gupta, Ph.D., Research Professor of Pharmacognosy, and Director, Center for Pharmacognostic Research on Panamanian Flora, College of Pharmacy, University of Panama
- William F. Popin, M.S., Chair, Dietary Supplements-General Chapters Expert Committee and Research Director, Young Living Essential Oils
- Dandapantula N. Sarma, Ph.D., Senior Scientist, Dietary Supplements, USP
- Maged H. Sharaf, Ph.D., Senior Scientist, Dietary Supplements, USP
- Eli Shefter, Ph.D., Chair, Dietary Supplements-Bioavailability Expert Committee and Chief Scientific Officer, IriSys Research and Development

### Speakers:

- Paula Gardiner, M.D., Member, Dietary Supplements-Information Expert Committee and Clinical Research Fellow, Division for Research and Education in Complementary and Integrative Medical Therapies, Osher Institute, Harvard Medical School
- Gabriel I. Giancaspro, Ph.D., Director, Dietary Supplements, USP
- Jana B. Hildreth, Chief Executive Officer, Blaze Science Industries
- Joy A. Joseph, M.S., Chair, Dietary Supplements-Non-Botanicals Expert Committee and President, Joys Quality Management Systems
- A. Douglas Kinghorn, Ph.D., Chair, Dietary Supplements-Botanicals Expert Committee and Jack L. Beal Professor and Chair, Ohio State University, College of Pharmacy
- Richard Ko, Ph.D., Member, Dietary Supplement-Information Expert Committee and Research Scientist, California Department of Health Services
- Raimar Löbenberg, Ph.D., Member, Dietary Supplements-Bioavailability Expert Committee and Associate Professor, University of Alberta
- Steven M. Mister, Esq., President and Chief Executive Office, Council for Responsible Nutrition (CRN)
- Andres Navarrete, Ph.D., Professor, Department of Pharmacy, School of Chemistry, National Autonomous University of Mexico
- Dandapantula N. Sarma, Ph.D., Senior Scientist, Dietary Supplements, USP
- Fabio Soldati, Ph.D., Member, Dietary Supplements-Botanicals Expert Committee and Head, Research and Development, Pharmaton SA

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### **SESSION I**      **The Science Behind Fast Growing Dietary Supplements** **Wednesday, September 27, 2006 (1:00–3:00 p.m.)**

**Session leader:** William F. Popin, M.S.

**Session speaker(s):** Joy A. Joseph, M.S.  
A. Douglas Kinghorn, Ph.D.

**Session format:** Presentations followed by a roundtable discussion.

**Session description:** The driving factors for the rapid growth in popularity of some dietary supplements will be discussed. Specific examples of the fast growing dietary supplements industry will

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Rockville, MD 20852

301-881-0666

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be analyzed with regard to chemical profile, clinical studies, benefits, and safety, as well as how this information can be applied to the development of public standards.

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**SESSION II**      **Public Standards for Dietary Supplements: Identity, Purity, Content and Performance**  
**Wednesday, September 27, 2006 (3:30–5:30 p.m.)**

**Session leader:** Eli Shefter, Ph.D.

**Session speaker(s):** Jana B. Hildreth  
Gabriel I. Giancaspro, Ph.D.  
Raimar Löbenberg, Ph.D.

**Session format:** Presentations followed by Q&A session.

**Session description:** Public standards are being developed by both the government and the private sector. The need for methods and acceptance criteria for identity, purity, content, and performance will be discussed. The USP process for the development of quality dietary supplement standards will be presented. Issues surrounding the use of standardized methods of analysis, harmonized protocols, certified reference materials, and appropriate technical training will be highlighted.

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**SESSION III**      **Global Regulatory Framework and Interrelation of Dietary Supplements, Natural Products, and Traditional Medicinal Products**  
**Thursday, September 28, 2006 (8:30 a.m.–12:00 noon)**

**Session leader:** Mahabir Prashad Gupta, Ph.D.

**Session speaker(s):** Europe: Fabio Soldati, Ph.D.  
Latin America: Andres Navarrete, Ph.D.  
Asia: Richard Ko, Ph.D.  
Canada: Raimar Löbenberg, Ph.D.

**Session format:** Presentations followed by roundtable discussion.

**Session description:** Botanicals, vitamins, and metabolites are being recognized differently according to the existing global regulatory framework. The speakers for this session will address these different approaches, followed by a roundtable discussion on how to bridge the gap.

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**SESSION IV**      **Dietary Supplements Adverse Event Reporting Systems**  
**Thursday, September 28, 2006 (1:30–5:00 p.m. with break 3:00-3:30 p.m.)**

**Session leader:** Steven J. Dentali, Ph.D.

**Session speaker(s):** Dandapantula N Sarma, Ph.D.  
Paula Gardiner, M.D.  
Steven M. Mister, Esq.

**Session format:** Presentations followed by Q&A session.

**Session description:** USP develops monographs for dietary supplements based on sound review of their safety. However, a monograph may need to be revised if adverse event reports (AERs) occur. While poison control centers recorded more than 24,000 adverse exposures in 2004, the current regulatory status of dietary supplements does not warrant filing of AERs by the manufacturers. This session will discuss the dietary supplement AER systems, the need for active monitoring of signals for dietary supplements safety revisions, and the industry perspective.