FDA COMPLIANCE CHECKLIST FOR DIETARY SUPPLEMENTS
Once you've chosen the key ingredients in your supplement line, it's time to move on to packaging and labeling. The Food & Drug Administration (FDA) is responsible for claims related to dietary supplements on packaging, inserts and other promotional materials. If a label makes a false claim, the FDA can take action against the business if proven unsafe.

To ensure your supplement labeling and marketing materials are compliant, it's imperative that you structure your claims around the functionality and health benefits of your product. If you choose to promote as a cure, treatment or preventative, your supplements may be subject to FDA regulation as “drugs.”

To avoid these issues altogether, our team at Ameri-Kal has created a quick labeling checklist to ensure your dietary supplement passes code with the FDA.

### CONTAINER REQUIREMENTS

**Five statements are required:** 1) the statement of identity (name of the dietary supplement), 2) the net quantity of contents statement (amount of the dietary supplement), 3) the nutrition labeling, 4) the ingredient list, and 5) the name and place of business of the manufacturer, packer, or distributor.

### LABEL STATEMENTS

You must place all required label statements either on the front label panel (the principal display panel) or on the information panel (usually the label panel immediately to the right of the principal display panel, as seen by the consumer when facing the product), unless otherwise specified by regulation (i.e., exemptions).

### SUPPLEMENT FACTS

Total calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium, and iron must be listed when they are present in measurable amounts. A measurable amount is an amount that exceeds the amount that can be 21 CFR 101.9(c).
INGREDIENT LIST

When present, you must place the ingredient list on dietary supplements immediately below the nutrition label, or if there is insufficient space below the nutrition label, immediately contiguous and to the right of the nutrition label.

WARNING STATEMENT

The regulations require the following warning statement on the labeling of iron-containing dietary supplements and drugs in solid oral dosage form:

WARNING: Accidental overdose of iron-containing products is a leading cause of fatal poisoning in children under 6. Keep this product out of reach of children. In case of accidental overdose, call a doctor or poison control center immediately.

DISCLOSURE STATEMENT

It is a statement that calls the consumer’s attention to one or more nutrients (other than the nutrient that is the subject of the claim) in a dietary supplement (e.g., “See nutrition information for fat content”).
You must use a disclosure statement when you make a nutrient content claim and your food (including dietary supplements) contains one or more of the following nutrients in excess of the levels listed below per reference amount customarily consumed, per labeled serving, or, for a product with a reference amount of 30 g or less or 2 tablespoons or less, per 50 grams.

**UNITS OF MEASUREMENT**

The amount of fat would be listed in terms of grams in both the “Nutrition Facts” and “Supplement Facts” panels. However, units of measurement for amounts of vitamins and minerals are not specified for use in the “Nutrition Facts” panel because they must be listed by % Daily Value, not by weight. You should use the units of measurement given in 21 CFR 101.9(c)(8)(iv) for the Daily Values of vitamins and minerals when listing these nutrients in “Supplement Facts” (e.g., the amount of vitamin C must be listed in terms of milligrams because its Daily Value is stated in milligrams).

**PERCENTAGE OF DAILY VALUE**

The % DV must be declared for all dietary ingredients for which FDA has established Daily Values, except that 1) the percent for protein may be omitted, and 2) on the labels of dietary supplements to be used by infants, children less than 4 years of age, or pregnant or lactating women, you must not list any percent for total fat, saturated fat, cholesterol, total carbohydrate, dietary fiber, vitamin K, selenium, manganese, chromium, molybdenum, chloride, sodium, or potassium. See Appendix B for the daily values to be used for adults and children 4 or more years of age and Appendix C for the daily values to be used for infants, children less than 4 years of age, or pregnant or lactating women.
DOMESTIC ADDRESS OR PHONE NUMBER

Section 403(y) of the FD&C Act (21 U.S.C. 343(y)) requires the label of a dietary supplement being marketed in the United States to include “a domestic address or domestic phone number through which the responsible person may receive a report of a serious adverse event with such dietary supplement.” If the label does not include the required domestic address or phone number, the dietary supplement is misbranded.

UPC BAR CODE

The UPC bar code may be obtained from the Uniform Code Council. Their website is www.uc-council.org. Click on the button that says “I Need a UPC Bar Code.”

SPICES, NATURAL AND ARTIFICIAL FLAVORS

You must declare these ingredients in ingredient lists by using either specific common or usual names or by using the declarations “spice,” “natural flavor” or “artificial flavor,” or any combination thereof.

CHEMICAL PRESERVATIVES

You must list the common or usual name of the preservative followed by a description that explains its function e.g., “preservative,” “to retard spoilage,” “a mold inhibitor,” “to help protect flavor,” or “to promote color retention.”
OTHER DIETARY INGREDIENTS

You must list “other dietary ingredients” by common or usual name in a column or linear display. FDA has not specified an order that you must follow. You must list the quantitative amount by weight per serving immediately following the name of the dietary ingredient or in a separate column. You must place a symbol in the column for “% Daily Value” that refers to the footnote “Daily Value Not Established,” except that the symbol must follow the weight when you do not use the column format.

LIQUID EXTRACTS

You must list liquid extracts using the volume or weight of the total extract and the condition of the starting material prior to extraction when it was fresh. You may include information on the concentration of the dietary ingredient and the solvent used, e.g., “fresh dandelion root extract, x (y:z) in 70% ethanol,” where “x” is the number of mL or mg of the entire extract, “y” is the weight of the starting material, and “z” is the volume (mL) of solvent. You must identify the solvent in either the nutrition label or ingredient list.

DRIED EXTRACTS

For dietary ingredients that are extracts from which the solvent has been removed, you must list the weights of the dried extracts.
CONSTITUENTS

You may list constituents of a dietary ingredient indented under the dietary ingredient and followed by their quantitative amounts by weight per serving. You may declare the constituents in a column or in a linear display.

PROPRIETARY BLENDS

You must identify proprietary blends by use of the term “Proprietary Blend” or an appropriately descriptive term or fanciful name. On the same line, you must list the total weight of all “other dietary ingredients” contained in the blend. Indented underneath the name of the blend, you must list the “other dietary ingredients” in the blend, either in a column or linear fashion, in descending order of predominance by weight. These ingredients should be followed by a symbol referring to the footnote “Daily Value Not Established.” Dietary ingredients having RDIs or DRV{s} must be listed separately and the individual weights declared.

HIGH POTENCY CLAIMS

The regulation states that the term “high potency” may be used in a claim on the label or in labeling to describe individual vitamins or minerals that are present at 100 percent or more of the Reference Daily Intakes (RDI) per reference amount customarily consumed (21 CFR 101.54(f)(1)(i)). This means a supplement may be labeled as “high potency” for each nutrient(s) that is present at 100% of the RDI per serving.
ANTIOXIDANT NUTRIENT CONTENT CLAIMS

A claim that describes the level of antioxidant nutrients present in a food is a nutrient content claim and may be used on the label or in the labeling of a food when the conditions of use in the regulation are met (21 CFR 101.54(g)).

The antioxidant nutrient must meet the requirements for nutrient content claims in 21 CFR 101.54(b), (c), or (e) for “High” claims, “Good source” claims, and “More” claims, respectively. For example, to use a “high” claim, the food would have to contain 20% or more of the Daily Reference Value (DRV) or RDI per serving. For a “good source” claim, the food would have to contain between 10-19% of the DRV or RDI per serving (21 CFR 101.54(g)(3)).

SUGAR-FREE CLAIMS

A dietary supplement may include claims in labeling such as “sugar free,” “no sugar,” or other claims described in 21 CFR 101.60(c) provided it meets all of the eligibility criteria set forth in the regulation (21 CFR 101.60(c)(1)(i)-(iii)).

Among other requirements, a food must be labeled as “low calorie” or “reduced calorie” or bear a relative claim of special dietary usefulness. However, a dietary supplement that is prohibited from bearing a “low calorie” or “reduced calorie” claim by 21 CFR 101.13(b)(5) and 101.60(a)(4) can still use a sugar-free claim provided it meets the “low calorie” requirement in 21 CFR 101.60(b)(2) (21 CFR 101.60(c)(1)(iii)).

HIGH OR GOOD SOURCE CLAIMS

You may make a “high” claim when your dietary supplement contains at least 20% of the Daily Value (DV) (i.e. the Reference Daily Intake (RDI) or Daily Reference Value (DRV)) of the nutrient that is the subject of the claim per reference amount customarily consumed. You may make a “good source” claim when your dietary supplement contains 10 to 19% of DV.
LOW OR FREE CLAIMS

If a similar dietary supplement is normally expected to contain a nutrient and your dietary supplement is specially processed, altered, formulated, or reformulated as to lower the amount of the nutrient in the food, remove the nutrient in the food, or not include the nutrient, then you are permitted to make a “low” or “free” claim as applicable.

LOW CALORIE CLAIMS

A “low calorie” claim may not be made on dietary supplements, except when an equivalent amount of a dietary supplement that the labeled dietary supplement resembles and for which it substitutes (e.g., another protein supplement), normally exceeds the definition for “low calorie.”

QUALIFIED HEALTH CLAIMS

FDA will permit the use of a qualified health claim provided that 1) FDA has issued a letter stating the conditions under which we will consider exercising enforcement discretion for the specific health claim, 2) the qualified claim is accompanied by an agency-approved disclaimer, and 3) the claim meets all the general requirements for health claims in 21 CFR 101.14, except for the requirement that the evidence for the claim meet the validity standard for authorizing a claim, and the requirement that the claim be made in accordance with an authorizing regulation.

* This guidance has been prepared by the Office of Nutritional Products, Labeling and Dietary Supplements (ONPLDS) in the Center for Food Safety and Applied Nutrition (CFSAN) at the U.S. Food and Drug Administration.
We hope this checklist serves as a quick resource in helping you get your supplement line FDA-approved. For more information about federal regulations, custom and private labeling, give us a call at (405) 225-1804.