

CODE OF ETHICS, BUSINESS CONDUCT AND TRADE REQUIREMENTS

March 2017

Prepared by the American Herbal Products Association



This document is the property of the American Herbal Products Association (AHPA) and is for AHPA purposes only. Unless given prior approval from AHPA, it shall not be reproduced, circulated, or quoted, in whole or in part, outside of AHPA and their members. Cite as: American Herbal Products Association, Code of Ethics and Business Conduct, March 2017. AHPA: Silver Spring, MD.

Contents

Preface	1
Expectations of Members in Good Standing of the Association	2
Conformity	1
Fair and Honest Business	1
Specific Guidelines for Herbal Products	1
Endangered Species	2
Cooperative Efforts	2
How to Amend the Code	2
Current Trade Requirements	3
I. Lady's Slipper	3
II. <i>Herbs of Commerce</i>	3
III. Chaparral	3
IV. Stimulant Laxatives	4
V. Pyrrolizidine Alkaloids	5
VI. Kava	5
VII. Drug Masking Claims	5
VIII. <i>Botanical Safety Handbook</i>	5
IX. Disclosure of Added Constituents	6
X. Pesticide Analysis for Ginseng	6
XI. Aristolochic Acid	7
XII. Caffeine-containing products	7
XIII. Use of Metals in Traditional Products	8
XIV. <i>Hoodia gordonii</i>	8
XV. Internet Sales of Dietary Supplements	9
XVI. Products for Use when Pregnant or Nursing	9
XVII. Labeling of Animal Products	9
XVIII. Extract Labeling	9
XIX. Labeling of Undiluted Essential Oils Used Topically and Offered for Retail Sale	9



Preface

The American Herbal Products Association (AHPA) was founded in 1982 by a group of companies active in the trade of botanicals. AHPA is now the national trade association and voice of the herbal products industry, comprised of domestic and foreign companies doing business as importers, growers, processors, manufacturers, marketers, and distributors of herbs and herbal products.

AHPA exists to promote the economic health of the herbal products industry and to help make high quality herbal products available to consumers. The Association serves its members by promoting the responsible commerce of products that contain herbs and that are used to enhance health and quality of life.

AHPA originally adopted its Code of Ethics & Business Conduct in 1991. Members of the Association are required to sign a statement of compliance with the Code and to adhere to all of its policies and principles. In their voluntary endorsement of these meaningful guidelines, AHPA members support the promotion of industry self-regulation. Responsible commerce is best assured by the adoption of policies that are developed from experience and knowledge, and the self-regulatory model relies on the experience of the governed industry.

One of the central tenets of AHPA's Code is its flexibility. As stated in this document, the Code can be revised either by the issuance of a trade requirement (which term has the same meaning as the term "trade recommendation" as used in the AHPA Bylaws, Article IX, Section 1) by the Association's elected Board of Trustees, or by action of the membership. While the latter mechanism is rarely used, the Board has actively pursued the adoption of specific trade requirements that serve to provide specific guidance for the herbal industry.

This Code of Ethics & Business Conduct reflects the ethics of the American Herbal Products Association, as determined by action of its members. Only an active and supportive membership, one that shares a commitment to responsible trade in quality herbal products, can give real meaning to the words contained here and make this document reflective of a vital and growing herbal industry.



Expectations of Members in Good Standing of the Association

Conformity

- Members must conform to the Bylaws, Code of Ethics & Business Conduct, and any other policies and regulations of the Association.
- Members must conform to all the regulatory requirements of their respective federal, state and local governments.

Fair and Honest Business

- All business transactions should be conducted in a fair and truthful manner, including all dealings with vendors and customers.
- Members will not engage in false or misleading advertising. Members may identify themselves as an AHPA member in advertising and marketing materials. However, Association involvement should not be used for personal or partisan gain. Members may not infer AHPA endorsement of any of their products.
- Members should never discuss or exchange information related to the following areas as they are generally recognized as unlawful or in violation of anti-trust laws:
 - Prices or pricing
 - Credit terms, discounts or elements of the terms and condition of sale
 - Profit levels, costs or market shares
 - Boycotts or agreements not to deal with competitors, customers or suppliers
 - Allocation or division of markets or customers
- Members should conduct themselves in a professional manner with all competitors and regulatory agencies.
- When the business conduct of any member becomes prejudicial to the character and welfare of the Association, or if any member exhibits conduct in any way contrary to or in violation of this Code or the Association Bylaws, such conduct will be referred to the Board of Trustees for its action under Article IV, Section 7 of the Bylaws, entitled “Suspension, Expulsion and Reinstatement of Membership.”

Specific Guidelines for Herbal Products

Members must follow all Board of Trustee trade requirements with regard to specific herbal products as outlined in detail in the section titled “Current Trade Requirements”.

Endangered Species (adopted September 1991; revised September 2000)

Endangered species of plants should not be traded by AHPA members. Members who wish to use such species in their products should obtain them from verifiable, commercially cultivated sources. Members should encourage selective harvesting and stewardship of wild stands of plants to maintain viable local plant populations.



The term “endangered species” is consistent with the definitions of endangered species as established by the U.S. Endangered Species Act or as established by CITES Appendix I.

AHPA members who use plants listed in CITES Appendix II are encouraged to do so in a manner consistent with the spirit and letter of CITES Appendix II.

Cooperative Efforts

Members are encouraged to fund and work cooperatively on industry-wide trade issues.

How to Amend the Code

The Code of Ethics & Business Conduct may, at times, need to be amended. There are two ways to amend the Code:

1. The Board of Trustees may issue a trade requirement, which becomes an amendment to the Code. This may be done without consultation or vote by the membership of the Association. There is a standard compliance time of six months for AHPA members to come into conformity with newly adopted or substantively amended trade requirements, unless otherwise stated by the Board at the time of adoption or amendment of a trade requirement.
2. Any AHPA member in good standing or an AHPA Committee may submit proposed amendments to the AHPA Board of Trustees for approval by majority vote of the Board of Trustees at the next duly constituted meeting of the Board. Upon approval by the Board, the amendment, along with a proposed effective date, in the event of approval by the membership under the terms of this section, shall be distributed to all voting members not less than 30 days before the date established by the Board for a vote by membership. Members will have no fewer than 30 days to cast their vote. Voting may occur either at a duly constituted meeting of the members, in which case a majority vote is required, or by written vote in compliance with the Article V of the Bylaws.

Any changes to the Code will be communicated to the members in writing.

Current Trade Requirements of the American Herbal Products Association

The Bylaws of the American Herbal Products Association define “Obligations of Membership” to include “adherence to all policies and principles of business practice as outlined in the Association’s Bylaws and Code of Ethics & Business Conduct.” Any such requirement adopted by the Board is thus automatically considered as a revision to the Code, requiring compliance from all members in good standing. The current trade requirements are listed on the following pages.

I. **Lady’s Slipper** (adopted July 1988; revised November 1999)

Businesses and individuals in the horticultural and herb trade refrain from domestic or international trade in wild-harvested Lady’s Slippers. AHPA encourages its members and others in the herb trade to support research in ecology, demographics, cultural methods, and sexual and asexual propagation of *Cypripedium* species.



II. Herbs of Commerce (adopted 1992; last revised March 2009)

The standardized common names recognized in *Herbs of Commerce*, 2nd Edition (2000), and as amended from time to time, are used as the common or usual names of botanical ingredients sold in bulk or used in foods, cosmetics, and other consumer goods, except where other regulations or standards take precedence.

III. Chaparral (adopted January 1995; revised October 2004)

Companies that offer products for sale for internal use that contain chaparral (*Larrea tridentata*) provide labeling that contains the following informational language:

Rare reports of serious liver disease have been associated with ingestion of chaparral. Seek advice from a health care practitioner before use and, in so doing, inform them if you have had, or may have had, liver disease, frequently use alcoholic beverages, or are using any medications. Discontinue use and see a doctor if vomiting, fever, fatigue, abdominal pain, loss of appetite, or jaundice (e.g., dark urine, pale stools, yellow discoloration of the eyes) should occur.

IV. Stimulant Laxatives (adopted July 1995; last revised March 2009)

Products offered for sale for internal use that contain, as an ingredient, any of the herbal articles listed below include the following information on labels:

1. The specific herbs that are subject to this trade requirement are:

Botanical Name	Common Name	Plant Part
<i>Aloe</i> spp.	aloe	dried latex
<i>Cassia fistula</i>	Indian laburnum	fruit or pod
<i>Frangula alnus</i>	frangula	bark
<i>Frangula purshiana</i>	cascara sagrada	bark
<i>Rhamnus cathartica</i>	buckthorn	fruit
<i>Rheum officinale</i>	Chinese rhubarb	root
<i>Rheum palmatum</i>	Chinese rhubarb	root
<i>Senna</i> spp.	senna	leaf, fruit or pod

NOTE: Senna was formerly listed in the genus *Cassia*, including the following species: *Cassia angustifolia*, *C. obtusifolia*, *C. senna*, and *C. tora*. Bulk raw materials labeled as one of these species of *Cassia* should be identified on finished consumer packages as “senna.”

2. (a) Any dietary supplement that contains any of the ingredients listed in paragraph 1 above and that is labeled in accordance with 21 CFR 101.93 with an express or implied structure/function statement that states that the supplement is a laxative or provides relief for occasional constipation is labeled in accordance with the Food and Drug Administration’s tentative final monograph for nonprescription laxative drugs.
 - (b) The following statement is included on the label of any other dietary supplement that contains any of the ingredients listed in paragraph 1 above in sufficient quantity to warrant such labeling:



NOTICE: Do not use this product if you have abdominal pain or diarrhea. Consult a health care provider prior to use if you are pregnant or nursing a baby. Discontinue use in the event of diarrhea or watery stools. Do not exceed recommended dose. Not for long-term use.

NOTE: The State of California has established labeling requirements that supersede the AHPA requirement for products sold in California. All dietary supplements that contain any amount of the above listed ingredients are required to bear the following label: *NOTICE: This product contains (name of substance(s) and common name(s) if different). Read and follow directions carefully. Do not use if you have or develop diarrhea, loose stools, or abdominal pain because (insert common name) may worsen these conditions and be harmful to your health. Consult your physician if you have frequent diarrhea or if you are pregnant, nursing, taking medication, or have a medical condition.*

Products sold nationally that are labeled in compliance with the above California labeling requirement are considered compliant with paragraph 2(b) of this trade requirement.

V. Pyrrolizidine Alkaloids (adopted July 1996; revised July 2010)

Products with botanical ingredients that contain toxic pyrrolizidine alkaloids* are not offered for sale for internal use and bear the following cautionary statement on the label:

For external use only. Do not apply to broken or abraded skin. Do not use when nursing.

*Including but not limited to: *Alkanna tinctoria* (alkanet); *Arnebia euchroma*, *Anchusa officinalis* (bugloss); *Borago officinalis*** (borage); *Crotalaria* spp., *Cynoglossum* spp., *Erechtites hieraciifolia*, *Eupatorium cannabinum* (hemp agrimony); *Eupatorium purpureum* (Joe Pye), *Gynura segetum*, *Heliotropium* spp., *Lithospermum officinale* (European gromwell); *Packera candidissima*, *Petasites* spp. (e.g., butterbur); *Pulmonaria* spp. (e.g., lungwort); *Senecio jacobaea* (European ragwort); *Senecio vulgaris* (groundsel herb); *Symphytum* spp. (comfrey); and *Tussilago farfara* (coltsfoot).

** Borage seed oil is specifically exempt from the above label requirement.

VI. Kava (adopted September 1997; revised October 2004)

Products that are offered for sale for internal use and that contain kava (*Piper methysticum*) bear the following or significantly similar statement:

Caution: US FDA advises that a potential risk of rare, but severe, liver injury may be associated with kava-containing dietary supplements. Ask a healthcare professional before use if you have or have had liver problems, frequently use alcoholic beverages, or are taking any medication. Stop use and see a doctor if you develop symptoms that may signal liver problems (e.g., unexplained fatigue, abdominal pain, loss of appetite, fever, vomiting, dark urine, pale stools, yellow eyes or skin). Not for use by persons under 18 years of age, or by pregnant or breastfeeding women. Not for use with alcoholic beverages. Excessive use, or use with products that cause drowsiness, may impair your ability to operate a vehicle or dangerous equipment.

VII. Drug Masking Claims (adopted March 1998; revised July 2005)

Marketers of dietary supplements refrain from labeling or marketing any herbal product in any manner that suggests that the product masks or defrauds drug testing.



VIII. Botanical Safety Handbook (adopted July 1998; revised July 2013)

Products that contain herbs are labeled in accordance with the labeling classification in the AHPA *Botanical Safety Handbook 2nd Ed. (2013)* or with alternate labeling to assure that current information that is material to the consumer of the product is stated.

Products that contain one or more herb that is classified as “Class 3” in the *Botanical Safety Handbook 2nd Ed. (2013)* (i.e., “An herb for which significant data exist to recommend the following labeling: *To be used only under the supervision of an expert qualified in the appropriate use of this substance*”) include proper use information, including dosage, contraindications, potential adverse effects and drug interactions, and any other relevant information related to the safe use of the substance; and are labeled as not for general retail sale and marketed in a manner that prevents general retail sale; except that, any product containing one or more Class 3 herbal ingredient that is manufactured, formulated or controlled in a manner that removes the concern that is the cause of such classification is exempted from the recommendation against retail sale so long as the manufacturer and marketer of the product have substantiation that concerns related to retail sale have been removed.

IX. Disclosure of Added Constituents (adopted October 1999)

Botanical ingredients, whether sold as an herb or other botanical or as a concentrate; metabolite; constituent; or extract of an herb or other botanical, are labeled with all of the following information:

- In the ingredient declaration of a bulk botanical raw material, disclosure of each ingredient contained in or added to the material by its common or usual name and in order of predominance, such contained or added ingredients including but not limited to botanical extractives; excipients; fillers; binders; solvents that have not been removed; and added constituents;
- In the specification sheet for a bulk botanical raw material, information for each contained or added ingredient with regard to the percentage, or range of percentages, of the entire raw material represented by each ingredient, so that finished product manufacturers can determine the order of ingredients in a finished product containing the raw material;
- In labeling of a bulk botanical raw material to which a constituent has been added and of finished products containing any such ingredient, the common name of the botanical raw material in the form of: botanical; plant part; form; “with added” constituent (e.g., “guarana seed extract with added caffeine”; “goldenseal leaf powder with added berberine”); and
- In labeling of finished products containing a botanical raw material to which a constituent has been added, listing of all ingredients contained in or added to the material in order of predominance.

X. Pesticide Analysis for Ginseng (adopted Nov 1999; revised July 2005)

Processors and/or manufacturers of cultivated ginseng (*Panax* spp.) ingredients and products analyze, by an appropriately validated analytical method at an appropriate and relevant limit of detection, for the presence of quintozone and related compounds, including known degradants and impurities of quintozone*, and also for the presence of difenoconazole;

and further, the analyses identified herein is performed by qualified analytical labs using validated analytical methods;



and further, bulk lots of ginseng are accompanied by a certificate that provides actual test results for quintozone and its degradants, and for difenoconazole;

and further, that in lieu of analysis by the processor or manufacturer, the accompanying certificate identified above may be accepted from a supplier provided that the processor or manufacturer establishes the reliability of the supplier's analysis in conformity with current good manufacturing practice;

provided that, any cultivated ginseng that is produced in a manner that assures that the ginseng is free of quintozone and related compounds and of difenoconazole is exempted from this requirement.

* PCNB, quintozone; PCA, pentachloroaniline; PCTA, pentachlorothioanisol; HCB, hexachlorobenzene; PCB, pentachlorobenzene; alpha-BHC, alpha-benzenehexachloride; beta-BHC, beta-benzenehexachloride; delta-BHC, delta-benzenehexachloride; gamma-BHC, gamma-benzenehexachloride (lindane); TCA, tetrachloroaniline; and TCZ, technazene.

NOTE: Contact the AHPA staff for information to assist in identifying an appropriately validated method for the purpose described in this trade requirement.

XI. Aristolochic Acid (adopted June 2001; last revised March 2009)

Herbal products offered for sale for oral consumption do not include any herbal ingredient that contains aristolochic acid; and further, bulk-packaged raw material containing aristolochic acid (e.g., all species of the genus *Aristolochia* which contain aristolochic acid; *Asarum canadense*; *Asarum europaeum*; *Asarum himalaicum*; etc.) are labeled for external use only.

If scientific evidence establishes an acceptable safe tolerance level for aristolochic acid, the AHPA Board will reconsider this trade requirement upon receipt of such evidence, and AHPA will support the development of such scientific evidence within its financial means.

The requirements identified here do not apply to *Aristolochia serpentaria* when used in alcoholic beverages in conformity with 21 CFR 172.515.

U.S. FDA has determined that any product for internal use that contains aristolochic acid, with the exception of *Aristolochia serpentaria* when used in alcoholic beverages in conformity with 21 CFR 172.515, is adulterated under the Federal Food, Drug & Cosmetic Act. In addition the State of California has listed aristolochic acid as a known carcinogen under the state's Clean Water and Toxic Enforcement Act (i.e., Proposition 65).

XII. Caffeine-containing products

1. Labeling of caffeine-containing products (adopted March 2005, last revised March 2013)

Dietary supplements that contain more than 5 mg of caffeine per serving, whether as added caffeine or as a naturally-occurring constituent of one or more herbal ingredients, and foods that contain added caffeine in which the total caffeine is more than 5 mg per serving conform to all of the following:

- The labels of such products disclose the presence of caffeine.
- The labels of any such products that contain 25 mg or more of caffeine per recommended serving disclose the specific quantity or quantitative range of caffeine per recommended



serving, stated in milligrams per serving and/or in equivalent approximate cups of coffee; except that this requirement does not apply to products in which the only caffeine-containing ingredients consist of crude raw botanicals or botanical ingredients in which the caffeine is not more concentrated than in the source crude botanical.

- The products are formulated and labeled in a manner to recommend a maximum of 200 mg of caffeine per serving not more often than every 3 to 4 hours.
- The following or similar information is included on the label of any such product that contains caffeine in sufficient quantity to warrant such labeling:
 - Do not use if sensitive to caffeine.
 - Not recommended for use by children under 18 years of age.
 - Not recommended for use by pregnant or nursing women.

For purposes of this policy the following definitions apply:

- “Caffeine” is a xanthine alkaloid with the chemical formula $C_8H_{10}N_4O_2$. Its systematic name is 1,3,7-trimethylxanthine or 3,7-dihydro-1,3,7-trimethyl-1H-purine-2,6-dione.
- “Added caffeine” means (1) caffeine that is a unique ingredient in a product’s formulation, irrespective of source (natural or synthetic) or form (pure caffeine; caffeine anhydrous; caffeine salts; caffeine compounds; etc.), or (2) the caffeine present in extracts of botanicals if the caffeine level is controlled or manipulated to a specific quantitative level or range that is higher than the naturally-occurring level.

In addition, for purposes of this policy the following clarification applies:

- Caffeine is found in several plant species, including in coffee seed (*Coffea* spp.), tea leaf (*Camellia sinensis*), kola fruit (*Cola* spp.), guaraná fruit (*Paullinia cupana*), yerba mate leaf (*Ilex paraguariensis*), and cacao seed (*Theobroma cacao*). Some references use synonyms for the caffeine found in plants other than coffee fruit (e.g., “thein” or “theine” if in tea leaf; “guaranine” if in guaraná; “mateine” or “mateina” if in yerba mate; “methyltheobromine” if in cacao*; etc.). This policy applies to caffeine irrespective of the synonymous or systematic name used to identify it. *NOTE: Cacao also contains theobromine ($C_7H_8N_4O_2$), which is a non-caffeine alkaloid.

2. Pure Caffeine Sold at Retail (adopted March 2015)

Pure caffeine will not be sold at retail (to consumers) in bulk form.

XIII. Use of Metals in Traditional Products (adopted July 2005, revised March 2009)

Whereas some traditions, such as Ayurveda and Traditional Chinese Medicine, may include ingredients that are heavy metal compounds or herbs that are processed with heavy metals*; and whereas the presence of several of these heavy metals in dietary supplements sold in the United States may cause such supplement products to be adulterated under the Federal Food, Drug and Cosmetic Act; therefore, manufacturers and marketers of products that are based on such traditions refrain from inclusion in such products of any ingredient that is processed with metals if the resultant presence of heavy metal(s)



causes the product containing the ingredient(s) to be adulterated under labeled or ordinary conditions of use.

*Reference AHPA White Paper on Heavy Metal Analysis for definition of “heavy metals”, January 2009

XIV. Hoodia gordonii (adopted January 2006, revised July 2009)

Marketers of products that contain any ingredient derived from Hoodia gordonii recognize the plant’s common or usual name to be “Hoodia gordonii;” and further, marketers of such products accurately identify the part of the plant used, which usually consists of parts that should be described as “aerial parts” or “above-ground parts.”

XV. Internet Sales of Dietary Supplements (adopted July 2006)

Websites on which dietary supplements or dietary ingredients are offered for sale provide contact information for the company that sponsors the website, consisting of at least the company name; phone number; and the city, state and zip code in which the company does business, and also consisting of the company’s physical street address if the company is not listed in a telephone directory, and of an optional email address, such contact information to be easily accessible to users of the website.

In addition, websites on which dietary supplements are offered for sale provide the supplement labeling information that is required on dietary supplement labels, or alternately, provide a statement to the effect that this information is available upon request.

In addition, the disclaimer that is required to accompany statements of nutritional support made in the labeling of dietary supplements (i.e., “This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure or prevent any disease.”) is included on any page of a website on which such statements are made.

XVI. Products for Use when Pregnant or Nursing (adopted July 2006)

Herbal products marketed for general retail sale and labeled specifically for use during pregnancy or while nursing are labeled in a manner that instructs the consumer to discuss their use of the product with a health care practitioner.

XVII. Labeling of Animal Products (adopted July 2008)

Products offered for sale and intended for ingestion by animals (1) if intended to provide nutritional value, are labeled in accordance with Association of American Feed Control Officials [AAFCO] guidelines; and (2) for all other such products, are labeled in a manner that (a) discloses all ingredients; (b) states the quantity of each ingredient or proprietary blend; and (c) lists ingredients in a proprietary blend in order of predominance; except that this policy does not apply to homeopathic products.

XVIII. Extract Labeling¹ (adopted October 2008, revised March 2010)

In labeling of herbal ingredients:

- The word “extract” is not used to describe plant materials that have not been extracted with one or more solvents.



- Quantitative extraction ratios are not used to represent the ratio between the fresh and dried weight of an herb, or on any product that is not, in fact an extract.

¹See additional information on AHPA’s Trade Requirement for extract labeling in AHPA’s Guidance Policies

XIX. Trade Requirement and Guidance Policy for Labeling of 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:

- 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;
- May include any of the information identified in the table below under “Guidance Policy,” either directly on the package labels or on labeling. *

SUBJECT	TRADE REQUIREMENT	GUIDANCE POLICY
Identity of the source plant:	<ul style="list-style-type: none"> Latin Name Plant Name 	<ul style="list-style-type: none"> Common or usual name
Product identity:		<ul style="list-style-type: none"> An expiration date or date of manufacture A lot number or other batch identifier The extraction process, (i.e., distilled; expressed; solvent extraction’ etc.), with any additional specific accurate information. For more information on specific types of extraction, click here.
Storage cautions:	<ul style="list-style-type: none"> “Keep out of reach of children.” 	<ul style="list-style-type: none"> “Keep away from flame.”
Usage instructions:		<ul style="list-style-type: none"> Instructions for use with, at minimum, the recommended amount for each application method described.
Usage cautions:	<ul style="list-style-type: none"> “External Use Only” or “Not for Internal Use” or “Not for Indigestion” “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. 	<ul style="list-style-type: none"> “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.”

Types of Distillation

- **Steam distillation:** Natural raw material is placed in or above water in a retort and exposed to steam, which carries the volatile oils into a condenser where the mixture is cooled.¹ The oils separate from the water and can be collected.
- **Hydro distillation:** Steam distillation in which the natural raw material is exposed to steam from above, rather than from below, the raw material.
- **Water distillation:** Natural raw material is submerged in water. The water is then slowly heated and brought to a boil.
- **Dry distillation:** Used primarily to obtain essential oils from wood. Natural raw material is heated in a retort in the absence of liquid to release vapors or liquids. The heat applied to the retort is commonly direct flame. This process may or may not involve pyrolysis.

Types of Expression

- **Cold-pressing:** Used primarily to obtain citrus essential oils. Fruit is punctured and then mechanically pressed. No external heat is applied during the extraction process.
- **Sponge expression:** Pulp is removed from the fruit and the remaining rind and pith are soaked in water. The softened peel is pressed against a sponge, which absorbs the exuded oil.
- **Scarification (aka: Écuelle à piquer):** Outer peel of a fruit is scarified. The liquid exuding from the ruptured oil glands collects in stem.
- **Machine abrasion:** Outer peel of a fruit is scarified and then removed by machine and dropped into a flow of water, which carries the result to a large centrifugal separator machine.

Types of Solvent

¹ When the natural raw material is placed in water during steam distillation it is sometimes called “water and steam distillation.”



- **Enfleurage:** Flower petals are placed on solid sheets of warm fat that absorbs the essential oil from the flowers. A solvent, usually alcohol, is then added to the saturated fat, which separates the essential oil from the fat.
- **Supercritical CO₂:** Carbon dioxide is liquefied and used as extraction solvent.
- **Solvent:** Use of a solvent other than those mentioned thus far, such as hexane. Solvent should be identified.
- **Extrait:** Extraction of flower oils (generally organic) without the use of harmful solvents, such as benzene and hexane, etc.

XX. Aconite Trade Requirement (adopted March 2017)

Sale and marketing of all species of aconite (*Aconitum* spp.) root is subject to all of the following criteria:

1. Unprocessed aconite root and products that contain unprocessed aconite root are not sold, offered for sale, or otherwise provided to consumers for oral consumption;
2. Distribution of consumer products that contain processed aconite root are limited to ensure use only under the supervision of a qualified expert; and
3. Compliance with the hazard analysis provisions of 21 CFR Part 117 is satisfied by suppliers of processed aconite root by conducting scientifically valid quantitative chemical analysis to determine that the level of aconitine and related compounds does not present a significant or unreasonable risk of illness or injury under normal or specified conditions of use.

