



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.

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

WHEREAS

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);

AND WHEREAS

articles consisting of or derived from hemp may also be used as ingredients in foods if generally recognized as safe for such uses;

AND WHEREAS

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(II), that cannabidiol (CBD), including CBD from hemp, may not be included in products marketed as dietary supplements or added to products marketed as foods;

AND WHEREAS

AHPA has expressed neither agreement nor disagreement with FDA’s position on 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;

AND WHEREAS

Products marketed as dietary supplements and foods and identified as containing hemp or CBD are readily available in the U.S. market;

AND WHEREAS

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;

AND WHEREAS

The robust federal regulatory systems for dietary supplements and foods protects consumers and the supplement and food industries;

AND WHEREAS

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;

NOW THEREFORE

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; and also, that dietary supplement operations comply with applicable obligations for timely submission to FDA of any received serious adverse event reports associated with their products;

AND FURTHER

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.

AND FURTHER

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