GUIDANCE:
Federal Labeling Requirements for Herbal Dietary Supplements

September 2019 (Revised)

Prepared by the American Herbal Products Association

Disclaimer

The information contained herein is not and should not be considered legal advice. This AHPA publication is not a substitute for the actual statutes, regulations, and agency guidance that apply to the products and activities that are discussed herein. The information contained herein is not intended to replace or supersede federal or any state statutes, regulations or guidance.

This document is specifically relevant to federal labeling requirements for dietary supplement products. No other issues related to the manufacture, marketing, or sale of food, dietary ingredients, dietary supplements, cosmetics, or any other class of consumer goods are addressed herein.

While AHPA believes the information herein is accurate, AHPA advises all individuals and entities using this information to discuss all aspects of their application of this information with an attorney or qualified consultant, or with personnel at relevant regulatory agencies.

Table of Contents

Introduction and purpose

Dietary supplements must bear labeling in accordance with applicable provisions of federal law, including the nutrition labeling requirements at sections 101.9 and 101.36 of Title 21 of the Code of Federal Regulations (21 C.F.R.).[1]

This document provides a general summary of the applicable Federal labeling requirements for members to use as a resource when labeling dietary supplement products. AHPA provides this document for informational purposes only, and AHPA intends for its members to use this document as a supplement to, and not a substitute for, the relevant statutes, regulations, and FDA's published resources (such as its Dietary Supplement Labeling Guide[2]). This guide does not comprehensively convey all of the nuances of the applicable statutes and regulations. Accordingly, AHPA recommends that all member companies and their regulatory counsel maintain familiarity with the Federal statutes and regulations that govern the labeling of dietary supplement products.

[1] Unless otherwise indicated, citations included in this document refer to sections of the 21 C.F.R.

[2] https://www.fda.gov/food/dietary-supplements-guidance-documents-regulatory-information/dietary-supplement-labeling-guide (accessed July 3, 2019). Note that FDA's Dietary Supplement Labeling Guide was originally issued in 2005 and, as of July 3, 2019, has not yet been updated to reflect the 2016 changes to the nutrition labeling regulations.

Background

The Federal Food, Drug, and Cosmetic Act (FDCA) defines certain foods as dietary supplements. In some regards, dietary supplements must comply with the same labeling requirements as conventional foods. For example, labels for both classes generally must include:

- a statement of identity on the principal display panel (PDP);
- a statement of net quantity of contents on the PDP; and
- a listing of all ingredients in order of decreasing predominance by weight (except for certain incidental additives).

The regulations applicable to both classes also include exemptions from nutrition labeling requirements for packages of a certain size as well as for certain companies with low-volume sales.

Dietary supplements also have additional, unique Federal labeling requirements of their own, such as:

- the term "dietary supplement" (or "herbal supplement," *etc.*) must appear as the statement of identity or as part of the statement of identity
- all botanical dietary ingredients must be identified either by their Latin binomial name or by the standardized common name given in AHPA's *Herbs of Commerce*, and the part of the plant must be identified
- the quantity by weight of each dietary ingredient or proprietary blend (or by volume, for liquid ingredients) must be declared.

The initial nutrition labeling requirements for dietary supplements were promulgated by the Food and Drug Administration (FDA) in 1999. Almost two decades later, on May 27, 2016, FDA published a final rule revising the nutrition labeling requirements for foods and dietary supplements. The revisions are intended to reflect the changes in science and dietary habits that have occurred since the nutrition labeling regulations were first established in 1999. The compliance dates for the revised requirements are:

- January 1, 2020 for manufacturers with $10 million or more in annual sales; and
- January 1, 2021 for manufacturers with less than $10 million in annual food sales.

FDA has indicated that products **labeled** on or after the relevant compliance date must comply with the revised regulations.

A brief summary of the revised regulations' changes to dietary supplement labeling requirements is contained in Appendix I. Major changes include revisions to what must be declared; for instance, vitamin D, potassium, and added sugars are now "mandatory nutrients"

required to be declared when present at significant amounts, while vitamin A and vitamin C are no longer "mandatory nutrients." Manufacturers must keep track of what sugars in the product are "added sugars" (including, for example, from acidulants and flavors) versus naturally-occurring sugars. Likewise, folic acid must now be distinguished from naturally-occurring folate. Additionally, reference values used to calculate the percent Daily Value (DV) for declaration on the Supplement Facts box were updated for most dietary ingredients with established DVs. Further, units of measure were changed for a few dietary ingredients, such as vitamin A, folate, vitamin D, and vitamin E.

For dietary supplements, the revisions mostly affect products that provide significant levels of dietary ingredients with Reference Daily Intake (RDI) values or Daily Reference Values (DRV) established in § 101.9(c) (collectively referred to as "Daily Values" or "DVs"), such as vitamins, or macronutrients such as fat, sugars, and cholesterol. Since herbal supplements often do not provide significant amounts of any, these products may not see many changes in nutrition labeling compared to the old regulations.

However, because the new regulations include changes to the list of "mandatory nutrients" and to the DVs for most vitamins and minerals, herbal supplement manufacturers should ensure that their products' Supplement Facts boxes are compliant, including by assessing whether any previously undeclared vitamins or minerals should now be added to the Supplement Facts box or if previously declared vitamins or minerals should now be removed.

Primary Required Information on Dietary Supplement Labels

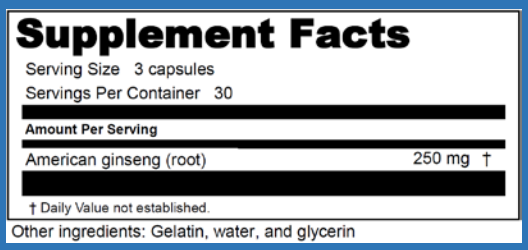
A mockup of an herbal dietary supplement label follows below:

Directions: Take 3 capsules twice a day.

[LOGO/PRODUCT NAME]

Herbal Supplement

90 capsules



Distributed by:
ABC Company, Inc.
Silver Spring, MD 20910
(301) 588-1171
Product of Canada

The table and descriptions below provide an overview of the primary required information on dietary supplement labels and the panel on which the information should appear.

Principal Display Panel	Information Panel (*panel to the immediate right of PDP*)	Any label panel
• **Statement of Identity** (e.g., *herbal supplement* or *dietary supplement*) – MUST include the word "supplement" • **Net Quantity of Contents Declaration** (in numerical count (e.g., 30 capsules), or if in volume or weight, both in metric and U.S. Customary System terms)	• **Supplement Facts** • **Ingredients** • **Major Food Allergens** • **Name and Place of Business of Manufacturer, Packer, or Distributor** (if the listed company is not the manufacturer, you must include, e.g., "Distributed by" or "Manufactured for") ***Note:*** *There should be no intervening material appearing between the information above. For example, any UPC, logos, directions for use, and claims may not separate the above information, but may be placed after all of the above information.*	• **Full Domestic Street Address or Phone Number** for receiving adverse event reports • **Directions for Use** (voluntary, unless necessary for safe use) • **Warnings** (voluntary, unless necessary for safe use) • **Country of Origin** (voluntary, unless product is foreign-sourced) • **DSHEA Disclaimer** (voluntary, unless structure/function claims are made)

Principal Display Panel

The Principal Display Panel (PDP) of packaged foods, including dietary supplements, is defined in § 101.1 as "the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for retail sale." The PDP must be "large enough to accommodate all the mandatory label information required to be placed thereon … with clarity and conspicuousness." Most commonly, the PDP is the front panel on a rectangular container, or, for a cylindrical container, 40% of the vertical surface area (i.e., 40% of the product of the height times the circumference).

The regulations require that PDPs on dietary supplements include:

Statement of Identity. The product must be designated using the term "dietary supplement," "except that the word 'dietary' may be omitted and replaced by the name of the dietary ingredients in the product (*e.g.*, calcium supplement) or an appropriately descriptive term indicating the type of dietary ingredients that are in the product (*e.g.*, herbal supplement with vitamins)" (§ 101.3). The statement of identity must appear in bold type, in "a size reasonably related to the most prominent printed matter on such panel … in lines generally parallel to the base on which the package rests as it is designed to be displayed."

Net Quantity of Contents Declaration. The net quantity of contents must be expressed in terms of weight, measure, numerical count, or a combination of numerical count and weight or measure (§ 101.7). The regulation specifies that, "[w]hen the declaration of quantity of contents by numerical count does not give adequate information as to the quantity of food in the package, it shall be combined with such statement of weight, measure, or size of the individual units of the foods as will provide such information." Quantities may be stated in either decimal (to two places) or common fraction (to 1/32). Except on very small packages, this information must be located in the bottom 30 percent of the PDP and sufficiently legible.

Liquids. Labels of foods in liquid form are generally required to state net quantity in fluid measure in terms of U.S. gallons and quart, pint, and fluid ounce divisions thereof. Per the Fair Packaging and Labeling Act, metric equivalents must also be included.

Solids. Labels of foods in solid form are generally required to state net quantity by weight and in terms of avoirdupois pounds and ounces. Per the Fair Packaging and Labeling Act, metric equivalents must also be included. If declaring the net quantity of contents in terms of weight, the term "net weight" or "net wt." is required.

Duplicate information. A duplication of all of the above information must be included on all PDPs for any packages that bear multiple PDPs (*e.g.*, a labeled bottle in an outer-package carton).

Information Panel

As defined by § 101.2, the information panel of packaged foods, including dietary supplements, is generally the panel contiguous to and immediately to the right of the PDP. The following information should appear on the information panel.

Supplement Facts. The nutrition information for a dietary supplement is required to appear in a Supplement Facts box. See *Nutrition Labeling/Supplement Facts section below.* Dietary ingredients[3] included in dietary supplements must be identified in the Supplement Facts box, except when a product is exempt (*see below*).

Ingredients. All of the ingredients in foods must be designated by their common or usual name in decreasing order of predominance by weight (§ 101.4). For dietary supplements, ingredients that are listed in the Supplement Facts box are not required to be repeated in a list of ingredients.

Other ingredients--such as fillers, binders, flavors, etc.--must be listed separately in the information panel, preceded by the word "Ingredients" or words "Other ingredients" (§ 101.4(g)). "Other ingredients" should be used if some of the ingredients appear in the Supplement Facts box and are therefore omitted from the list of ingredients.

Incidental additives that are present in a dietary supplement "at insignificant levels and do not have any technical or functional effect" in the product are not required to be listed on the label (§ 101.100(a)(3)). Note that this is a rare exception; generally, carriers, binders, preservatives, and other similar ingredients must be declared. AHPA recommends consulting legal counsel before determining that an ingredient meets the definition of an incidental additive and thus may be omitted from the ingredient listing.

Major Food Allergens. The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) revised the FDCA, adding the requirement for the labels of food products that contain any ingredient (including a flavor, color, or incidental additive) that is or contains protein from a major food allergen to declare those major food allergens. The major food allergens are milk, eggs, fish (e.g., bass, flounder, cod), Crustacean shellfish (e.g., crab, lobster, shrimp), tree nuts (e.g., almonds, walnuts, pecans, coconuts[4]), peanuts, wheat, and soybeans. FALCPA requires the type of tree nut (e.g., almonds, pecans, walnuts); the type of fish (e.g., bass, flounder, cod); and the type of Crustacean shellfish (e.g., crab, lobster, shrimp) to be declared. Exemptions include highly refined oils derived from one of the eight major food allergens and any ingredient derived from such highly refined oil.

[3] Per FDCA § 201(ff), a dietary ingredient is: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any of the above.

[4] FDA has included a list of nuts it considers to be tree nuts for the purposes of FALCPA labeling requirements in its Guidance for Industry: Questions and Answers Regarding Food Allergens (Edition 4) (November 2006) (available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-allergens-edition-4) (accessed July 3, 2019).

Food manufacturers have two options for labeling major food allergens in the product. The first option is to ensure that the names of the major food allergen food sources are included in the list of ingredients. If the common or usual names of the ingredients do not already include the names of the major allergen food sources, then the names of the major allergen food sources should appear in parentheses after the common or usual names of the ingredients in the list of ingredients (e.g., "lecithin (soy)" or "whey (milk)").

The second option is to place the word "Contains" followed by the name of the major allergen food source immediately after or adjacent to the list of ingredients, in type size that is no smaller than the type size used for the list of ingredients (e.g., "Contains soy and milk").

Name and Place of Business of Manufacturer, Packer, or Distributor. In addition to the name of the manufacturer, packer, or distributor, the label must identify its place of business by city, state, and ZIP code (§ 101.5). A street address is also required if the business address is not listed in a current city or telephone directory (*But also see the separate requirement below to include either the full domestic street address or phone number of a responsible person on the label*). If the company named is not the manufacturer, the label must clearly disclose this fact using a statement like "Manufactured for..." or "Distributed by..."

The regulations provide that no intervening material shall appear between the Supplement Facts, Ingredients, and Name and Place of Business information above. For example, any UPC, logos, directions for use, and claims may not separate the above information.

Information that May Appear on Any Panel

The following summarizes other information that is or may be required on a dietary supplement label but is not specifically required to appear on a particular panel.

Full Domestic Street Address or Phone Number. The Dietary Supplement and Nonprescription Drug Consumer Protection Act requires dietary supplement labels to bear either a full domestic street address or a domestic phone number through which the responsible person may receive reports of serious adverse events. Accordingly, a U.S. manufacturer, packer, or distributor may wish to include its full street address even if the address is listed in a current city or telephone directory and thus could be omitted for purposes of the name and place of business requirement above. If the full street address is omitted, a U.S. phone number would need to be included on the label.

Directions for Use. Dietary supplements commonly contain recommended directions for use. Directions are voluntary unless they are necessary to assure safe use. Note that the serving size for a dietary supplement product as stated in the Supplement Facts panel is determined based on any recommended directions for use appearing on the label. Specifically, FDA's regulations specify that the appropriate serving size for a dietary supplement is the "maximum amount recommended . . . on the label for consumption per eating occasion or, in the absence of recommendations, 1 unit, e.g., tablet, capsule, packet, teaspoonful, etc." (§101.12). Thus, for example, if the directions on the label state to "Take 3 capsules twice a day," the serving size

that should appear in the Supplement Facts box is "3 capsules," and all nutrition information should be declared accordingly.

Warnings. Specific warning label requirements are defined in §101.17 for products in pressurized containers or containers containing ozone-depleting compounds; certain protein products represented for use in reducing weight; certain dietary supplement products containing iron or iron salts; foods containing psyllium husk or psyllium seed husk and bearing a health claim regarding an associated reduced risk of coronary heart disease; and unprocessed juices.

In addition, the FDCA generally requires that the labeling of all products must provide any information that would be considered material to the consumer for use of the product under the conditions of use recommended in the labeling or the usual conditions of use. This would include any relevant warnings necessary for safe use of the product.

AHPA recommends certain specific cautionary label statements; these may be found in AHPA's *Code of Ethics*[5] and in related AHPA Guidance Policies.[6] These cautionary statements apply to products that contain certain specific herbs-e.g., senna and other stimulant laxative herbs; chaparral; kava; St. John's wort; caffeine-containing herbs; herbs labeled for use my pregnant or nursing women; and herbs listed in Classes 2b (not to be used during pregnancy) and 2c (not to be used while nursing) of AHPA's *Botanical Safety Handbook*, 2nd edition (2013).

Country of Origin. Under the U.S. Tariff Act, U.S. Customs and Border Protections (CBP) implements the requirement to "mark" the country of origin for products of foreign origin. If dietary supplement products or their ingredients are imported, a country of origin declaration may be required. The determination of the appropriate country of origin for a product is a very fact-specific analysis, including, for instance, determining whether the processing in one country of ingredients from another country constitutes a "substantial transformation" such that the country in which the ingredients were processed should be considered the country of origin of the resulting product. AHPA recommends that members work with their legal counsel on questions about country of origin labeling.

***Note*:** While substantiation of claims is beyond the scope of this guide, AHPA notes here a caution about "Made in the USA" claims. Making such a claim is distinct from compliance with country of origin labeling requirements. The U.S. Federal Trade Commission, the Federal agency that enforces the Federal Trade Commission Act's prohibitions on false and deceptive advertisements, considers "Made in the USA" claims for a product to be misleading unless the product was "all, or virtually all" made in the United States. Thus, the FTC would likely consider a "Made in the USA" claim to be misleading for a dietary supplement product that contains a significant amount of foreign ingredients, even if the subsequent processing of the ingredients in the United States qualified as a "substantial transformation" under a CBP country-of-origin analysis.

[5] http://www.ahpa.org/AboutUs/AHPASPolicies/CodeofEthics.aspx (accessed July 3, 2019).

[6] http://www.ahpa.org/AboutUs/AHPASPolicies/GuidancePolicies.aspx (accessed July 3, 2019).

Bioengineered Food Disclosure Standard. The National Bioengineered ("BE") Food Disclosure Standard ("NBFDS"), codified in 7 C.F.R. part 66, requires food manufacturers, importers, and certain retailers to disclose whether food offered for sale is BE or uses BE food ingredients. BE food means a food (including dietary supplements) that contains detectable genetic material that has been modified through *in vitro* rDNA techniques and for which such modification could not otherwise be obtained through conventional breeding or found in nature. The regulation sets forth the method for concluding that such modification is not "detectable" (7 C.F.R. § 66.9(a)).

The NBFDS includes categories of exemptions to the disclosure requirement that may be relevant to member companies, including: (i) very small food manufacturers, defined as any food manufacturer with annual receipts of less than $2,500,000; (ii) a food in which no ingredient intentionally contains a BE substance, with an allowance for inadvertent or technically unavoidable BE presence of up to five percent (5%) for each ingredient; and (iii) food certified under the National Organic Program (7 C.F.R. § 66.5).

The NBFDS requires that disclosure be made on particular panels of the product packaging (detailed at 7 C.F.R. § 66.100(d), except in the case of bulk food (7 C.F.R. § 66.114)). The BE disclosure contained on the food package may be made in one of the following four forms: (i) text, (ii) symbol, (iii) electronic or digital link, or (iv) text message (7 C.F.R. § 66.100(b)); however, there are additional alternatives for small food manufacturers or for disclosures to be included on small and very small packages (7 C.F.R. § 66.110 and 7 C.F.R. § 66.112, respectively).

Relevant dates for implementation and compliance with the NBFDS are as follows:

1. Implementation Date: January 1, 2020 (January 1, 2021, for small food manufacturers, defined as any food manufacturer with annual receipts of at least $2,500,000 but less than $10,000,000) (7 C.F.R. § 66.13(a)). The USDA understands this to mean the date when regulated entities should prepare to fully comply with the NBFDS (e.g., identifying foods that may require a BE disclosure, records to meet the recordkeeping requirements, etc.).
2. Voluntary Compliance Date: Ends on December 31, 2021. The USDA understands this to mean the last date when foods entering commerce may voluntarily comply with the NBFDS and the last date that preempted state labels may enter commerce (7 C.F.R. § 66.13(b)). The USDA considers a food to have "entered commerce" on the date it is labeled for retail sale.
3. Mandatory Compliance Date: January 1, 2022 (7 C.F.R. § 66.13(c)). The USDA understands this to be the date when foods entering commerce must be labeled in accordance with the NBFDS.

DSHEA Disclaimer. Any dietary supplement label that displays a so-called "structure/function claim," e.g., a statement describing the role of or characterizing the documented mechanism by which a nutrient or dietary ingredient is intended to affect or maintain the structure or function of the body in humans, must include a disclaimer (§101.93). The disclaimer reads "This statement has [or These statements have] not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

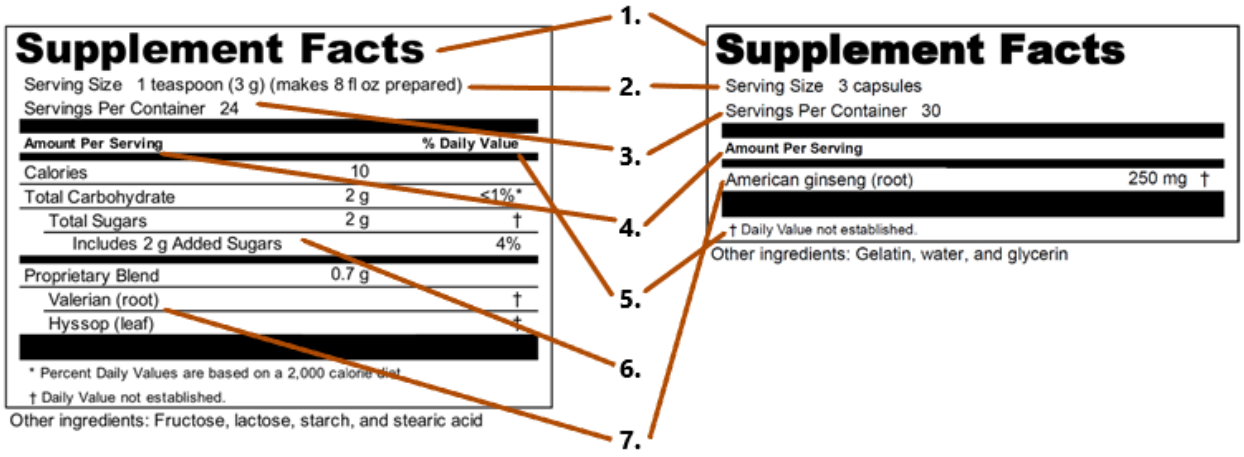
The disclaimer must appear in bold type on the same display panel as the structure/function claim. If the disclaimer is not immediately adjacent to the structure/function claim(s) on the label, then it must be set off in a box and be linked to the structure/function claim(s) with a symbol (e.g., an asterisk).

Nutrition Labeling/Supplement Facts

Federal regulations for "nutrition labeling of dietary supplements" are codified in 21 C.F.R. §101.36, which refers to other sections of the title, especially §101.9, "Nutrition labeling of food."

Nutrition labeling, in the form of a Supplement Facts box, is required on all dietary supplements, unless an exemption applies (*see below*). Although many of the nutrition labeling requirements for conventional foods apply to dietary supplements, there are significant differences. For example, conventional foods must bear nutrition labeling in the form of a Nutrition Facts box, which is subject to different formatting requirements from those applicable to a Supplement Facts box. In addition, Supplement Facts are not permitted to declare nutrients that are not present or are present in amounts reportable as zero. Thus, while a conventional food label may include Nutrition Facts declaring "0 g" of total fat, such a declaration would not be permitted in the Supplement Facts on a dietary supplement label.

Below are two sample Supplement Facts boxes derived from FDA's examples, which AHPA has annotated to show the major elements of a Supplement Facts box:



The following items must be included as part of the nutrition label on all dietary supplements that do not qualify for an exemption *(for a discussion of exemptions, see below):*

1. the title **"Supplement Facts"**
2. the subheading "Serving Size," with the serving size "expressed using a term that is appropriate for the form of the supplement, such as 'tablets,' 'capsules,' 'packets,' or 'teaspoonfuls'." FDA's regulations specify that the appropriate serving size for a dietary supplement is the "maximum amount recommended . . . on the label for consumption per eating occasion or, in the absence of recommendations, 1 unit, e.g., tablet, capsule, packet, teaspoonful, etc." (§101.12). Thus, for example, if the directions on the label state to "Take 3 capsules twice a day," the serving size

that should appear in the Supplement Facts box is "3 capsules," and all nutrition information should be declared accordingly

3. the subheading "Servings Per Container," with the servings per container rounded to the nearest whole number if > 5, and to the nearest 0.5 serving if < 5. Any rounding must be indicated by the use of the term "about" (e.g., "about 2 servings" or "about 3.5 servings"). (§101.9(b)(8)). ***Note:*** Servings Per Container is not required if the number of servings per container is the same as the net quantity of contents stated on the PDP
4. the column heading **"Amount Per Serving,"** or a heading consistent with the serving size, e.g., "Amount Per Capsule" or "Each Capsule Contains"
5. the column heading **"% Daily Value"** on the same line and to the right of the "Amount Per Serving" heading. ***Note:*** "Daily Value" can be abbreviated as "DV" if the acronym is explained in a footnote. In addition, this heading may be omitted entirely if the Supplement Facts box does not include any dietary ingredients with an RDI or DRV established in §101.9(c)
6. information on dietary ingredients that have a Reference Daily Intake (RDI) or Daily Reference Value (DRV) established in §101.9(c). These ingredients include vitamins and minerals as well as macronutrients like calories, fats, sugars, etc., and certain of their subcomponents. These are referred to collectively in §101.36 as the **"(b)(2)-dietary ingredients"** because they are discussed in §101.36(b)(2). Whether information must be provided on each (b)(2)-dietary ingredient depends on several factors, including the level at which it is present, whether a claim is made about the dietary ingredient, and whether the dietary ingredient is added for supplementation. The required information consists of:
   a) the name of the (b)(2)-dietary ingredient
   b) the quantitative amount per serving by weight
   c) the %DV represented by the quantitative amount per serving-- *except that* no such percent is given for calories or for those (b)(2)-dietary ingredients that lack an established DV (e.g., total sugars, polyunsaturated fat, and soluble fiber). If the %DV is declared for total fat, saturated fat, total carbohydrates, dietary fiber, protein or added sugars, the values must be accompanied by a symbol that refers to a footnote in the Supplement Facts Box that states, "Percent Daily Values are based on a 2,000 calorie diet."

Note: Requirements related to nutrition labeling for the (b)(2)-dietary ingredients are specified in the accompanying table, *Nutrition Labeling of "(b)(2)-dietary ingredients" in Dietary Supplements*.

7. Information on dietary ingredients for which RDIs and DRVs have not been established. These ingredients are referred to in §101.36 as "other dietary ingredients" and include all the "dietary ingredients" defined by DSHEA that are not (b)(2)-dietary ingredients. For AHPA members, the most relevant "other dietary ingredients" are herbs and herbal extracts.[7] Information on "other

[7] Note that AHPA's Code of Ethics includes a trade requirement related to the labeling of herbal extracts, which is available at http://www.ahpa.org/AboutUs/AHPAsPolicies/CodeofEthics.aspx (accessed July 3, 2019). AHPA has also issued several Guidance Policies on this subject, including:

- AHPA Guidance Policy on Extract Labeling (rev. 2010), available at http://www.ahpa.org/Portals/0/PDFs/Policies/Guidance-Policies/AHPA_Extract_Labeling.pdf (accessed July 3, 2019); and
- AHPA Guidance Policy on Labeling of Alcohol-Removed Products (2016), available at http://www.ahpa.org/Portals/0/PDFs/Policies/Guidance-Policies/AHPA_Labeling_Alcohol_Removed_Products.pdf (accessed July 3, 2019).

dietary ingredients" must appear in the section below the section listing (b)(2)-dietary ingredients in the Supplement Facts box, and include:

a. the common or usual name of the ingredient. Botanical ingredients (including fungi and algae) must be identified by the Latin binomial, unless the botanical is listed in AHPA's *Herbs of Commerce*. In the latter case, the standardized common name given in *Herbs of Commerce* can be used instead. For guidance on labeling fungi ingredients, see AHPA's Guide *Labeling of Dietary Supplements Containing Fungi Dietary Ingredients* in Appendix II.[8]
b. for a botanical, the part of the plant from which the ingredient is derived (except for algae)
c. the quantitative amount of the ingredient by weight, stated in metric measure. (But see §101.36(b)(3)(ii)(B) and (C) for information on declaring liquid extracts.[9]) This amount must be exclusive of the amount of any of its components or its source. The constituents of any such ingredient, however, may be listed and quantified as subcomponents. Also, all of the source ingredients that supply a dietary ingredient may be identified immediately following the listed dietary ingredient in parentheses. For example, "calcium (as calcium carbonate)"
d. a symbol, such as an asterisk, that refers to the statement "Daily Value not established."

Note: A proprietary blend of dietary ingredients may be identified as "Proprietary Blend" or by some other appropriately descriptive term (§101.36(c)). All the ingredients contained in the proprietary blend must be listed -- indented under the term "Proprietary Blend" -- in descending order of predominance in either column or linear format. The quantitative requirement is satisfied for a proprietary blend merely by stating the quantity of the blend; the quantities of each ingredient of the blend need not be stated. Reference to the statement "Daily Value not established" is, however, required for a listed "Proprietary Blend."

Specific type size and layout requirements for all nutrition labeling for dietary supplements can be found at §101.36(e); for small packages, such requirements may be found at §101.36(i)(2) and 101.9(j)(13). Special labeling provisions can be found at §101.36(i) and the specified corresponding provisions at 101.9(j) (e.g., those for dietary supplements represented to be specifically for infants or children 3 years or under, for small or intermediate-sized packages, for products sold in multiunit food containers or in bulk containers, and for products in packages that are not small- or intermediate-sized but that do not provide sufficient space to accommodate all required label information).

[8] AHPA's Guide *Labeling of Dietary Supplements Containing Fungi Dietary Ingredients* is available at http://www.ahpa.org/Portals/0/PDFs/Policies/Guidance-Policies/AHPA_Guidance_on_fungi_labeling.pdf.

[9] For a liquid extract from which the solvent has not been removed, the quantity listed shall be the weight or volume of the total extract. For an extract from which the solvent has been removed, the weight of the ingredient shall be the weight of the dried extract.

Nutrition Labeling of "(b)(2)-dietary ingredients" in Dietary Supplements

The table below lists the "(b)(2) dietary ingredients" that may require declaration in the Supplement Facts box of a dietary supplement product's label. As noted in the table, different requirements apply to determine whether each dietary ingredient should be declared in the Supplement Facts box, depending on whether the amount is above or below a certain threshold, whether a claim is made about the dietary ingredient, and whether the dietary ingredient is added to the product for supplementation purposes. Note that:

- These dietary ingredients appear in the order in which they must be listed
- None of these dietary ingredients may be declared in the Supplement Facts box if they are present at an amount that can be declared as zero.
- Generally, these dietary ingredients must be identified by the name as listed in the table, and the quantity should be rounded in accordance with the increments listed in the "Round To:" column.
- This table reflects only the established Daily Values for adults and children over 4 years of age and the labeling requirements for dietary supplement products intended for this age group. There are different established Daily Values for infants, children 1 to 3 years old, and pregnant and lactating women (see § 101.9(c)(8)(iv) & (9)), and some labeling requirements may differ for products intended for these other populations.
- When calculating the %DV, the actual (unrounded) weight of the dietary ingredient should be used, except that the weight declared on the label (rounded) may be used when calculating the %DV for total fat, saturated fat, cholesterol, sodium, potassium, total carbohydrate, and dietary fiber (§101.36 (b)(2)(iii)(B)).
- Generally, the %DV must be expressed to the nearest whole percent, except that "less than 1%" or "<1%" must be used if the nearest whole percent is zero.

Dietary Ingredient	Units	**Amount** that can be declared zero	**Mandatory** Must declare when present above the amount that can be declared zero	**Voluntary** Must declare when a claim is made	**Voluntary** Must declare when added for supplementation	**Daily value** (Adults & children ≥ 4 years)	Round to
Calories or "Calories (Energy)" [1]	Calories	< 5 cal	X			N/A	Nearest 5 (for ≤ 50 Cal) Nearest 10 (for > 50 Cal)
Calories from Saturated Fat	Calories	< 5 cal		X		N/A	Nearest 5 (for ≤ 50 Cal) Nearest 10 (for > 50 Cal)
Total Fat	Grams (g)	< 0.5 g	X			78	Nearest 0.5 g (for < 5 g) Nearest 1 g (for > 5 g)
Saturated Fat	Grams (g)	< 0.5 g	X			20	Nearest 0.5 g (for < 5 g) Nearest 1 g (for > 5 g)
Trans Fat	Grams (g)	< 0.5 g	X			N/A	Nearest 0.5 g (for < 5 g) Nearest 1 g (for > 5 g)
Polyunsaturated Fat[2]	Grams (g)	< 0.5 g		X		N/A	Nearest 0.5 g (for < 5 g) Nearest 1 g (for > 5 g)
Monounsatured Fat[3]	Grams (g)	< 0.5 g		X		N/A	Nearest 0.5 g (for < 5 g) Nearest 1 g (for > 5 g)
Cholesterol	Milligrams (mg)	< 2 mg	X			300	Nearest 5 mg
Total Carbohydrate[4]	Grams (g)	< 0.5 g	X			275	Nearest 1 g
Dietary Fiber	Grams (g)	< 0.5 g	X			28	Nearest 1 g
Soluble Fiber	Grams (g)	< 0.5 g		X		N/A	Nearest 1 g
Insoluble Fiber[5]	Grams (g)	< 0.5 g		X		N/A	Nearest 1 g
Total Sugars[6]	Grams (g)	< 0.5 g	X			N/A	Nearest 1 g
Added Sugars[7]	Grams (g)	< 0.5 g	X			50	Nearest 1 g

[1] The amount in kilojoule units may also be declared, in parentheses, immediately after the number of Calories. Calorie calculations should take into account caloric contributions from all sources (e.g., amino acids, flavors, carriers, and acidulants).

[2] Must be declared if monounsaturated fat is declared.

[3] Must be declared if polyunsaturated fat is declared.

[4] May declare "<1g" (for 0.5 - <1 g). Carbohydrate calculations should take into account contributions from all sources (e.g., carbohydrates from flavors, sugar, sugar alcohols, and fiber).

[5] May declare "<1g" (for 0.5 - <1 g)

[6] May declare "<1g" (for 0.5 - <1 g)

[7] May declare "<1g" (for 0.5 - <1 g). Should be stated as "Includes X g Added Sugars". Generally, "added sugars" include sugars, sugars from syrups and honey, and sugars from concentrated fruit or vegetable juices. See 101.9(c)(6)(iii) for full definition.

Dietary Ingredient	Units	**Amount** that can be declared zero	**Mandatory** Must declare when present above the amount that can be declared zero	**Voluntary** Must declare when a claim is made	**Voluntary** Must declare when added for supplementation	**Daily value** (Adults & children ≥ 4 years)	Round to
Sugar Alcohol[8]	Grams (g)	< 0.5 g		X		N/A	Nearest 1 g
Protein[9]	Grams (g)	< 0.5 g	X			50	Nearest 1 g
Vitamin A[10]	Micrograms RAE (mcg)	< 2% DV		X	X	900	
Vitamin C or "Vitamin C (ascorbic acid)"	Milligrams (mg)	< 2% DV		X	X	90	
Vitamin D[11]	Micrograms (mcg)	< 2% DV	X			20	
Vitamin E[12]	Milligrams (mg)	< 2% DV		X	X	15	
Vitamin K	Micrograms (mcg)	< 2% DV		X	X	120	
Thiamin or "Thiamin (vitamin B1)"	Milligrams (mg)	< 2% DV		X	X	1.2	
Riboflavin or "Riboflavin (vitamin B2)"	Milligrams (mg)	< 2% DV		X	X	1.3	
Niacin	Milligrams NE (mg)	< 2% DV		X	X	16	
Vitamin B6	Milligrams (mg)	< 2% DV		X	X	1.7	
Folate[13]	Micrograms DFE (mcg)	< 2% DV		X	X	400	
Vitamin B12	Micrograms (mcg)	< 2% DV		X	X	2.4	
Biotin	Micrograms (mcg)	< 2% DV		X	X	30	
Pantothentic acid	Milligrams (mg)	< 2% DV		X	X	5	
Choline	Milligrams (mg)	< 2% DV		X	X	550	

[8] May declare "<1g" (for 0.5 - <1 g). May use name of specific sugar alcohol (e.g., sorbitol), provided that only one sugar alcohol is present.

[9] May declare "<1g" (for 0.5 - <1 g). The % DV is voluntary, but if present, it must be calculated using the corrected amount of protein as specified in 101.9(c)(7). There are requirements regarding protein quality. See 101.9(c)(7). See AHPA *Guidance Policy on Labeling of Protein in Food and Dietary Supplements* at Appendix III and available at: www.ahpa.org/Portals/0/PDFs/Policies/Guidance-Policies/AHPA_Labeling_Protein_FoodDietarySupplements.pdf (accessed July 3, 2019).

[10] Beta-carotene must be declared as the percent of Vitamin A present if a beta-carotene claim is made. Otherwise, declaration is voluntary and may be declared with or without quantity (e.g., "Vitamin A (90% as beta-carotene)" or "Vitamin A (90% (810 mcg) as beta-carotene"). RAE = Retinol activity equivalents; 1 microgram RAE = 1 microgram retinol, 2 micrograms supplemental β-carotene, 12 micrograms dietary β-carotene, or 24 micrograms dietary α-carotene, or 24 micrograms dietary β-cryptoxanthin.

[11] The amount of vitamin D may include an additional declaration in International Units (IU) in parentheses after the mcg declaration.

[12] 1 mg α-tocopherol (label claim) = 1 mg α-tocopherol = 1 mg RRR- α-tocopherol = 2 mg *all rac*-α-tocopherol.

[13] DFE = Dietary Folate Equivalents; 1 DFE = 1 mcg naturally occurring folate = 0.6 mcg folic acid. Folate may be expressed as a %DV in conventional foods. When folic acid is added or when a claim is made about the nutrient, folic acid must be declared in parentheses, as mcg of folic acid.

Dietary Ingredient	**Units**	**Amount** that can be declared zero	**Mandatory** Must declare when present above the amount that can be declared zero	**Voluntary** Must declare when a claim is made	**Voluntary** Must declare when added for supplementation	**Daily value** (Adults & children ≥ 4 years)	**Round to**
Calcium	Milligrams (mg)	< 2% DV	X			1,300	
Iron	Milligrams (mg)	< 2% DV	X			18	
Phosphorus	Milligrams (mg)	< 2% DV		X	X	1,250	
Iodine	Micrograms (mcg)	< 2% DV		X	X	150	
Magnesium	Milligrams (mg)	< 2% DV		X	X	420	
Zinc	Milligrams (mg)	< 2% DV		X	X	11	
Selenium	Micrograms (mcg)	< 2% DV		X	X	55	
Copper	Milligrams (mg)	< 2% DV		X	X	0.9	
Manganese	Milligrams (mg)	< 2% DV		X	X	2.3	
Chromium	Micrograms (mcg)	< 2% DV		X	X	35	
Molybdenum	Micrograms (mcg)	< 2% DV		X	X	45	
Chloride	Milligrams (mg)	< 2% DV		X	X	2,300	
Sodium	Milligrams (mg)	< 5 mg	X			2,300	Nearest 5 mg for 5-140 mg Nearest 10 mg for > 140 mg
Potassium	Milligrams (mg)	< 2% DV	X			4,700	
Fluoride	Milligrams (mg)	< 0.1 mg		X	X	N/A	Nearest 0.1 mg for ≤ 0.8 mg Nearest 0.2 mg for > 0.8 mg

Exemptions from Nutrition Labeling

Products may be exempted from the requirement to provide nutrition labeling under certain circumstances. Exemptions to nutrition labeling for dietary supplements are:

1. Products not offered for sale, such as samples (§ 101.36(a)).
2. Products with labels, labeling, and advertising that do not provide nutrition information or make a nutrient content or health claim and are sold by a retailer who has annual gross sales of not more than $500,000 or has annual gross sales of food of not more than $50,000 (§ 101.36(h)(1) and § 101.9(j)(1)).
3. Products shipped in bulk and not intended for distribution to customers in such form that are for use solely in the manufacture of other dietary supplements or that are to be processed, labeled, or repacked at a site other than where originally processed or packed (§ 101.36(h)(3)).
4. Products in small packages with less than 12 square inches of total surface area to bear labeling provided that (a) the product's label, labeling, and advertising do not provide nutrition information or bear a nutrition claim (except for calorie labeling of products sold in vending machines per § 101.8(c)); and (2) package labels provide an address or telephone number that consumers can contact to obtain nutrition information (e.g., "For nutrition information call 1-800-123-4567") (§ 101.36(i)(2) and § 101.9(j)(13)(i)).
5. Low-volume products of small businesses, if each of the following conditions is met: (a) the product must have annual U.S. sales (or anticipated sales, for new products) of fewer than 100,000 units[10] in the previous 12-month period; (b) the company claiming the exemption (together with its affiliates) had fewer than an average of 100 full-time-equivalent employees in the preceding 12 months; (c) the product's label, labeling, or advertising does not provide nutrition information or make a nutrient content or health claim; and (d) an annual notice is filed with FDA to request the exemption.[11] If any of these conditions ceases to apply (e.g., the company sells more than 100,000 units of the product), the product has 18 months to come into compliance from the date that the condition ceased to apply (§ 101.36(h)(2) and § 101.9(j)(18)).

[10] § 101.9(j)(18)(vi) states that a unit is a package (i.e., not a capsule or tablet), or, if there is no packaging, the form in which the product is offered for sale to the consumer. The regulation also indicates that, in calculating the units of a product sold, all package sizes of a product with the same statement of identity and similar preparation methods, manufactured by a single manufacturer or bearing the same brand name, should be cumulated.

[11] The notice must certify the average number of full-time equivalent employees and sales units in the previous year. (See § 101.9(j)(18)(iv) for specific notice information requirements.) The annual filing requirement for products that have annual sales of less than 10,000 units is waived for companies that are not importers and have fewer than 10 full-time-equivalent employees.

Small- and Intermediate-Sized Packages – Other Special Provisions

In addition to the exemption from nutrition labeling (*above*), products in small- and intermediate-sized packages are permitted some flexibility in complying with the requirements.

Calculating Package Size. The "total surface area available to bear labeling" is not clearly defined in this part of the regulations, but it is presumably measured in a manner consistent with that provided at § 101.1 (determining the size of the PDP), including, for example, excluding tops, bottoms, flanges at tops and bottoms of cans, and shoulders and necks of bottles or jars.

Formats. Dietary supplements packaged in intermediate-sized packages that have a total surface area available to bear labeling of 40 or less square inches may bear modified nutrition labeling according to special formatting provisions – including the use of tabular or linear formats and certain specifically defined abbreviations (§ 101.36(i)(2) and § 101.9(j)(13)(ii)).

Type Size. Smaller packages may use a smaller type-size, as follows (§ 101.36(i)(2)(i) and (ii)):

Small-sized packages (Less than 12 $in.^2$ of total surface area available to bear labeling): May use no smaller than 4.5 point font.

Intermediate-sized packages (12-40 $in.^2$ of total surface area available to bear labeling): Generally must use minimum 6 point font. *Except*, a minimum 4.5 point font may be used for:

1. packages with less than 20 $in.^2$ of total surface area available to bear labeling and that list more than 8 dietary ingredients; and
2. packages with between 20 and 40 $in.^2$ of total surface area available to bear labeling and that list more than 16 dietary ingredients

Packages permitted to use 4.5 point font may omit the hairlines centered between lines of text and use a row of dots to connect columns containing the name of each dietary ingredient, the quantitative amounts, and the %DVs (§ 101.36(i)(2)(v)).

Boxed Products. If a product's immediate packaging (e.g., bottle or container) is too small to comply with these requirements, but is securely enclosed in a box that conforms to the type-size requirements, the type size on the immediate package can be "as small as needed to accommodate all of the required label information…" (§ 101.36(i)(2)(iv)).

Appendix I

Summary of Changes to Nutrition Labeling for Dietary Supplements

AHPA has summarized below several significant changes from the 2016 final rule amending the existing regulations relevant to dietary supplement products.

- "Calories from fat" will no longer be declared in the Supplement Facts box.
- In the Supplement Facts box, "Sugars" is changed to "Total Sugars," and "Added Sugars" must be declared by using the statement "Includes [X] g Added Sugars" indented under "Total Sugars." The final rule also requires a declaration of the percent Daily Value (DV) for added sugars
- Dietary fiber is now defined as including non-digestible soluble and insoluble carbohydrates (with 3 or more monomeric units), lignin that are intrinsic and intact in plants, and isolated or synthetic non-digestible carbohydrates (with 3 or more monomeric units) determined by FDA to have physiological effects that are beneficial to human health. FDA has identified the following non-digestible carbohydrates as meeting the dietary fiber definition: beta-glucan soluble fiber, psyllium husk, cellulose, guar gum, pectin, locust bean gum, and hydroxypropylmethylcellulose.

  In addition, FDA stated it intends to propose that the following non-digestible carbohydrates also be added to the definition of dietary fiber: mixed plant cell wall fibers (a broad category that includes fibers like sugar cane fiber and apple fiber, among many others), arabinoxylan, alginate, inulin and inulin-type fructans, high amylose starch (resistant starch 2), galactooligosaccharide, polydextrose, resistant maltodextrin/dextrin, cross linked phosphorylated RS4. FDA has stated that, until it engages in rulemaking to add the second group to the regulatory definition of dietary fiber, it intends to exercise enforcement discretion to allow manufacturers to include the amount of these fibers in the dietary fiber declaration on nutrition labels.
- Vitamin D and potassium are now included in the list of so-called "mandatory nutrients" and thus are required to be declared in the Supplement Facts box when present in a dietary supplement product at ≥2% DV per serving.
- Vitamins A and C are no longer "mandatory nutrients" that require declaration for when present, but they may be voluntarily declared if present at ≥ 2%DV per serving. In addition, they are required to be declared if they are added to the product for purposes of supplementation or when a claim is made about them.
- Fluoride and choline were added as nutrients that may voluntarily be declared on the label if present at significant levels. Declaration of fluoride is mandatory if claims are made on the label or in labeling about the fluoride content of the dietary supplement product. Declaration of choline is mandatory if choline is added to the product for purposes of supplementation or if claims are made on the label or in labeling about the choline content of the dietary supplement product.
- Reference values used to calculate the percent DVs were updated for most nutrients. In some cases, the units of measure were also changed from those established in the previous regulations. For example:

  - Vitamin A must now be declared in mcg Retinol Activity Equivalents (RAE) instead of International Units (IU). One mcg RAE is equivalent to 1 mcg retinol, 2 mcg supplemental ß-carotene, 12 mcg of dietary ß-carotene, or 24 mcg of other dietary provitamin A carotenoids (α-carotene or ß-cryptoxanthin).
  - Folate is distinguished from folic acid. The amount of folate and folic acid must be declared in mcg Dietary Folate Equivalents (DFE). One mcg DFE is equivalent to 1 mcg of naturally-occurring folate or to 0.6 mcg folic acid.
  - Vitamin D must be declared in mcg instead of IUs. However, the amount of vitamin D in IUs may optionally be declared in parentheses after the declaration of the amount of vitamin D in mcg.
  - Vitamin E must be declared in mg instead of IUs.
- The age ranges for the age categories of infants and children have been revised. "Infants" now refers to infants through 12 months of age. The category of "children less than 4 years" is now replaced with "children 1 through 3 years of age." The established DVs for these age groups and for pregnant and lactating women are also now included in the regulations.
- The revised regulations added a requirement to maintain records to support the declarations for certain nutrients (added sugars, dietary fiber, soluble fiber, insoluble fiber, vitamin E, and folate/folic acid) under the following specified circumstances:
  - When a mixture of dietary fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber is present in the product
  - When a mixture of soluble fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber is present in the product
  - When a mixture of insoluble fiber and added non-digestible carbohydrate(s) that does not meet the definition of dietary fiber is present in the product
  - When a mixture of naturally occurring and added sugars is present in the product
  - When the amount of sugars added to the product is reduced through non-enzymatic browning and/or fermentation
  - When a mixture of all rac-α-tocopherol and RRR-α-tocopherol is present in the product
  - When a mixture of folate and folic acid is present in the product

  These records must be kept for a period of at least 2 years after introduction or delivery for introduction into interstate commerce of any batch of product and must be provided to FDA upon request. Failure to make and keep these records or provide them to appropriate regulatory authorities would result in the product being misbranded.

Appendix II

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[12] 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[13,14]; 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 (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

[12] 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.
[13] 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.
[14] Spores naturally present in a fruitbody do not need to be identified as a separate part unless added as a stand-alone ingredient.

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.

B. Terms relevant to dietary supplement labels:

"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).

Appendix III

Labeling of Protein in Food and Dietary Supplements

(adopted March 2014)

Marketers of conventional foods and dietary supplements adhere to the following guidelines in labeling the protein in any such product:

- Notwithstanding the allowance in 21 CFR § 101.9(c)(7) to calculate the amount of protein to be declared in nutrition labeling of a food or dietary supplement on the basis of the factor of 6.25 times the nitrogen content of the food, the quantity of protein in a product is calculated to include only proteins that meet the following definition: "A chain of amino acids connected by peptide bonds."
- As further clarification, non-protein nitrogen-containing (NPN) substances are not counted toward total protein content on product labels. NPN substances are accounted for and subtracted from the total nitrogen content when protein is measured by nitrogen content.
- Nothing in this guidance is intended to replace or conflict with any regulatory requirement established under any other subpart or section of 21 CFR Part 101 for labeling of food and dietary supplement product.