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**

**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
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<th>Time</th>
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<tr>
<td>10:30 a.m.</td>
<td><strong>BREAK</strong></td>
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<td>10:50 a.m.</td>
<td><strong>Poisonous Plant Active Constituents: Challenges of Natural Diversity</strong>&lt;br&gt;Dale Gardner, Ph.D., USDA</td>
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<td>11:10 a.m.</td>
<td><strong>Integrating Biological and Chemical Datasets to Identify Active Constituents of Natural Products</strong>&lt;br&gt;Nadja Cech, Ph.D., University of North Carolina at Greensboro</td>
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<td>11:30 a.m.</td>
<td><strong>Panel Discussion</strong>&lt;br&gt;Scott Auerbach, Ph.D., NIEHS (&lt;em&gt;moderator&lt;/em&gt;)&lt;br&gt;Nadja Cech, Ph.D., University of North Carolina at Greensboro&lt;br&gt;Dale Gardner, Ph.D., USDA&lt;br&gt;Edmund Lui, Ph.D., Schulich School of Medicine &amp; Dentistry at Western University&lt;br&gt;Richard van Breemen, Ph.D., University of Illinois at Chicago&lt;br&gt;Larry Walker, Ph.D., University of Mississippi</td>
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<td>12:30 p.m.</td>
<td><strong>LUNCH</strong></td>
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<td><strong>Topic Three: Best Practices for Assessing Absorption, Distribution, Metabolism, and Elimination (ADME) of Botanical Dietary Supplements</strong>&lt;br&gt;Moderator: Joseph Betz</td>
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<td>1:30 p.m.</td>
<td><strong>Understanding ADME Properties of Botanicals: Challenges, Current Status, and Future Needs</strong>&lt;br&gt;Suramya Waidyanatha, Ph.D., NIEHS</td>
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<td>1:50 p.m.</td>
<td><strong>The Polypharmacokinetics of Herbal Medicines</strong>&lt;br&gt;Wei Jia, Ph.D., University of Hawaii</td>
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<td>2:10 p.m.</td>
<td><strong>Assessing Herb-Drug Interactions: Screening Approaches</strong>&lt;br&gt;Amy Roe, Ph.D., Procter &amp; Gamble</td>
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<td>2:50 p.m.</td>
<td><strong>Quantitative Prediction and Clinical Evaluation of Herb-Drug Interactions</strong>&lt;br&gt;Mary Paine, Ph.D., Washington State University</td>
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<td>3:10 p.m.</td>
<td><strong>Practical Considerations When Designing Clinical Herb-Drug Interaction Studies</strong>&lt;br&gt;Bill Gurley, Ph.D., University of Arkansas</td>
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<td>3:30 p.m.</td>
<td><strong>Achieving Enhanced Benefit From Herbal Products for Personalized Cancer Chemotherapy – Efficacy and Safety Considerations</strong>&lt;br&gt;Moses Chow, Ph.D., Western University of Health Sciences</td>
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<td>3:50 p.m.</td>
<td><strong>Panel Discussion</strong>&lt;br&gt;Michael DeVito, Ph.D., NIEHS (&lt;em&gt;moderator&lt;/em&gt;)&lt;br&gt;Moses Chow, Ph.D., Western University of Health Sciences&lt;br&gt;Bill Gurley, Ph.D., University of Arkansas&lt;br&gt;Wei Jia, Ph.D., University of Hawaii&lt;br&gt;Mary Paine, Ph.D., Washington State University&lt;br&gt;Amy Roe, Ph.D., Procter &amp; Gamble&lt;br&gt;Kevin Welch, Ph.D., USDA</td>
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<td>4:50 p.m.</td>
<td><strong>Wrap up</strong></td>
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