NTP
National Toxicology Program

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

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**

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**