



AHPA Guidance Policy

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.

Quantifying liquid propriety blends in Supplement Facts under 21 C.F.R. § 101.36 (adopted June 2019)

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.”

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

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*.