Addressing Challenges in the Assessment of Botanical Dietary Supplement Safety
April 26-27, 2016
Lister Hill Center Auditorium • National Institutes of Health • Bethesda, Maryland

Agenda

Day One

9:00 a.m.  Welcome
Paul Coates, Ph.D., Director, Office of Dietary Supplements (ODS), National Institutes of Health (NIH)

9:10 a.m.  Opening Remarks
Linda Birnbaum, Ph.D., Director, National Institute of Environmental Health Sciences (NIEHS) and National Toxicology Program (NTP), NIH

9:20 a.m.  Introduction to the Workshop
Cynthia Rider, Ph.D., NIEHS

Perspectives on the Challenges Associated With Botanicals
Moderator: Nigel Walker, Ph.D., NIEHS

9:30 a.m.  The Complexity of Herbal Supplements
Joseph Betz, Ph.D., ODS

9:50 a.m.  The FDA Regulatory Landscape
Cara Welch, Ph.D., U.S. Food and Drug Administration (FDA)

10:10 a.m.  BREAK

10:30 a.m.  The Quest for Rigor and Reproducibility in Botanical Research
Craig Hopp, Ph.D., National Center for Complementary and Integrative Health, NIH

10:50 a.m.  Ensuring Safety of Botanical Dietary Supplements – The Industry’s Role
Duffy MacKay, N.D., Council for Responsible Nutrition

11:10 a.m.  U.S. Pharmacopeia (USP) Botanical Quality Standards for Ensuring Proper Identity
Hellen Oketch, Ph.D., U.S. Pharmacopeial Convention

11:30 a.m.  LUNCH

This workshop is sponsored by the National Toxicology Program/National Institute of Environmental Health Sciences

U.S. Department of Health and Human Services
**Topic One: Determining Phytoequivalence of Botanicals**  
Moderator: Kristine Witt, M.S., NIEHS

12:30 p.m.  **How Similar Is Similar Enough? Case Studies Exploring Phytoequivalence of Botanicals**  
Cynthia Rider, Ph.D., NIEHS

12:50 p.m.  **Whole Mixtures Risk Assessment: Considering Sufficient Similarity**  
Glenn Rice, Ph.D., U.S. Environmental Protection Agency (EPA)

1:10 p.m.  **Characterization of Botanical Materials Using Chemometric Methods**  
James Harnly, Ph.D., U.S. Department of Agriculture (USDA)

1:30 p.m.  **Targeted Analysis of Herbs: Markers, Actives, Natural Toxins, and More**  
Kerri LeVanseler, Ph.D., NSF International

1:50 p.m.  **Evaluation of Biological Similarity of Ginkgo Biloba Extracts in Sandwich Cultures of Primary Human Hepatocytes**  
Stephen Ferguson, Ph.D., NIEHS

2:10 p.m.  **Genotoxicity of Cohosh Samples Assessed Using the In Vitro Micronucleus Assay**  
Stephanie Smith-Roe, Ph.D., NIEHS

2:30 p.m.  **BREAK**

2:50 p.m.  **Statistical Strategy for Determining Sufficient Similarity of Related Botanicals: A Case Study of Ginkgo Biloba Extract**  
Chris Gennings, Ph.D., Mount Sinai Hospital

3:10 p.m.  **Inferring Toxicological Similarity With Multidimensional Relational Analysis**  
Scott Auerbach, Ph.D., NIEHS

3:30 p.m.  **Panel Discussion**  
Cynthia Rider, Ph.D., NIEHS (*moderator*)
James Harnly, Ph.D., USDA
Ikhlas Khan, Ph.D., University of Mississippi
Kerri LeVanseler, Ph.D., NSF International
James MacGregor, Ph.D., Toxicology Consulting Services
Glenn Rice, Ph.D., EPA

4:45 p.m.  **Adjourn**

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**Day Two**

9:00 a.m.  **Welcome/Opening Remarks**  – John Bucher, Ph.D., Associate Director, NTP

**Topic Two: Identifying Active Constituents in Botanical Dietary Supplements**  
Moderator: Paul Foster, Ph.D., NIEHS

9:10 a.m.  **Why Do We Care About Active Constituents?**  
Paul Howard, Ph.D., FDA

9:30 a.m.  **Challenges to Identifying Active Constituents**  
Edmund Lui, Ph.D., Schulich School of Medicine & Dentistry at Western University

9:50 a.m.  **Identification of Active Compounds in Botanical Dietary Supplements**  
Richard van Breemen, Ph.D., University of Illinois at Chicago

10:10 a.m.  **Tracking Toxic Constituents in Botanicals: The Right Sample and the Right Question**  
Larry Walker, Ph.D., University of Mississippi
10:30 a.m.  **BREAK**

10:50 a.m.  **Poisonous Plant Active Constituents: Challenges of Natural Diversity**
Dale Gardner, Ph.D., USDA

11:10 a.m.  **Integrating Biological and Chemical Datasets to Identify Active Constituents of Natural Products**
Nadja Cech, Ph.D., University of North Carolina at Greensboro

11:30 a.m.  **Panel Discussion**
Scott Auerbach, Ph.D., NIEHS (moderator)
Nadja Cech, Ph.D., University of North Carolina at Greensboro
Dale Gardner, Ph.D., USDA
Edmund Lui, Ph.D., Schulich School of Medicine & Dentistry at Western University
Richard van Breemen, Ph.D., University of Illinois at Chicago
Larry Walker, Ph.D., University of Mississippi

12:30 p.m.  **LUNCH**

**Topic Three: Best Practices for Assessing Absorption, Distribution, Metabolism, and Elimination (ADME) of Botanical Dietary Supplements**
Moderator: Joseph Betz

1:30 p.m.  **Understanding ADME Properties of Botanicals: Challenges, Current Status, and Future Needs**
Suramya Waidyanatha, Ph.D., NIEHS

1:50 p.m.  **The Polypharmacokinetics of Herbal Medicines**
Wei Jia, Ph.D., University of Hawaii

2:10 p.m.  **Assessing Herb-Drug Interactions: Screening Approaches**
Amy Roe, Ph.D., Procter & Gamble

2:30 p.m.  **BREAK**

2:50 p.m.  **Quantitative Prediction and Clinical Evaluation of Herb-Drug Interactions**
Mary Paine, Ph.D., Washington State University

3:10 p.m.  **Practical Considerations When Designing Clinical Herb-Drug Interaction Studies**
Bill Gurley, Ph.D., University of Arkansas

3:30 p.m.  **Achieving Enhanced Benefit From Herbal Products for Personalized Cancer Chemotherapy – Efficacy and Safety Considerations**
Moses Chow, Ph.D., Western University of Health Sciences

3:50 p.m.  **Panel Discussion**
Michael DeVito, Ph.D., NIEHS (moderator)
Moses Chow, Ph.D., Western University of Health Sciences
Bill Gurley, Ph.D., University of Arkansas
Wei Jia, Ph.D., University of Hawaii
Mary Paine, Ph.D., Washington State University
Amy Roe, Ph.D., Procter & Gamble
Kevin Welch, Ph.D., USDA

4:50 p.m.  **Wrap up**