NATURAL PRODUCTS ASSOCIATION

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Via Electronic Submission

Division of Dockets Management
U.S. Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Rm 1061
Rockville, Maryland 20852

Re: CITIZEN PETITION REGARDING DIETARY SUPPLEMENT LABELING OF MUSHROOMS AND MYCELIA

Dear all:

The undersigned, on behalf of the Natural Products Association[1] ("NPA") (collectively referred to herein as "Petitioners,") submit this petition under 21 C.F.R. § 10.30, among other provisions of law, to request that the Commissioner of the Food and Drug Administration ("FDA" or "the Agency"), based on the facts and arguments set forth herein, either (1) amend 21 C.F.R. § 101 to incorporate the following labeling aspects, based on the American Herbal Products Association labeling guidelines/guidance, for mushrooms[2] and/or (2) commit to exercise enforcement discretion until the Agency provides guidance or publishes a regulation concerning a standard of identity for dietary supplements or ingredients from fungal ingredients, including mushrooms, mycelia and fruiting bodies. 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 must conform to all such federal regulations and the label and labeling standards discussed within this petition.

[1] www.npanational.org
[2] https://www.ahpa.org/Files/Document%20Library/AHPAGuidancePolicies/AHPA_Guidance_on_fungi_labeling.pdf

Alternatively, Petitioners request that FDA recommend that the Secretary of the Department of Health and Human Services ("HHS") promptly issue a regulation, after notice and comment, finding that these terms are appropriate for labeling of a dietary supplement under the Act.[3]

I. ACTION REQUESTED

For the reasons that follow, Petitioners request that the FDA Commissioner, based on the facts and arguments set forth herein, either (1) amend 21 C.F.R. § 101 to incorporate the following labeling aspects, primarily based on the American Herbal Products Association (AHPA) labeling guidelines/guidance, for mushrooms and/or (2) commit to exercise enforcement discretion until the Agency provides guidance or publishes a regulation concerning a standard of identity for ingredients and supplements derived from any multicellular fungal species, along with the terms "mushroom," "mycelia," and "fruiting bodies," and their combinations and associated constituents. This Petition lists proposed guidelines and definitions that should be adopted for any guidance or regulation established by the Agency.

Alternatively, Petitioners request that FDA recommend that the Secretary of HHS promptly issue a regulation, after notice and comment, finding that these terms are appropriate for labeling of a dietary supplement under the Act.

Following either course of action, instructions should be placed in the compliance policy guidance manual (CPGM) to monitor imports for compliance with these labeling standards.

[3] Pub. L. No. 75-717, 52 Stat. 1040 (1938), as amended 21 U.S.C. §§ 301, *et seq.*

II. STATEMENT OF GROUNDS

1. Petitioner

a. NPA

Founded in 1936, NPA is the nation's largest and oldest nonprofit organization dedicated to the natural products industry. Natural products are represented by a wide array of consumer goods that grow in popularity each year. These products include natural and organic foods, dietary supplements, pet foods, health and beauty products, "green" cleaning supplies and more. Generally, natural products are considered those formulated without artificial ingredients and that are minimally processed. NPA advocates for the right of consumers to have access to products that will maintain and improve their health, and for the right of retailers and suppliers to sell these products. NPA represents over 700 members, accounting for more than 10,000 retail, manufacturing, wholesale, and distribution locations of natural products, including foods, dietary supplements, and health/beauty aids. NPA unites a diverse membership, from the small health food stores to large dietary supplement manufacturers.

NPA played a key role in the passage of the Dietary Supplement Health and Education Act of 1994 ("DSHEA").[4] This important legislation struck a balance between the need for consumers to have access to and information about safe and effective dietary supplements while also preserving the government's interest in protecting the public from unsafe products and false and misleading claims. Currently, NPA advocates before Congress, the Food and Drug Administration, the Federal Trade Commission, and other federal and state agencies, legislatures, state attorneys' general and the court.

[4] Pub. L. No. 103-417, 108 Stat. 4325.

2. DSHEA mandates clarity

DSHEA established the definition of a dietary supplement under Section 201(ff) of the Act.[5] Under this definition, a dietary supplement must, among other things, contain at least one dietary ingredient, be swallowed, not be intended to replace a meal, and not contain an ingredient found to be excluded under the race-to-market clause. DSHEA also established, under Section 413(d) of the Act, the definition of a "new dietary ingredient" ("NDI") to mean a dietary ingredient that was not marketed in the United States before October 15, 1994.[6] Although there is no statutory or regulatory definition, the term "old dietary ingredients" ("ODIs") has come to describe ingredients that were on the market prior to DSHEA and would satisfy the definition of a dietary ingredient under DSHEA. In DSHEA, Congress recognized the importance of labels, calling for them to include information, such that "consumers may make informed and appropriate health care choices for themselves and their families." Labels can be particularly significant, given that dietary supplements are often used as self-care products, and labels are an easily accessible source of information. Furthermore, label oversight is a key regulatory tool for FDA to promote the safe use of dietary supplements among consumers.

A "label" is a display of written, printed, or graphic matter upon the immediate container of any article. In contrast, 'labeling' is a more general term that includes the label and other written, printed, or graphic matter upon any article or any of its containers or wrappers or accompanying the article.

DSHEA and other federal regulations require the following information to appear on dietary supplement labels that are germane to this citizen's petition:

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[5] 21 U.S.C. § 321(ff).
[6] 21 U.S.C. 350b(d).

    - a statement of identity that contains the words “dietary supplement.” The word “dietary” may be replaced by the name of the dietary ingredient (e.g., “mushroom supplement”);
    - nutrition information in the form of a “Supplement Facts” panel, including the product serving size, the amount, and percent daily value, if established, of each dietary ingredient;
    - if a supplement contains a proprietary blend, the net weight of the blend as well as a listing of each ingredient in descending order of weight must be identified;
    - the part of the plant used, if an herb or botanical;
- a complete list of ingredients by their common or usual names, either in descending order of prominence or with the source of the dietary ingredient in the “Supplement Facts” panel following the name of the dietary ingredient (e.g., calcium (from calcium carbonate));
- safety information that is considered “material” to the consequences that may result from the use of the supplement.

While other provisions of the Act may be applicable to dietary supplement labels, this Petition arises out of an area in the regulations that needs clarity regarding nomenclature and declaratory guidelines regarding fungal ingredient dietary supplements derived from any multicellular fungal species, along with the terms “mushroom,” “mycelia,” and “fruiting bodies,” and their combinations and associated constituents. NPA and its member companies are seeking a commonsense approach to establishing a standard of identify for these ingredients and supplements in light of increasing public interest on this topic. Although FDA did not address the issue of establishing a standard of identify for these mushroom supplements and ingredients when

it recently updated its Nutrition and Supplement Facts labeling rules, agency action is urgently needed. Agency action is needed so that determinations about the appropriate declarations associated with dietary supplements derived from any multicellular fungal species are appropriately established by the regulatory body authorized by Congress to make such determinations—FDA—rather than by the courts, inconsistent labelling practices, or public opinion.

The following guidelines are appropriate for notice and comment rulemaking to 21 C.F.R. § 101 and eventual adoption by the Agency, which clarify this emerging area are as follows:

a) Each fungal dietary ingredient included in a dietary supplement is identified in the product label's declaration of nutrition information under the Supplement Facts heading, as defined in 21 C.F.R. § 101.36(b), by its common or usual name; by the part or parts of the fungal ingredient present; and in order of predominance by weight (whether listed separately or as part of a proprietary blend).

b) 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.

c) Parts may include, for example, fruitbody; mycelium; sclerotium; spores; etc.

d) 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 C.F.R. § 101.4(g). These ingredients may include, for example, the specific substrate on which the fungal ingredient is grown (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").

e) 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:

i) 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.

ii) 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").

iii) 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)”).

iv) 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.

3. Definitions

Section 201(ff) of the Act, as amended by DSHEA, specifically defines what it means to be a “dietary supplement.” All authorities from that definition apply. Specific to this Petition we request the following definitions should govern the treatment and standard of identify for fungal ingredients:

a. “Hypha” means one unit of the filamentous structure of a fungus which together make up the mycelium. Plural form “hyphae.”

b. “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.”

c. “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”).

d. “Mycelium” means the vegetative portion of a fungus composed of a mass of hyphae. Plural form “mycelia.”

e. "Primordium" means the first recognizable but undifferentiated mass of hyphae from which the fruitbody develops. Plural form "primordia."

f. "Sclerotium" means a compact aggregate of hyphae. Plural form "sclerotia."

g. "Spore" means the survival or dispersal reproductive unit that is capable of germinating to produce a new hypha.

h. "Substrate" means the surface or material on or from which a fungus lives, grows, or obtains its nourishment.

Further, 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. Spores naturally present in a fruitbody do not need to be identified as a separate part unless added as a stand-alone ingredient.

Fungi are 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, and the definitions set out in the Petition do not deviate from those federal regulations except as specifically applicable to dietary ingredients and supplements as set forth herein.

4. FDA's Interpretation and Application of 21 CFR 101.4

In passing the Act, Congress charged the FDA to "protect the public health" by ensuring that "foods are safe, wholesome, sanitary, and properly labeled." 21 U.S.C. § 393(b)(2)(A). In 1994, DSHEA established a new category of food products—dietary supplements—that have unique, comprehensive safety, labeling, manufacturing, and other related standards. DSHEA was introduced to counteract unnecessarily stringent federal intervention into the manufacturing, sale,

and labeling of products that it defined as dietary supplements.[7] Code of Federal Regulations Title 21 § 101 governs the activity of manufacturers of fungal ingredients because the FDA has specific regulations on food packaging and labels that they must follow when creating products, and specifically fungal ingredient products. Appropriate labelling and standard(s) of identify guidelines and regulations are also important because the factors on the label influence the consumer's decision to purchase the product. Section 101 of Title 21 of the CFR is also important because the label needs to state what is in the product, as not to be misleading to the consumer. The product name and label need to be truthful, as the consumer should not be misled, and the consumer needs to understand what they are purchasing.

IV. ENVIRONMENTAL IMPACT

Petitioners contend that there is no adverse environmental impact with the guidelines and definitions set forth herein. This is because a categorical exclusion from the requirements for an Environmental Assessment exists under 21 CFR § 25.30(h) in light of the fact that FDA granting this petition will not affect the environment. These guidelines and definitions should have no material impact on growing conditions, distribution channels, raw material consumption, waste production, or other potential harm to the environment. The environment is not affected because the proposed definitions and requested guidance and regulatory action do not implicate any harm to the environment, but instead, is proposed to provide information and clarity for consumers to benefit the public.

V. ECONOMIC IMPACT

[7] *See, e.g.*, 103 CONG. REC. S17049 (daily ed. Nov. 23, 1993) (statement of Sen. Hatch).

Petitioners contend that there is no material economic harm imposed by the relief sought by the Petition. To the extent that these proposed guidelines and requested agency actions impact producers, manufacturers, or distributors or fungal ingredients and supplements arising from revisions to current product labels and product definitions, the benefit to consumers and public health weighs in favor of the relief sought in this Petition. To the extent any question exists concerning the economic impact, Petitioners can supplement this Petition with information on the economic impact of this proposal can be provided if requested by the Agency.

VI. CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioners that is unfavorable to the Petition.

The undersigned has not received nor expects to receive payments, including cash and other forms of consideration, to file this information or its contents, they received or expect to receive those payments from the following persons or organizations.

The undersigned verifies, based on belief and information available to them, under penalty of perjury, that the foregoing is true and correct as of the date of the submission of this petition.

VII. CONCLUSION

For all the foregoing reasons, Petitioners request that the Agency engage in rulemaking, enaction of regulatory authority, or adoption of the definitions and guidelines proposed in this Petition. FDA's labeling authorities, including the provisions of the Act, give FDA the authority to adopt and establish the requested relief. Petitioners believe that the solution provided in this

Petition benefits the public health, inform and benefit consumers, and carry little—if any—economic or environmental impact. Accordingly, Petitioners ask the Agency to enact the various forms of requested relief.

Sincerely,
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