AHPA Guidance Policies

AHPA develops guidance policies to promote responsible commerce in herbal supplements. These policies address a variety of labeling and manufacturing issues and reflect the consensus of AHPA’s members and its board of trustees. AHPA encourages its members and non-member companies to adopt these policies to establish consistent and informed trade practices.

General Practices

Dietary supplement label registries (adopted March 2015, revised June 2017)
Members that market supplement products under their own brands are encouraged to submit labels for inclusion in at least one of the current supplement label registries, that is, the Dietary Supplement Label Database from the National Institutes of Health and the Supplement Online Wellness Library (Supplement OWL).

Dietary supplements and food containing hemp and hemp-derived cannabidiol (CBD) (adopted March 2019, revised June 2020)

Background
This guidance is established based on the following considerations:

- Hemp is an herb or other botanical and CBD is a naturally occurring constituent of hemp, such that these ingredients conform with the description of dietary ingredients under the Federal Food, Drug and Cosmetic Act at 21 U.S.C. 321(ff)(1). Articles consisting of or derived from hemp may also be used as ingredients in foods if generally recognized as safe for such uses.

- The U.S. Food and Drug Administration (FDA) has taken the position, citing the “prior-IND” and “prior-new drug” provisions at 21 U.S.C. 321(ff)(3)(B) and 21 U.S.C. 331(ll), that cannabidiol (CBD), including CBD from hemp, may not be included in products marketed as dietary supplements or added to products marketed as foods.

- AHPA has expressed neither agreement nor disagreement with FDA’s position on the use of CBD in supplements and foods, but has been informed that some marketers of CBD and affiliated legal experts believe FDA’s interpretations of these provisions are inaccurate, and have presented certain arguments that potentially counter FDA’s position on CBD as an ingredient in dietary supplements and foods. Products marketed as dietary supplements and foods and identified as containing hemp or CBD are readily available in the U.S. market.
- AHPA has been informed that some hemp and CBD supplement and food marketers understand FDA’s position on the lawful status of CBD to mean that FDA does not regulate hemp or CBD supplements or foods, an interpretation that AHPA believes to be inaccurate.

- The robust federal regulatory systems for dietary supplements and foods protects consumers and the supplement and food industries: FDA has issued several warning letters to companies marketing CBD products for use by infants and other children and has communicated its view that there is significant cause for concern regarding possible harmful effects of use of CBD during pregnancy and while breastfeeding.

Guidance

(1) 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
- timely submission to FDA of any received serious adverse event reports associated with their products, where applicable.

(2) AHPA recommends that consumer products that contain CBD at sufficient quantities to warrant such labeling include a statement to restrict use by pregnant or nursing women and by children under the age of 18, except with parental or health professional supervision.

AHPA may reconsider this position if FDA issues a regulation to allow CBD in dietary supplements and foods.

Disclosure of herb use to healthcare providers (adopted October 2001)

AHPA recommends that consumers of herbal supplements inform their healthcare provider(s) of such use. In the interest of seeing this recommendation broadly accepted by consumers, AHPA encourages healthcare providers to receive such communication with respect for the consumers’ healthcare choices. In addition, AHPA encourages healthcare providers to seek out accurate and truthful information about herbs.

Ingredients that are or are produced from genetically modified organisms (GMOs) (adopted June 2003; revised March 2015, November 2021)

AHPA recognizes that:
The use of genetically modified organisms (GMO)\(^1\) as a tool in agriculture is viewed by some as providing the potential to meet basic global food needs and deliver a wide range of health, environmental and economic benefits;

Concerns have also been expressed by others about the potential impact of agricultural use of GMO on the environment and health; Numerous countries have established laws controlling the cultivation of GMO crops and the labeling of food and feed derived from such crops, for example the European Union has enacted regulations requiring labeling of foods that are derived from GMO crops\(^2\);

The National Bioengineered Food Disclosure Standard (NBFDS; 7 C.F.R. Part 66) requires entities that label foods for retail sale to disclose the presence of foods and food ingredients that contain genetic material that has been detectably modified through recombinant DNA techniques, subject to additional exceptions and restrictions stated in that rule;

AHPA supports positions that are based on scientific reasoning and also supports positions that favor a sustainable approach to environmental issues and a responsible approach to health issues related to commerce in herbs and herbal products;

AHPA supports consumers' right to be informed on issues that affect their purchasing decisions.

AHPA therefore:

- Encourages companies that grow, process, manufacture, market or sell herbal products to refrain from using herbal raw agricultural products cultivated with GMO technologies, or extracts and flavors thereof;
- Supports labeling of consumer goods to identify any ingredients that are herbal raw agricultural products knowingly and intentionally cultivated - 2 - with GMO technologies, or extracts and natural flavors thereof, in a manner that assures that consumers are informed that the ingredient was cultivated with GMO technology and in conformity with the NBFDS, including its voluntary disclosure provisions;
- Opposes labeling of foods that contain GMO ingredients as “natural” or with any similar term.

Nothing in this policy is meant to comment on research regarding GMO technology or minimal and/or unintentional mixing of GMO and non-GMO crops. This resolution does not create an obligation for any AHPA member.

1) GMO is used here as it is a commonly recognized term that refers to genetically modified materials. The term is synonymous with “genetically engineered”, defined in the National Organic Standards Board’s Biotechnology Policy (September 1996) as: “Made with techniques that alter the molecular or cell biology of an organism by means that are not possible under natural conditions or processes...[and]...is not limited to recombinant DNA, cell fusion, micro- and macro-encapsulation, gene deletion and doubling, introducing a foreign gene and changing the position of genes...[and]...does not include breeding, conjugation, fermentation, hybridization, in-vitro fertilization and tissue culture.”

The terms “micro- and macro-encapsulation” as referenced in the above definition are assumed to be used in the context of genetic modification. These terms may also be
used to describe manufacturing processes that do not include genetically modified material. Micro- and macro-encapsulation manufacturing processes that do not include genetically modified material are not encompassed by this policy.

Of additional relevance, the term “bioengineered food” is defined by USDA in the NBFDS somewhat narrowly as “A food that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature”, subject to additional factors, conditions and limitations. As the scope of this term is narrower than the term “GMO” as used in this document, compliance with NBFDS does not ensure compliance with this guidance policy.


Marketing of concentrated Δ-8 tetrahydrocannabinol, artificial, or synthesized cannabinoids (Adopted June 2021)

AHPA recognizes that:

- “Hemp” is defined by U.S. federal law as “the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent (0.3%) on a dry weight basis”;¹
- The above-quoted definition of “hemp” places no quantitative limits or restrictions on other naturally occurring hemp constituents, including other tetrahydrocannabinols;
- Hemp may contain detectable levels of delta-8 tetrahydrocannabinol, which is a naturally occurring, minor cannabinoid constituent;²
- While naturally occurring at low levels in hemp, delta-8 tetrahydrocannabinol can be synthesized from other cannabinoids such as cannabidiol and delta-9-tetrahydrocannabinol; and
- At concentrations in excess of the naturally occurring level in hemp, delta-8 tetrahydrocannabinol can produce a psychoactive or intoxicating effect when consumed by humans.³

AHPA therefore:

- Discourages the marketing of goods for consumption by any route that both (i) consist of or contain any amount of synthesized cannabinoids, including but not limited to synthesized delta-8 tetrahydrocannabinol, and (ii) are labeled as hemp products; and
- Discourages the marketing of goods for consumption by any route that consist of or contain any amount of artificial cannabinoids.⁴

¹. 7 U.S.C. § 1639o(a).
². For example, see Berthold et al., 2020, available at https://jcannabisresearch.biomedcentral.com/articles/10.1186/s42238-020-00050-0.
³. For example, see National Cancer Institute Drug Dictionary, available at...

4. Synthesized cannabinoids means a cannabinoid synthesized in a laboratory or by industry using directed synthetic or biosynthetic chemistry rather than traditional food preparation techniques such as heating or extracting. They may be nature-identical or artificial since this definition refers only to the process of their creation (AHPA Hemp Lexicon, May 2021).

5. Artificial cannabinoids means any cannabimimetic compound that interacts with cannabinoid receptors but whose molecular structure is not found in nature (AHPA Hemp Lexicon, May 2021).

**Standardized information on dietary ingredients (SIDI)** (adopted July 2007, confirmed as current March 2023)

AHPA recommends that its members who buy and sell dietary ingredients use the Standardized Information on Dietary Ingredients (SIDI) protocol as a standard reporting form for providing information about these ingredients.

**Labeling**

**Extract labeling**¹ (adopted October 2008, revised March 2010)
Any non-liquid herbal extract that discloses a quantitative extraction ratio stated as a ratio of two numbers represents the first number as the weight of starting plant material and the second number as the weight of the finished extract produced from the starting plant material, and that information on the condition of the starting material should be indicated when it is fresh and may be indicated when it is dried*.

*Herbal extracts in liquid form are required by federal regulation, whether or not a concentration ratio is declared, to disclose the condition of the starting material when it is in a fresh state (21 CFR 101.36 (b)(3)(ii)(B)

¹See additional information on AHPA’s Trade Requirement for extract labeling in AHPA’s Code of Ethics

**Labeling of alcohol-removed products** (Adopted March 2016)
AHPA recommends that manufacturers of liquid herbal products in which ethanol is used as a solvent and is subsequently removed refrain from using “alcohol-free” on product labeling, unless the manufacturer establishes through appropriate testing that alcohol* is not detected in the product. AHPA instead encourages the use of such terms as “alcohol-removed,” “dealcoholized,” or “nonalcoholic” if the product contains less than 0.5 percent ethanol by volume. AHPA also encourages the inclusion of the phrase “contains less than 0.5 percent alcohol by volume” or a significantly similar phrase.

*The term “alcohol” used here refers to ethanol (also called ethyl alcohol). The following regulations may be relevant to labeling of these or similar products:

- **U.S. Federal law** defines a product with a 0.5 percent or more ethanol by volume as an alcoholic beverage. [27 U.S. Code § 214(1).]

- **The U.S. Food and Drug Administration (FDA)** does not consider the terms “non-alcoholic”* and “alcohol-free” to be synonymous when applied to wine and malt beverages, and this Agency takes the position that the term “alcohol-free” may be used only when such products contain no detectable alcohol. FDA considers such products containing less than 0.5 percent alcohol by volume as “non-alcoholic.” [FDA Compliance Policy Guide (CPG) Sec. 510.400: Dealcoholized Wine and Malt Beverages – Labeling.]

- In its regulations on labeling and advertising of malt beverages, the Department of the Treasury’s Alcohol and Tobacco Tax and Trade Bureau (TTB) allows, unless otherwise prescribed under State law, the term “non-alcoholic” on such products but only provided the statement “contains less than 0.5 percent (or .5%) alcohol by volume” also appears on the label. This regulation also limits use of the term “alcohol free” only to such products that contain no alcohol. [27 Code of Federal Regulations § 7.65 (e) and (f).]
Labeling of articles of commerce derived from *Cannabis* spp.  
(adopted March 2015)

Numerous articles of commerce are derived from *Cannabis* spp. * These include:

- Fiber from the plant’s stem, used in the manufacture of commercial products such as rope, textiles and paper.
- The seed, used in some traditional medicines and in bird feed and other animal food.
- Seed oil, which has diverse uses in foods, food supplements and personal care products, and also has industrial applications.
- The female inflorescence (i.e., flower or flower bud), the isolated trichomes naturally present in the inflorescence, and to a lesser degree the leaf, which find uses as a medicine and an inebriant due to the concentrated presence in certain cultivars of various compounds that produce physiological effects on users through oral consumption or inhalation of the vaporized or combusted material.
- Extracts and concentrates of the female inflorescence, its trichomes, or the leaf, which have the same uses as the source materials.

The AHPA Cannabis Committee has an interest in ensuring that consumers of products consisting of, derived from, or containing these varied articles are able to readily differentiate them. The committee recognizes that federal food labeling regulations exist that require the use of the “common or usual” name of food ingredients, and further recognize that dietary supplement labeling regulations require all botanical ingredients to be labeled to identify the part of the plant used.

The AHPA Cannabis Committee recommends that lawfully marketed products that consist of or include *Cannabis* spp. ingredients and that are intended for oral ingestion, topical application, or inhalation be labeled to identify the part of the Cannabis plant from which the ingredient is derived, for example “seed oil,” “flower extract,” “extract of aerial parts” to describe the above ground parts of the plant, etc.; except that this policy does not apply to parts of the Cannabis plant in unprocessed and recognizable forms.

*Disagreement exists among botanists and taxonomists as to whether there is only one species (*C. sativa*) or two (*C. sativa* and *C. indica*) in the genus *Cannabis*. This policy takes no position on this matter, as clarification of this detail is not necessary to address its purpose.

Labeling of dietary supplements containing fungi dietary ingredients  
(adopted March 2017; effective March 2019)

U.S. federal regulations establish specific labeling requirements for dietary supplement products. Marketers of dietary supplements that consist of or contain dietary ingredients derived from any multicellular fungal species should conform to all such federal regulations and the following label and labeling standards:

- Each fungal dietary ingredient included in a dietary supplement is identified in the product label's declaration of nutrition information under the Supplement Facts

Rev. 6/12/23
heading, as defined in 21 CFR 101.36(b), by its common or usual name; by the part or parts of the fungal ingredient present\textsuperscript{2,3}; and in order of predominance by weight (whether listed separately or as part of a proprietary blend).

- For purposes of this guidance, the part(s) of fungi ingredients are the stage(s) of the fungi present or, in the case of an extract, the stage(s) of the fungi from which the extract was manufactured. Parts may include, for example, fruitbody; mycelium; sclerotium; spores; etc. (see Glossary for applicable definitions).

- Ingredients other than dietary ingredients in such products are disclosed in the product label's ingredient list preceded by the words “Other ingredients,” as described in 21 CFR 101.4(g). These ingredients may include, for example, the specific substrate on which the fungal ingredient is grown (including the natural substrate present in a wild-harvested ingredient) if any is still remaining in the fungal ingredient; other non-dietary ingredients used in the manufacture of the dietary supplement product, i.e., excipients such as fillers, binders, flow agents, etc.; and non-dietary ingredients that are ingredients within ingredients and are present in non-trivial amounts, such as excipients that are added to an extract (e.g., maltodextrin or the marc from the extraction starting material (e.g., “shiitake fruitbody marc”).

- Inclusion of the word “mushroom” is not required on the label and in labeling of a dietary supplement product that consists of or includes fungi dietary ingredients; however, if the word is used then all of the following apply:
  - The word “mushroom” may be included in the marketer’s company name wherever located on labels or labelling irrespective of the part(s) of the fungal ingredient(s) contained in the product.
  - If the word “mushroom” appears on the label’s principal display panel (PDP) other than in the marketer’s company name and the product contains a single fungal ingredient or more than one fungal ingredient that each consist of the same part of each of the contained fungi, the word is modified on the PDP to identify the part(s) of the fungal dietary ingredient(s) contained in the product; for example “mushroom mycelium,” “mushroom spore,” etc.; except that the fruitbody may be identified with the unmodified word “mushroom” (e.g., “shiitake mushroom” or “Ganoderma lucidum mushroom”).
  - If the word “mushroom” appears on the label’s PDP other than in the marketer’s company name and the product contains more than one fungal ingredient consisting of different fungi parts, the word is modified on the PDP with specific terms such as “mushroom mycelia and fruitbodies” or general terms such as “mushroom complex” or “mushroom composite”. When such terms are used, however, the specific fungi and/or fungi parts present are disclosed in order of predominance by weight in nutrition labeling under the Supplement Facts heading (e.g., “reishi mushroom composite (mycelium, fruitbody, spores)”).

- On parts of a label other than the PDP and in labeling, sufficient information is provided to clearly communicate the part(s) of the fungi ingredient(s) contained in the
Glossary
For purposes of this guidance, the following definitions apply.

1. Terms relevant to fungal ingredients:
   - “Hypha” means one unit of the filamentous structure of a fungus which together make up the mycelium. Plural form “hyphae.”
   - “Fruitbody” means the fleshy reproductive stage, primarily composed of hyphae, that produces spores and provides a mechanism for their dispersion. Alternative forms are “fruit body” and “fructifying body.”
   - “Mushroom” when used as a noun may be used as a synonym for “fruitbody” as defined here; when used as an adjective or descriptor, “mushroom” may be used to indicate an association with a multicellular species in the Kingdom Fungi (e.g., “mushroom mycelium”).
   - “Mycelium” means the vegetative portion of a fungus composed of a mass of hyphae. Plural form “mycelia.”
   - “Primordium” means the first recognizable but undifferentiated mass of hyphae from which the fruitbody develops. Plural form “primordia.”
   - “Sclerotium” means a compact aggregate of hyphae. Plural form “sclerotia.”
   - “Spore” means the survival or dispersal reproductive unit that is capable of germinating to produce a new hypha.
   - “Substrate” means the surface or material on or from which a fungus lives, grows, or obtains its nourishment.

2. Terms relevant to dietary supplement labels:
   - “Label” means the display of written, printed, or graphic matter upon the immediate container of any article. (21 U.S.C. 321(k)).
   - “Labeling” means all labels and other written, printed, or graphic matter (a) upon any article or any of its containers or wrappers, or (b) accompanying such article. (21 U.S.C. 321(m)).
   - “Marc” means the botanical (including fungi) material that remains after an extraction process is complete.
   - “Principal display panel” (or PDP) means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. (21 CFR 101.1).

References
1. Fungi are actually classified in Kingdom Fungi and not in Kingdom Plantae; nonetheless, the federal regulation for labeling of dietary supplements is clear in its application to products derived from fungi species.
2. The term “mycelium biomass” (or “mycelial biomass”) may be used to mean the combination of the mycelium grown on a solid substrate and any remnant of the myceliated substrate still present.
3. Spores naturally present in a fruitbody do not need to be identified as a separate part unless added as a stand-alone ingredient.

**Labeling protein in food and dietary supplements** (adopted March 2014)

Marketers of conventional foods and dietary supplements adhere to the following guidelines in labeling the protein in any such product:

- Notwithstanding the allowance in 21 CFR § 101.9(c)(7) to calculate the amount of protein to be declared in nutrition labeling of a food or dietary supplement on the basis of the factor of 6.25 times the nitrogen content of the food, the quantity of protein in a product is calculated to include only proteins that meet the following definition: “A chain of amino acids connected by peptide bonds.”
- As further clarification, non-protein nitrogen-containing (NPN) substances are not counted toward total protein content on product labels. NPN substances are accounted for and subtracted from the total nitrogen content when protein is measured by nitrogen content.
- Nothing in this guidance is intended to replace or conflict with any regulatory requirement established under any other subpart or section of 21 CFR Part 101 for labeling of food and dietary supplement products.

**Trade requirement and guidance policy for labeling undiluted essential oils used topically and offered for retail sale** (Trade requirement adopted July 2009, revised July 2011; Guidance policy adopted July 2012)

Undiluted plant essential oils offered for retail sale and intended for topical use:

1. Do include all of the information and statements, or significantly similar statements, identified in the table below as a “trade requirement,” directly on package labels;
2. May include any of the information identified in the table below under “Guidance Policy,” either directly on package labels or on labeling. *

<table>
<thead>
<tr>
<th>Subject</th>
<th>Trade requirement</th>
<th>Guidance policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identity of the source plant:</td>
<td>• Latin name</td>
<td>• Common or usual name</td>
</tr>
<tr>
<td></td>
<td>• Plant part</td>
<td></td>
</tr>
<tr>
<td>Product identity:</td>
<td></td>
<td>• An expiration date or date of manufacture.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• A lot number or other batch identifier.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• The extraction process, (i.e., distilled; expressed; solvent extraction; etc.), with any additional specific accurate information.</td>
</tr>
<tr>
<td>Storage cautions:</td>
<td>• “Keep out of reach of children.”</td>
<td>• “Keep away from flame.”</td>
</tr>
</tbody>
</table>

* Rev. 6/12/23
### Usage instructions:
- Instructions for use with, at minimum, the recommended amount for each application method described.

### Usage cautions:
- “External Use Only” or “Not for Internal Use” or “Not for Ingestion”
- “Keep away from eyes and mucous membranes.”
- “Do not apply undiluted directly on skin,” except that information may be included on direct application in an undiluted state if the marketer has expert support that such use is appropriate and safe for the intended use.
- “If swallowed, seek medical attention or contact a Poison Control Center.”
- “If skin irritation or sensitivity develops or increases, stop use and, if condition persists, seek medical attention.”
- Risk and safety information regarding photosensitizing effects, if applicable to the specific essential oil.
- Risk and safety phrases for specific oils as identified by the Research Institute for Fragrance Materials (RIFM) and the International Fragrance Association (IFRA), if applicable to the specific essential oil.

*For purposes of this guidance, the following definitions apply:
- “Label” has the meaning ascribed in 21 U.S.C. 321(k) and means a display of written, printed, or graphic matter upon the immediate container of any article.
- “Labeling” has the meaning ascribed in 21 U.S.C. 321(m) and means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

In addition, for purposes of these policies, the following notes apply:

- These policies do not address the safety of specific essential oils. Contraindications exist for the use of some essential oils in special populations, such as infants and children; pregnant and lactating women; and those with certain health conditions (e.g., hypertension). Such individuals should use essential oils under the supervision of a professional or qualified person.
- All of the required storage and usage cautions can be stated succinctly, for example, as: “Keep away from children. No use orally, in eyes or mucus membranes, or undiluted on skin.”

### Product labeling for St. John's wort (Hypericum perforatum)
(adopted July 2000, confirmed as current March 2023)

AHPA recommends the following or similar language appear on the label of products containing St. John's wort:

Notice: Do not use this product while taking any prescription drug(s) without the

Rev. 6/12/23
advice of your prescribing physician. Avoid excessive exposure to UV irradiation (e.g., sunlight; tanning) when using this product.


WHEREAS
AHPA and its members are committed to compliance with federal labeling regulations and value labeling that communicates clearly to consumers in terms that are easily understood and rational.

AND WHEREAS
A dietary supplement that contains a liquid extract from which the solvent has not been removed may, for example, consist of any of the following dietary ingredients:

i. a liquid botanical extract of a single botanical substance; or
ii. a liquid botanical extract of two or more botanical substances, including one or more proprietary blends of botanical substances; or
iii. a combination of two or more liquid botanical extracts, including one or more proprietary blends of liquid botanical extracts; or
iv. any of the above with any other dietary ingredient as defined in 21 U.S.C. § 321(ff)(1).

AND WHEREAS
Federal regulations for nutrition labeling of dietary supplements require the quantitative amount per serving presented in the Supplement Facts panel for any dietary ingredient that is a liquid extract from which the solvent has not been removed to be declared as the volume or weight of the total extract. 21 C.F.R. § 101.36(b)(3)(ii)(B).

AND WHEREAS
Federal regulations for nutrition labeling of dietary supplements also provide specific rules for declaring the quantitative amount of any proprietary blend of dietary ingredients in a dietary supplement, when declaring this amount by weight, as follows:

“The quantitative amount by weight specified for the proprietary blend shall be the total weight of all other dietary ingredients contained in the proprietary blend.” 21 C.F.R. § 101.36(c)(3).

AND WHEREAS
The Federal regulations for nutrition labeling of dietary supplements are silent on the rules that apply when declaring the quantitative amount of any dietary ingredient that is a proprietary blend extract when declaring this amount by volume, instead of by weight, as is allowed by 21 C.F.R. § 101.36(b)(3)(ii)(B) for any dietary ingredient that is a liquid extract from which the solvent has not been removed.

THEREFORE, AHPA RECOMMENDS
The label of a dietary supplement that contains one or more liquid extracts of one or more proprietary blends from which the solvent has not been removed, and that declares
the quantitative amount of the extract(s) of the proprietary blend(s) by volume, rather
than by weight, shall declare the amount(s) as follows:

“The quantitative amount by volume declared for the proprietary blend extract
shall be the total volume of the proprietary blend extract.”

Retail labeling of dietary supplements containing soft or powdered
botanical extracts (adopted July 2000)

AHPA recommends the following labeling standards:

- **Standardized statement of quantity.** For soft or powdered botanical extracts listed
  in the Supplement Facts box (as defined by 21 CFR §101.36) the quantity stated
  shall correspond to the total amount of that extract included in the product (i.e., the
  quantity shall include carriers and other excipients).\(^1\) If they so choose, AHPA
  members may also disclose the percent of native extract for each extract listed in the
  Supplement Facts Box.\(^2\)

- **Extract ratios.** Listing of the extract ratio of a soft or powdered botanical extract is
  not a mandatory labeling requirement for retail products. There are differing opinions
  concerning the value of listing extract ratios on the retail label. However, where such
  ratios are stated, they shall conform to the following convention:\(^2\): The first number
  shall represent the amount of dried botanical starting material, the second number
  shall represent the amount of finished total extract. For example, a 4:1 extract is one
  in which each kilogram (or other unit) of finished total extract represents the
  extractives from four kilograms (or other unit) of dried botanical starting material.\(^3\)
  Where fresh rather than dried starting material is used in determining the ratio, this
  fact must be disclosed.

- **Statement of manufacturing ranges.** For soft or powdered extracts where the
  percent native extract or the concentration ratio varies from lot to lot of extract, this
  variation may be expressed on the label in either of the following forms:

  - **The range.** The range of percent of native extract or of concentration ratios
    described in the extract manufacturer's product specification may be stated on
    the retail label. Any range specified by the extract manufacturer must
    correspond to the actual variability that occurs from batch to batch of extract.
    Where the percent native extract range or ratio is listed on the label, it shall be
    stated in the form "x–y% native" (e.g., "40–50% native") or "x–y:1" (e.g., "4–
    5:1")

  - **The average.** The average of the range described in the extract
    manufacturer's product specification may be stated on the retail label, so long
    as (a) The range does not vary by more than ± 20% from the stated average;
    and (b) The fact that the labeled value represents the average of a range is
    disclosed on the label. If the range varies by more than 20% from the average,
    the average may not be stated on the label; rather, the entire range must be
    disclosed. Where an average value is listed on the label, it shall be in the form
    "average % native" or "average x:1." Where desired, the word "average" may
    be abbreviated to "av." or "avg."

1. Carriers and other excipients are required to be listed in the ingredients

Rev. 6/12/23
statement in accordance with §101.4(g).
2. It is not meant to imply that the items discussed (i.e., listing of percent native extract and the extract ratio) are the optimal or proper way to describe the extract on the retail label.
3. Any appropriate unit may be used, so long as the amounts of starting plant material and finished extract are expressed in the same unit of measure.

"Guidance for the Retail Labeling of Dietary Supplements Containing Soft or Powdered Botanical Extracts" is also available from the AHPA Bookstore, as part of AHPA's Guidance Documents for the Manufacture and Sale of Botanical Extracts.
Manufacturing and Product Specifications

**Limits of foreign matter in herbal ingredients** (adopted October 2017)

The American Herbal Products Association (AHPA) provides the following guidance on maximum quantitative limits of foreign matter in herbal raw materials: Plant parts of the same herbal raw material species, other than those named in specifications, should not exceed 5% (by weight), and all other foreign matter should not exceed 2% (by weight).

**Notes:**
- For purposes of this guidance, herbal raw materials are parts of plants that may be dehydrated and subject to minimal cutting but have not been subject to any additional processing, such as powdering, extraction, etc., at a stage in commerce in which the material is for use as a component in a consumer product or processed into an ingredient for use as a component in a consumer product.
- An article (e.g., herb powder, extract, essential oil, traditionally processed herb, etc.) derived or manufactured from herbal raw materials that is in compliance with this guidance is also assumed to be in compliance with this guidance.
- For quantitative determination of foreign matter content in an herbal raw material, suitable physical test procedures, as described in the 2011 WHO publication, *Quality control methods for herbal materials: Updated edition of quality control methods for medicinal plant materials 1998*, may be utilized. Note that determination of foreign matter content in processed herbal ingredients and articles derived or manufactured from herbal raw materials may not be possible by such procedures.
- This guidance is relevant only to foreign matter consisting of those identified in the “Context and background” section of the full, linked guidance document.
- This guidance does not allow or imply allowance of any portion of an herbal raw material to consist of economically motivated adulterants, deliberately substituted ingredients, or diluents.
- This guidance does not allow or imply allowance of presence of allergens, potential choking hazard objects, or poisonous, dangerous or otherwise harmful foreign matter or residue.
- This AHPA guidance does not apply to an herbal ingredient labeled or otherwise identified as meeting a different standard, whether more or less stringent than the limits established in this guidance.

**Heavy metals (elemental impurities)** (adopted October 2008; last revised October 2020)

Dietary supplement manufacturers determine what, if any, tests or examinations are appropriate for their finished products, whether to meet specifications established for these products (21 CFR §§ 111.70 and 111.75) or for other purposes. Similarly, food manufacturers identify and evaluate known and reasonably foreseeable hazards, including chemical hazards, to determine those requiring preventive controls (21 CFR § 117.130).
With respect to herbal products, there are a number of non-essential heavy metals\(^1\) that dietary supplement and food companies may consider in relation to their manufacturing and quality control operations, if appropriate. This guidance addresses four such elements. Not all of these, however, are applicable to every herbal food or supplement product, and others not included here may be relevant for some such products.

Where companies choose to establish specifications or make hazard determinations for one or more of the elements listed below for finished herbal products intended for oral consumption, AHPA provides the following as guidance on maximum quantitative limits:

- for inorganic arsenic: 10 mcg/day
- for cadmium: 4.1 mcg/day
- for lead: 6 mcg/day; 3 mcg/day for products intended to be used by children
- for methyl mercury: 2.0 mcg/day

In this policy the following terms, limitations, and conditions apply:

- The terms “herbal product,” “herbal supplement” and “herbal food” mean a finished product, a dietary supplement, or a food, respectively, that contains one or more herbal ingredients (i.e., an herb or other botanical, including fungi and algae, or a concentrate, extract or combination of an herb or other botanical). An herbal product may or may not also contain non-herbal ingredients.
- This guidance is not intended to suggest that companies should, for any or all of the elements identified here, establish specifications for any specific herbal supplement or determine these as hazards that require preventive controls for any specific herbal food. This guidance is not, in fact, applicable for some herbal products, but is instead intended to provide guidance for limits in the event any such specifications are set or such determinations are made. In addition, it may not be relevant to test any specific herbal product to determine the level of any or all of the elements identified in this guidance.
- The above quantitative limits may be determined at either the highest daily intake based on the highest labeled serving size or upon average daily consumption of a food or supplement.
- The above quantitative limits are most applicable to herbal products consumed in a total daily amount of 5 grams or less.
- A product in compliance with this guidance may require a warning in order to comply with California Proposition 65’s listing of these chemicals. Click this link for information on California Proposition 65.

**Known adulterants** (adopted July 1997; revised July 2012)

\(^1\) There is some inconsistency in how the term “heavy metals” is defined, and some disagreement as to whether the term should even be used to describe certain metallic elements associated with adverse health effects. Alternative terms in use include “toxic elements” and “elemental contaminants.” In this policy the word “elements” is used to describe the subject substances, including methyl mercury, which is more accurately an organometallic compound.
AHPA recommends that appropriate steps be taken to assure that the raw materials in
the following table are free of the noted adulterant. This list identifies herbs and potential
adulterants that are known at this time to have been encountered in trade.

Additional information may be added if further such instances are observed. Marketers
of products that contain herbal ingredients are responsible for assuring accurate
identification of all ingredients. Contact AHPA for additional information regarding
relevant analytical methods.

<table>
<thead>
<tr>
<th>Article of trade</th>
<th>Adulterant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eleuthero root (Eleutherococcus senticosus)</td>
<td>Periploca sepium root</td>
</tr>
<tr>
<td>Plantain leaf (Plantago lanceolata)</td>
<td>Digitalis lanata leaf</td>
</tr>
<tr>
<td>Skullcap herb (Scutellaria lateriflora)</td>
<td>Germander herb (Teucrium chamaedrys)</td>
</tr>
<tr>
<td>Stephania root (Stephania tetrandra)(^a)</td>
<td>Aristolochia fangchi root (guang fang jì)</td>
</tr>
<tr>
<td>Asian species of Cocculus, Diploclisia, Menispermum and Sinomenium root</td>
<td>Aristolochia fangchi root (guang fang jì)</td>
</tr>
<tr>
<td>Asian species of Akebia and Clematis stem</td>
<td>Aristolochia manshuriensis stem (guan mu tong)</td>
</tr>
<tr>
<td>Costus root (Saussurea costus)(^b)</td>
<td>Aristolochia debilis root (qing mu xiang)</td>
</tr>
<tr>
<td>Vladimíria souliei root</td>
<td>Aristolochia debilis root (qing mu xiang)</td>
</tr>
<tr>
<td>Black cohosh root/rhizome (Actaea racemosa)(^c)</td>
<td>Chinese cimicifuga root/rhizomed (Actaea spp.)</td>
</tr>
<tr>
<td>Ginkgo (Ginkgo biloba) leaf extract standardized to flavonol glycosides and terpenes</td>
<td>Ginkgo (Ginkgo biloba) leaf extract with added flavonol glycosides or aglycones (e.g., rutin, quercetin, etc.)</td>
</tr>
<tr>
<td>Bilberry fruit extract</td>
<td>Red dye #2 (amaranth dye)</td>
</tr>
<tr>
<td><em>Hoodia gordonii</em> aerial parts powder</td>
<td>Various powders, possibly including Opuntia spp. and other Hoodia species</td>
</tr>
<tr>
<td>(Chinese) star anise (<em>Illicium verum</em>) fruit</td>
<td>Japanese star anise (<em>Illicium anisatum</em>) fruit</td>
</tr>
<tr>
<td>Grapefruit Seed extract</td>
<td>Benzalkonium chloride, benzethonium chloride, triclosan, methyl paraben, or any other synthetic antimicrobial agent</td>
</tr>
</tbody>
</table>

\(^a\) Synonym = *Saussurea lappa*
\(^b\) Synonym = *Cimicifuga racemosa*
\(^c\) Also known as *sheng ma* or *Rhizoma Cimicifugae*; consists of *Actaea cimicifuga*, syn. *Cimicifuga foetida*; *Actaea dahurica*, syn. *C. dahurica*; *A. heracleifolia*, syn. *C. heracleifolia*; and possibly other Asian species of *Actaea*.

**Microbiology & mycotoxins** (adopted June 2003; last revised July 2012)

Rev. 6/12/23
Food ingredient suppliers, dietary ingredient suppliers, and dietary supplement manufacturers determine what, if any, tests or examinations are appropriate for their ingredients and products, whether to meet specifications established for these ingredients and products or for other purposes.

With respect to herbal ingredients and supplements, there are a variety of microbiological characteristics and mycotoxins for which companies may consider implementing tests or examinations, if appropriate. This guidance discusses some of the more commonly used ones. Not all of these, however, are applicable to every herbal ingredient and supplement, and others not included here may be relevant for some herbal ingredients or supplements.

Where manufacturers choose to establish one or more microbiological and/or mycotoxin specifications for herbal ingredients or dietary supplements identified in this guidance, AHPA provides the following as guidance on maximum quantitative limits:

(a) (i) for dried, unprocessed herbs for use as ingredients in dietary supplements, and (ii) for herbal supplements in solid form consisting of dried, unprocessed herbs:
- Total aerobic plate count: $10^7$ colony forming units/gram
- Total yeasts and molds: $10^5$ colony forming units/gram
- Total coliforms: $10^4$ colony forming units/gram
- *Salmonella* spp.: not detected in 25 grams
- *Escherichia coli*: not detected in 10 grams
- Total aflatoxins (B$_1$ + B$_2$ + G$_1$ + G$_2$): 20 μg/kg (ppb)
- Aflatoxin B$_1$: 5 μg/kg (ppb)

and (b) (i) for powdered extracts and for soft extracts, and (ii) for herbal supplements in solid form consisting of powdered extracts or soft extracts:
- Total aerobic plate count: $10^4$ colony forming units/gram
- Total yeasts and molds: $10^3$ colony forming units/gram
- Total coliforms: $10^2$ colony forming units/gram
- *Salmonella* spp.: not detected in 25 grams
- *Escherichia coli*: not detected in 10 grams
- Total aflatoxins (B$_1$ + B$_2$ + G$_1$ + G$_2$): 20 μg/kg (ppb)
- Aflatoxin B$_1$: 5 μg/kg (ppb)

For purposes of this guidance the following definitions apply:
- “Dried unprocessed herb” means an herb or other botanical that is dehydrated from its fresh state and that has not been subjected to any further processing other than cleaning, grading, or size reduction (e.g., cutting or powdering).
- “Dietary supplement” has the same meaning as described in 21 U.S.C. 321 (ff). For purposes of this guidance a dietary supplement is a product in finished form ready for consumer use.
- “Herbal supplement” means a dietary supplement, as described in 21 U.S.C. 321 (ff), that contains one or more herbal ingredients (i.e., an herb or other botanical, or a concentrate, extract, or combination of an herb or other botanical). An herbal supplement may or may not contain additional non-herbal dietary ingredients.

Rev. 6/12/23
(e.g., vitamins, minerals, amino acids, etc.) or excipients.

- “Botanical extract” means the complex, multi-component mixture obtained after using a solvent to dissolve components of an herbal or other botanical biomass. Botanical extracts may be in dry, liquid or semi-solid form. Excipients may be added to botanical extracts for various technical purposes (e.g., to adjust concentration; enhance stability; limit microbial growth; or improve drying, flow or other manufacturing characteristics). Botanical extracts are not the same as expressed juices, pure chemicals isolated from an herb, or synthetically modified plant constituents (though it should be noted that some chemical modifications might occur as the natural consequence of the extraction process).
- “Powdered extract” means a botanical extract that has been dried into a powder.
- “Soft (a.k.a. pilular, semi-solid, or solid) extract” means a botanical extract having a consistency of a thick liquid or paste.

In addition, for purposes of this guidance the following limitations and conditions apply:

- This guidance is not intended to suggest that manufacturers should establish specifications for any or all of the identified microbiological characteristics or mycotoxins in any specific herbal ingredient or supplement, but is rather intended to provide guidance for limits in the event any such specifications are set. This guidance is not, in fact, applicable for some herbal ingredients and supplements. In addition, it may not be relevant to test any specific herbal ingredient or supplement to determine the level of any or all of the microbiological characteristics or mycotoxins identified in this guidance.
- In determining whether *Salmonella* spp. and *E. coli* are not detected, the sample size may vary depending on the method used.
- Depending on the analytical methods used to detect *Salmonella* spp. or *E. coli*, failure to detect a microorganism may be reported as “absent,” “not detected,” “negative,” or “less than” the detection limit.
- For dried, unprocessed herbs for use as ingredients in dietary supplements, the above quantitative limits may be exceeded in either of the following circumstances:
  - When, due to naturally occurring conditions, an individual herb requires higher limits on total aerobic plate count, total yeasts and molds, and/or total coliforms. When acceptable techniques, such as steam sterilization, will be employed in subsequent processing to eliminate pathogens.
  - However, such treatment is not acceptable if the untreated materials are spoiled prior to such treatment.
- For herbal products in solid form, the above quantitative limits do not apply to products where boiling water is added before use, and may not apply to products containing other dietary ingredients (such as vitamins and minerals) and excipients.

**Pesticide specifications** (adopted March 2017, confirmed as current March 2023)

AHPA recommends food and dietary supplement manufacturers that choose to set pesticide specifications consider the following approach to determine when such
specifications should be established for herbal ingredients. This guidance may be useful for dietary supplement manufacturers complying with 21 CFR Part 111 (Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements) and food (including tea) manufacturers complying with hazard analysis provisions in 21 CFR Part 117 (Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventative Controls for Human Food).

- Crops that are certified as organic under USDA’s National Organic Program (NOP), including herbal crops, are required to comply with specific NOP regulations, such that any pesticide residues present in such crops must not exceed limits established under the NOP. Therefore, no specifications for pesticides are required to comply with 21 CFR 111.70 (c)(3) or 21 CFR 117.130(b) for herbal ingredients certified as organic under the NOP.

- All other crops grown in the United States, including herbal crops, are required to comply with pesticide regulations established by the Environmental Protection Agency (EPA), such that any pesticide residues present in such crops must not exceed limits established by EPA. Therefore, no specifications for pesticides are required to comply with 21 CFR 111.70 (c)(3) or 21 CFR 117.130(b) for herbal ingredients grown in the United States.

- Imported crops including herbal crops that are not certified as organic under the NOP are required to be in compliance with EPA’s pesticide regulations at the time of importation and are subject to inspection and testing by the Food and Drug Administration (FDA) to insure compliance. FDA maintains Import Alerts to identify any crops found to be out of compliance with EPA pesticide regulations, and specifically IA #99-05, organized by individual growers / shippers; and #99-14, organized by country. These Import Alerts are updated frequently and may be checked at the time of import. Therefore, specifications for pesticides may need to be established to comply with 21 CFR 111.70 (c)(3) or 21 CFR 117.130(b) for herbal crops identified on any of these FDA Import Alerts.

**Residual solvents in extracts** (adopted October 2010, revised July 2011)

AHPA recommends that herbal extracts marketed in the U.S. limit any contained residual solvents to the levels established by the current International Conference on Harmonization’s (ICH’s) document, *Impurities: Guideline for Residual Solvents*, except that this guidance does not apply to the ICH limit of 50 mg per day for the class 3 solvent ethanol when it is present in liquid extracts formulated to contain ethanol, or for the class 3 solvent acetic acid when it is present in liquid extracts formulated to contain acetic acid or vinegar.

With regard to this guidance, solvents identified in the cited ICH document as class 1 solvents (benzene;* carbon tetrachloride;* 1,2-dichloroethane;* 1,1-dichloroethene; and 1,1,1-trichloroethane), which are considered by ICH as unacceptably toxic or an environmental hazard, are not appropriate for use, and should not be used, in the manufacture of herbal extracts.

With regard to this guidance, solvents identified in the cited ICH document as class 2 solvents, which are considered by ICH to be inherently toxic, are listed in the table below.
with the ICH recommended upper limits for Permissible Daily Exposures (PDE) and concentration limits given in ppm assuming a 10 gram daily dose.

<table>
<thead>
<tr>
<th>Class 2 solvent</th>
<th>PDE (mg/day)</th>
<th>limit (ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetonitrile</td>
<td>4.1</td>
<td>410</td>
</tr>
<tr>
<td>Chlorobenzene</td>
<td>3.6</td>
<td>360</td>
</tr>
<tr>
<td>Chloroform*</td>
<td>0.6</td>
<td>60</td>
</tr>
<tr>
<td>Cyclohexane</td>
<td>38.8</td>
<td>3880</td>
</tr>
<tr>
<td>1,2-Dichloroethene</td>
<td>18.7</td>
<td>1870</td>
</tr>
<tr>
<td>Dichloromethane*</td>
<td>6.0</td>
<td>600</td>
</tr>
<tr>
<td>1,2-Dimethoxyethane</td>
<td>1.0</td>
<td>100</td>
</tr>
<tr>
<td>N,N-Dimethylacetamide*</td>
<td>10.9</td>
<td>1090</td>
</tr>
<tr>
<td>N,N-Dimethylformamide</td>
<td>8.8</td>
<td>880</td>
</tr>
<tr>
<td>1,4-Dioxane*</td>
<td>3.8</td>
<td>380</td>
</tr>
<tr>
<td>2-Ethoxyethanol</td>
<td>1.6</td>
<td>160</td>
</tr>
<tr>
<td>Ethyleneglycol</td>
<td>6.2</td>
<td>620</td>
</tr>
<tr>
<td>Formamide</td>
<td>2.2</td>
<td>220</td>
</tr>
<tr>
<td>Hexane</td>
<td>2.9</td>
<td>290</td>
</tr>
<tr>
<td>Methanol</td>
<td>30.0</td>
<td>3000</td>
</tr>
<tr>
<td>2-Methoxyethanol</td>
<td>0.5</td>
<td>50</td>
</tr>
<tr>
<td>Methylbutyl ketone*</td>
<td>0.5</td>
<td>50</td>
</tr>
<tr>
<td>Methylcyclohexane</td>
<td>11.8</td>
<td>1180</td>
</tr>
<tr>
<td>N-Methylpyrrolidone*</td>
<td>5.3</td>
<td>530</td>
</tr>
<tr>
<td>Nitromethane*</td>
<td>0.5</td>
<td>50</td>
</tr>
<tr>
<td>Pyridine*</td>
<td>2.0</td>
<td>200</td>
</tr>
<tr>
<td>Sulfolane</td>
<td>1.6</td>
<td>160</td>
</tr>
<tr>
<td>Tetrahydrofuran</td>
<td>7.2</td>
<td>720</td>
</tr>
<tr>
<td>Tetralin</td>
<td>1.0</td>
<td>100</td>
</tr>
<tr>
<td>Toluene*</td>
<td>8.9</td>
<td>890</td>
</tr>
<tr>
<td>1,1,2-Trichloroethene</td>
<td>0.8</td>
<td>80</td>
</tr>
<tr>
<td>Xylene</td>
<td>21.7</td>
<td>2170</td>
</tr>
</tbody>
</table>

With regard to this guidance, solvents identified in the cited ICH document as class 3 solvents, which are considered by ICH as having low toxic potential, should be limited to 50 mg/day,† which equates to 5000 ppm or 0.5% in 10 grams. Their use should be limited by good manufacturing practice (GMP) or other quality based requirements.

They are identified as the following:

<table>
<thead>
<tr>
<th>Class 3 solvents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetic acid</td>
</tr>
<tr>
<td>Ethanol*</td>
</tr>
<tr>
<td>3-Methyl-1-butanol</td>
</tr>
<tr>
<td>Acetone</td>
</tr>
<tr>
<td>Ethyl acetate</td>
</tr>
<tr>
<td>Methyl ethyl ketone</td>
</tr>
<tr>
<td>Anisole</td>
</tr>
<tr>
<td>Ethyl ether</td>
</tr>
<tr>
<td>Methyl isobutyl ketone</td>
</tr>
<tr>
<td>1-Butanol</td>
</tr>
<tr>
<td>Ethyl formate</td>
</tr>
<tr>
<td>2-Methyl-1-propanol</td>
</tr>
<tr>
<td>2-Butanol</td>
</tr>
<tr>
<td>Formic acid</td>
</tr>
<tr>
<td>Pentane</td>
</tr>
<tr>
<td>Butyl acetate</td>
</tr>
<tr>
<td>Heptane</td>
</tr>
<tr>
<td>1-Pentanol</td>
</tr>
<tr>
<td>tert-Butyl methyl ether</td>
</tr>
<tr>
<td>Isobutyl acetate</td>
</tr>
<tr>
<td>1-Propanol</td>
</tr>
</tbody>
</table>

Rev. 6/12/23
†This limit does not apply for ethanol when it is present in liquid extracts formulated to contain ethanol or for acetic acid when it is present in liquid extracts formulated to contain acetic acid or vinegar.

Adherence to this AHPA guidance does not infer compliance with California Proposition 65. Several of these solvents are listed by the State of California as chemicals known to the State to cause cancer or reproductive toxicity, including, as of the date of the last revision of this guidance, at least those solvents marked with an asterisk (*). The listing of ethanol with regard to California Proposition 65 refers only to its presence in alcoholic beverages.