

Mission and Activities of the American Herbal Products Association (AHPA)

2019 Mary Frances Picciano Dietary Supplement Research Practicum

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About AHPA





-  **Mission:** To support the responsible commerce of herbal products
-  **Founded:** 1982
-  **Members:** Over 400 members, including domestic and international companies that grow, process, manufacture and market herbs and herbal products.
-  **Affiliates:** Share the same interests and serve some of the same constituents that AHPA serves, or associated communities
-  **Products:** Dietary supplements, teas, cosmetics, OTC drugs, medical marijuana, and other consumer goods.

AHPA: Areas of Activity



-  **Representation:** With regulators (FDA, FTC, USDA, FWS, DOC, CA OEHHA, etc.) and legislators
-  **Education:** Training opportunities (cGMP issues; FDA inspections; product labeling; etc.) and guidance documents (NDIs; AERs; etc.)
-  **Communication:** To members and media
-  **Self regulation:** Ingredient names; safety labeling information; standards for ingredients; etc.
-  **Direct member support**
-  **Collaboration:** AOAC International, NCCIH, NIST, ODS, USP, etc.

Industry Opportunities

Self-regulation

-  Trade requirements
-  Guidance
-  Educational
-  Tools

Interaction with regulators







-  Comments submission in rulemaking
-  Cooperation with enforcement agencies

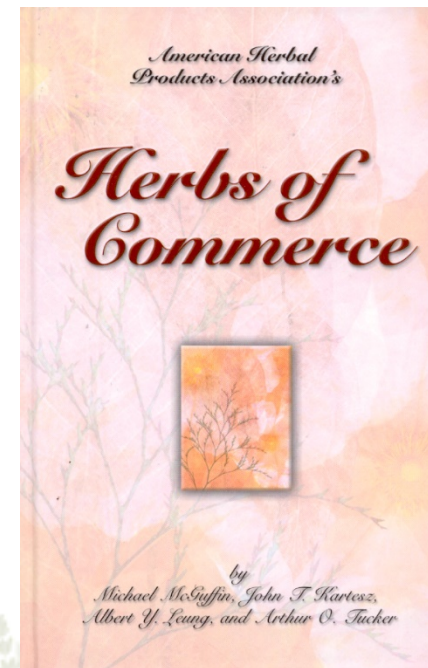
Legislative attention

-  Advocate for new laws
-  Amend restrictive legislation

Self-regulation – Trade Requirements

AHPA's *Herbs of Commerce*

-  Published in 1992 with “English standardized common name” for >500 herbal ingredients
-  Established as trade requirement (obligation to comply)
-  Incorporated by reference in FDA rule in 1997:
 -  The common or usual name of ingredients of dietary supplements that are botanicals (including fungi and algae) shall be consistent with the names standardized in *Herbs of Commerce* (21 CFR 101.4(h)).
-  2nd ed. (2000) ~2050 herbal ingredients
-  3rd ed. (upcoming) ~3000 herbal ingredients







Self-regulation - Guidance

-  Good Agricultural and Collection Practice for Herbal Raw Materials
-  Wild American Ginseng Good Stewardship Harvesting
-  Use of Marker Compounds in Manufacturing and Labeling Botanically Derived DS
-  Dietary Supplement Claims and Claims Substantiation
-  GMP Implementation Guidance
-  Contract Manufacturers and their customers: Best practices for effective partnerships
-  Demystifying Microbiology for the herbal product and dietary supplement industry

Self-regulation - Guidance

Guidance

-  Labeling Guidance for Fungi Products
-  Shelf Life Guidance
-  Slack Fill Guidance (Revised 2019)
-  Formulation and Marketing of Dietary Supplements under the National Organic Program


Guidance on various contaminants

-  Guidance on Heavy Metals
-  Guidance on Microbiology and Mycotoxins
-  Guidance on Residual Solvents in Extracts





Identifying known adulterants

Self-regulation – Education


AHPA's Yearly Botanical Congress

-  An annual industry gathering covering global supply chain management techniques, regulatory issues, the latest research, current and emerging financial trends, botanical identity, and other to-the-minute topics










Regular Technical Trainings

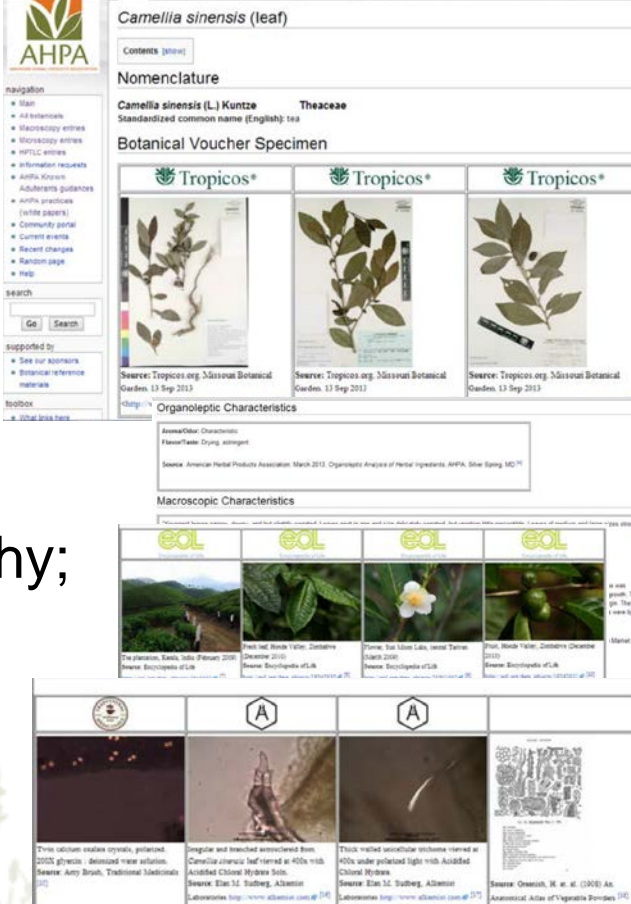
-  HPTLC for Popular Botanical Materials
-  Microbiological Testing for Herbal Products
-  Microscopic Identification of Popular Botanical Materials
-  Macroscopy and Organolepsy Identification Methods

AHPA Botanical Identity References Compendium

-  Free online resource organizing accessible botanical identity reference information for herbs in commerce

AHPA's Botanical Identity References Compendium

-  Title
-  Nomenclature
-  Botanical Voucher Specimen
-  Organoleptic/Macroscopic characteristics
-  Macroscopy images and description
-  Microscopy images and description
-  Phyisco-chemical methods (chromatography; spectrophotometry; color reactions; etc.)
-  Other tools, as specific information becomes available, (e.g., DNA; etc.)
-  Cited references for every entry



Camellia sinensis (leaf)

Contents [show]





Nomenclature

Camellia sinensis (L.) Kuntze **Theaceae**
Standardized common name (English): tea

Botanical Voucher Specimen

Organoleptic Characteristics









Macroscopic Characteristics

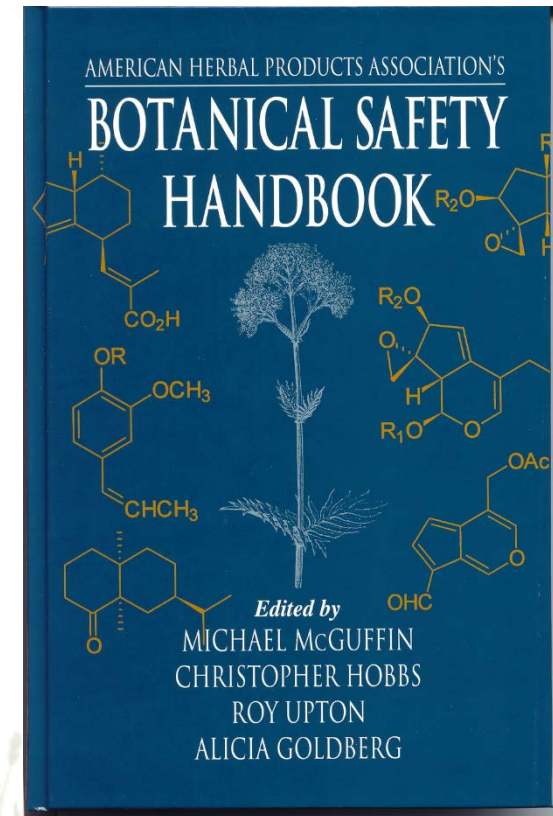
			
Thick-walled unicellular stichocyst, polarized at 400x; glycosylated; dehiscent; muree solution. Source: Amy Brown, Traditional Botanicals LLC	Singular and branched associated stomata. <i>Camellia sinensis</i> leaf viewed at 400x with Acidified Chinese Stigmae Stain. Source: Elin S.L. Sutbey, Alabaster Laboratories http://www.alabaster.com [17]	Thick-walled unicellular stichocyst, viewed at 400x under polarized light with Acidified Chinese Stigmae. Source: Elin S.L. Sutbey, Alabaster Laboratories http://www.alabaster.com [17]	Source: Osmann, K. et al. (2002) An Annotated Atlas of Vignettes Proves [18]

<http://www.botanicalauthentication.org/>

Self-regulation – Tools & Education










Botanical Safety Handbook (1997)

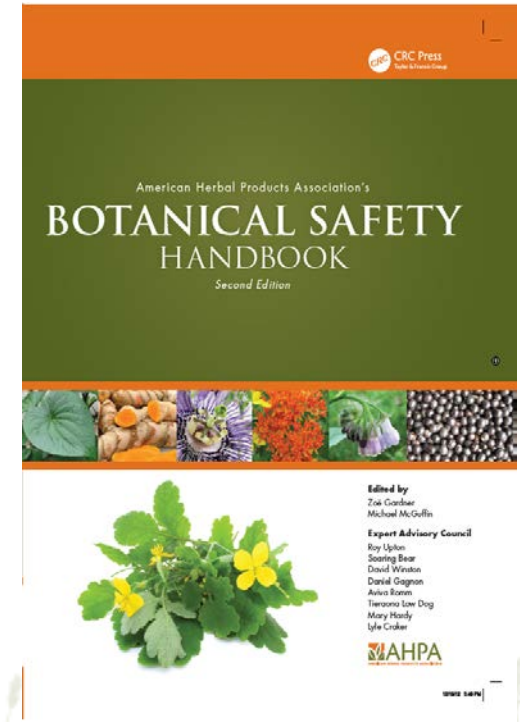
-  ~550 herbs
-  Systematic, evidence-based review, primarily of (~150) secondary references
-  Original classification system
 -  Class 1: Generally safe
 -  Class 2: Some caution identified
 -  Class 3: For use only under expert supervision
 -  Class 4: Insufficient information to classify
-  Additional information on known compounds



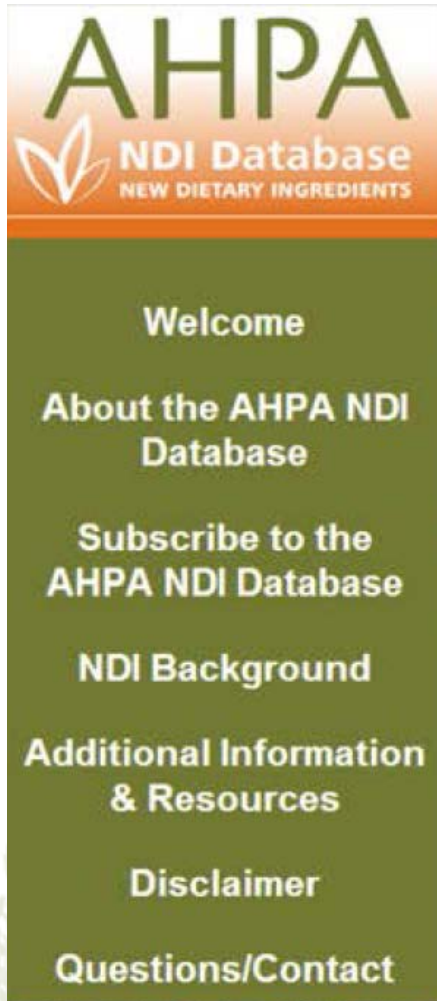
Self-regulation – Tools & Education

Botanical Safety Handbook, 2nd ed. (2013)









-  Partially funded by ODS (THANKS!)
-  ~700 herbs
-  Primary literature review; some individual herbs with over 60 references
-  Retaining original classification system
-  Additional classification re: drug interaction potential
 -  Class A: Safe to use with drugs
 -  Class B: Interaction is plausible
 -  Class C: Interaction has been established
-  Upcoming 3rd edition additions and revisions being released as revisions to electronic edition (at <http://bsh.ahpa.org/>)



Self-regulation - Tools







AHPA NDI Database

-  Records new dietary ingredient notifications
-  Searchable by name of ingredient or submitter
-  Original and succinct summary of outcomes
-  Links to available documents
-  Connections to related notifications
-  Launched in 2005 in cooperation with NPIcenter
-  Currently operated by AHPA
-  Available by subscription at <http://ndi.ahpa.org/>

The Federal Food, Drug and Cosmetic Act (FFDCA) as amended by the Dietary Supplement Health and Education Act (DSHEA) defines a "new dietary ingredient" as one that was not marketed in the United States prior to October 15, 1994.





Tools for Consumers

-  A Field Guide to Herbal Dietary Supplements (AHPA Foundation for Education and Research on Botanicals) at <http://ahpafoundation.org/FieldGuide.html>
-  HerbDay, a coordinated series of independently produced, public, educational events celebrating the importance of herbs and herbal products at <http://www.herbday.org/>
-  Keep Supplements Clean, a consumer/industry reference identifying illegal tainted products masquerading as dietary supplements at <http://www.KeepSupplementsClean.org/>
-  A print/web directory of responsible manufacturers of quality products at AHPA's homepage, <http://www.ahpa.org/>

Industry Opportunities





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Legislative attention

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-  Amend restrictive legislation

Working with Regulators

Comments essential in rulemaking



2000 FDA: DS Claims regulation



AHPA Comments → allowance for some OTC claims for DS



2004-5 USDA NOP: No “organic” labeling for DS



AHPA Testimony/comments → Clarification of allowance



2007 FDA: SAER Law implementation



AHPA Comments → Clarification of manufacturer responsibility



2011 FDA Draft NDI Guidance



AHPA Comments → Call for withdrawal



2013 FDA Proposed FDA Food Safety Modernization Act (FSMA)




AHPA Comments → Streamline the rules, minimize burden, and still maintain safety

Working with Regulators


Comments essential in rulemaking




2014 FDA: FSMA Animal Food rule

 AHPA Testimony/comments → Additional cycle to provide public involvement on newly proposed provisions, coordinate changes between related FSMA rulemaking activities


2015 FDA: FSMA mandatory food recalls

 AHPA Comments → Inclusion of more examples in guidance, improvements to communication throughout the recall process

2016 FDA's Draft NDI Guidance

 AHPA Comments → Improved over previous draft, requests for the guidance to cover particular topics apparently needing clarification as reflected in NDI notifications FDA has made available for public review

2017 FDA: Reducing Regulation and Controlling Regulatory Cost

 AHPA Comments → Over 100 pages of comments identifying numerous ways to improve regulations, guidances, and enforcement practices to protect the public health more effectively and efficiently.

Working with Regulators





Supporting FDA enforcement on fake products masquerading as supplements

-WASHINGTON, D.C., *December 15, 2010-*

Dietary Supplement Industry Commends FDA's Actions to Eliminate Drugs Masquerading as Supplements

-  AHPA's continuing follow-up: <http://www.KeepSupplementsClean.org> provides ongoing attention to FDA's message to industry

Good Agricultural Collection Practices and Good Manufacturing Practices Standards and Seminars





-  Developing wide-ranging standards to provide a template for small and large growers, harvesters, and processors to implement and document best practices.
-  Continuing series of cooperative educational events to maintain and increase industry performance in conducting manufacturing activities

Yearly Dietary Supplements Regulatory Summits, in collaboration with CHPA, CRN, NPA, and UNPA



-  With updates from FDA and legal experts present to industry leaders about collaborating to accomplish the industry and regulators' shared goal of ensuring informed consumer access to high-quality, safe supplements.

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Legislative Attention


Advocating for new laws and amending restrictive legislation


-  2002: AHPA requests to FDA to require DS firms “communicate to FDA any reports of serious adverse events”
 -  FDA response: “...would require a change in the current law.”
 -  2006: “Dietary Supplement and Nonprescription Drug Consumer Protection Act”: passed by U.S. Senate
-  2018: AHPA Hemp Farming Act endorsements
 -  Eventual passage of the 2018 Farm Bill, including support for domestic farming of hemp

Legislative Attention (continued)

 2019: Hemp Farming Act: *AHPA Guidance Policy updates*

 **Guidance: Dietary supplements and food containing hemp and hemp-derived cannabidiol** (adopted March 2019)

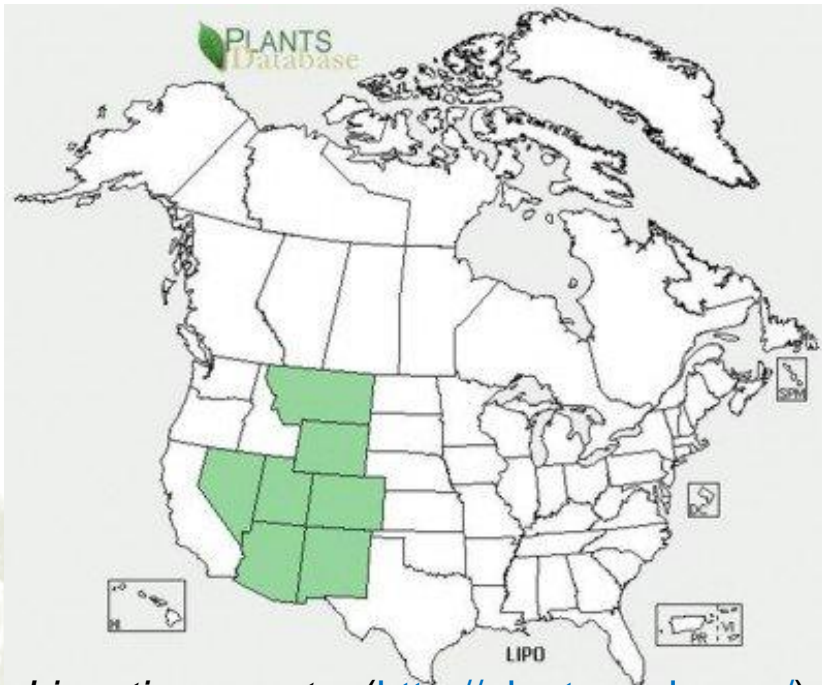
 AHPA recommends that any manufacturer, labeler, packer, holder or marketer of dietary supplements or foods that contain hemp or CBD comply with the following federal regulations that apply to such operations: food facility registration; current good manufacturing and good agricultural practice regulations; labeling requirements, including nutrition labeling, allergen disclosure, listing of required contact information, absence of drug claims, etc.; new dietary ingredient and food additive provisions, where applicable; and also, that dietary supplement operations comply with applicable obligations for timely submission to FDA of any received serious adverse event reports associated with their products.

 Adopted to address misinterpretation that FDA's position on the lawful status of CBD implies these products are not regulated.

AHPA-ERB Research Foundation

AHPA Foundation for Education and Research on Botanicals

To promote education and research on medicinal, therapeutic, and health-promoting herbs.



Ligusticum porteri (<http://plants.usda.gov/>)



<http://www.ahpafoundation.org/Osha.html>

Osha Harvest Sustainability Project

The AHPA-ERB Foundation awarded a research project on the “Harvest Sustainability Study of Wild Populations of Osha, *Ligusticum porteri*” to Kelly Kindscher, Ph.D., Kansas Natural Heritage Inventory, Kansas Biological Survey, University of Kansas.



Osha, umbels with fruits.

Study Objectives

- Compile data on the natural distribution of osha and assess potential threats to populations throughout its natural range.
- Examine the impact of variable harvest pressures on osha's populations.

Study Duration & Location

- ❖ A ongoing field experiment (2012 – 2019)
- ❖ Started in Cumbres Pass region of the Rio Grande National Forest in Southern Colorado, expanded into Missionary Ridge (near Durango), then Wolf Creek Pass.

http://www.ahpa.org/Portals/0/PDFs/ERB_Foundation/OSHA%20US%20Forest%20Report%20Final.pdf

AHPA-ERB Foundation Goldenseal Sustainable Harvest Study RFP

The AHPA ERB Foundation has issued a request for proposals to award grant funding to eligible applicants in order to enhance and promote knowledge and understanding of sustainable harvest of goldenseal (*Hydrastis canadensis*).

The grant supports research on goldenseal populations, root production, and effects of varying rates of harvest on plant population health and recovery across multiple growing sites in order to inform sustainable harvest and management decisions for the herb. The anticipated amount of funding available for a sustainable goldenseal harvest research project is up to \$10,000 annually for up to 5 years.

<http://www.ahpa.org/AboutUs/ERB-Foundation/ERB-Foundation-Grants.aspx>

THANK YOU!

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