AMERICAN HERBAL PRODUCTS ASSOCIATION

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.

Labeling of Dietary Supplements Containing Fungi Dietary Ingredients
(adopted March 2017; effective March 2019)

U.S. federal regulations establish specific labeling requirements for dietary supplement products. Marketers of dietary supplements that consist of or contain dietary ingredients derived from any multicellular fungal species should conform to all such federal regulations and the following label and labeling standards:

- Each fungal dietary ingredient included in a dietary supplement[1] is identified in the product label's declaration of nutrition information under the Supplement Facts heading, as defined in 21 CFR 101.36(b), by its common or usual name; by the part or parts of the fungal ingredient present[2,3]; and in order of predominance by weight (whether listed separately or as part of a proprietary blend).
- For purposes of this guidance, the part(s) of fungi ingredients are the stage(s) of the fungi present or, in the case of an extract, the stage(s) of the fungi from which the extract was manufactured. Parts may include, for example, fruitbody; mycelium; sclerotium; spores; etc. (see Glossary for applicable definitions).
- Ingredients other than dietary ingredients in such products are disclosed in the product label's ingredient list preceded by the words "Other ingredients," as described in 21 CFR 101.4(g). These ingredients may include, for example, the specific substrate on which the fungal ingredient is grown

[1] Fungi are actually classified in Kingdom Fungi and not in Kingdom Plantae; nonetheless, the federal regulation for labeling of dietary supplements is clear in its application to products derived from fungi species.
[2] The term "mycelium biomass" (or "mycelial biomass") may be used to mean the combination of the mycelium grown on a solid substrate and any remnant of the myceliated substrate still present.
[3] Spores naturally present in a fruitbody do not need to be identified as a separate part unless added as a stand-alone ingredient.

(including the natural substrate present in a wild-harvested ingredient) if any is still remaining in the fungal ingredient; other non-dietary ingredients used in the manufacture of the dietary supplement product, i.e., excipients such as fillers, binders, flow agents, etc.; and non-dietary ingredients that are ingredients within ingredients and are present in non-trivial amounts, such as excipients that are added to an extract (e.g., maltodextrin or the marc from the extraction starting material (e.g., "shiitake fruitbody marc").

- Inclusion of the word "mushroom" is not required on the label and in labeling of a dietary supplement product that consists of or includes fungi dietary ingredients; however, if the word is used then all of the following apply:
  - The word "mushroom" may be included in the marketer's company name wherever located on labels or labelling irrespective of the part(s) of the fungal ingredient(s) contained in the product.
  - If the word "mushroom" appears on the label's principal display panel (PDP) other than in the marketer's company name and the product contains a single fungal ingredient or more than one fungal ingredient that each consist of the same part of each of the contained fungi, the word is modified on the PDP to identify the part(s) of the fungal dietary ingredient(s) contained in the product; for example "mushroom mycelium," "mushroom spore," etc.; except that the fruitbody may be identified with the unmodified word "mushroom" (e.g., "shiitake mushroom" or "*Ganoderma lucidum* mushroom").
  - If the word "mushroom" appears on the label's PDP other than in the marketer's company name and the product contains more than one fungal ingredient consisting of different fungi parts, the word is modified on the PDP with specific terms such as "mushroom mycelia and fruitbodies" or general terms such as "mushroom complex" or "mushroom composite". When such terms are used, however, the specific fungi and/or fungi parts present are disclosed in order of predominance by weight in nutrition labeling under the Supplement Facts heading (e.g., "reishi mushroom composite (mycelium, fruitbody, spores)").
- On parts of a label other than the PDP and in labeling, sufficient information is provided to clearly communicate the part(s) of the fungi ingredient(s) contained in the dietary supplement product.

Glossary. For purposes of this guidance, the following definitions apply.

A. Terms relevant to fungal ingredients:

- “Hypha” means one unit of the filamentous structure of a fungus which together make up the mycelium. Plural form “hyphae.”
- “Fruitbody” means the fleshy reproductive stage, primarily composed of hyphae, that produces spores and provides a mechanism for their dispersion. Alternative forms are “fruit body” and “fruiting body.”
- “Mushroom” when used as a noun may be used as a synonym for “fruitbody” as defined here; when used as an adjective or descriptor, “mushroom” may be used to indicate an association with a multicellular species in the Kingdom Fungi (e.g., “mushroom mycelium”).
- “Mycelium” means the vegetative portion of a fungus composed of a mass of hyphae. Plural form “mycelia.”
- “Primordium” means the first recognizable but undifferentiated mass of hyphae from which the fruitbody develops. Plural form “primordia.”
- “Sclerotium” means a compact aggregate of hyphae. Plural form “sclerotia.”
- “Spore” means the survival or dispersal reproductive unit that is capable of germinating to produce a new hypha.
- “Substrate” means the surface or material on or from which a fungus lives, grows, or obtains its nourishment.

<u>B. Terms relevant to dietary supplement labels:</u>

- “Dietary ingredient” means an ingredient defined in 21 U.S.C. 321(ff)(1).
- “Dietary supplement” means a product defined in 21 U.S.C. 321(ff).
- “Label” means the display of written, printed, or graphic matter upon the immediate container of any article. (21 U.S.C. 321(k)).
- “Labeling” means all labels and other written, printed, or graphic matter (a) upon any article or any of its containers or wrappers, or (b) accompanying such article. (21 U.S.C. 321(m)).
- “Marc” means the botanical (including fungi) material that remains after an extraction process is complete.
- “Principal display panel” (or PDP) means the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale. (21 CFR 101.1).