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.

Heavy Metals (adopted October 2008; revised July 2012)

Dietary supplement manufacturers determine what, if any, tests or examinations are appropriate for their products, whether to meet specifications established for these products or for other purposes.

With respect to herbal supplements, there are a variety of heavy metals 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 supplement, and others not included here may be relevant for some such products.

Where manufacturers choose to establish one or heavy metal specifications for herbal supplements, 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;
- for methyl mercury: 2.0 mcg/day.

For purposes of this guidance the following definition applies:

“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 (e.g., vitamins, minerals, amino acids, etc.) or excipients.

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 heavy metals in any specific herbal 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 supplements. In addition, it may not be relevant to test any specific herbal supplement to determine the level of any or all of the heavy metals identified in this guidance.

- The above quantitative limits are determined at the highest labeled dose of a supplement, and are applicable only to herbal supplements that are 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 Proposition 65.