



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.

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 convention²: 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 $\pm 20\%$ 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 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](#).