FDA Dietary Supplement Labeling Requirements: Comply or Die

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FDA labeling is one of the most important regulatory requirements for dietary supplements in that it provides the consumer the necessary information on the product. Indeed, ensuring that all information concerning that particular dietary supplement is in compliance with FDA labeling requirements, may be difficult and often very onerous. As a matter of fact, labeling errors may result in FDA enforcement action which could tarnish your company's reputation and business.

To begin with, it is important to understand the meaning of Dietary Supplements.

What are Dietary Supplements?

Dietary supplements are "food" as defined in the Federal Food, Drug, and Cosmetic Act (FD&C Act)[1]. In general, a foreign or domestic facility that manufactures, processes, packs, or holds human food for consumption in the United States has to register with FDA under section 415 of the FD&C Act[2] and is subject to the requirements related to preventive controls of the Current Good Manufacturing Practice[3], Hazard Analysis Critical Control Point (HACCP is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product)[4], and Risk-Based Preventive Controls for Human Food rule.[5]

In more simple terms, dietary supplements are defined, in part, as products (other than tobacco) intended to supplement the diet that bear or contain one or more of the following dietary ingredients:

1. A vitamin;
2. A mineral;
3. An herb or other botanical;
4. An amino acid;
5. A dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
6. A concentrate, metabolite, constituent, extract, or a combination of any ingredient mentioned above.[6]

Furthermore, dietary supplements are products intended for ingestion, are not represented for use as a conventional food or as a sole item of a meal or the diet, and are labelled as dietary supplements.

Now that we have briefly explained the meaning of a dietary supplement, let's move on to explore the main labeling requirements to insert on your product.

Why is labeling important and what information is needed on the Principal Display Panel (PDP)?

Proper labeling is an important aspect of putting the dietary supplement on the market. Moreover, labeling gives the consumer the correct information to make an informed decision of whether or not to purchase that particular dietary supplement.

The following are five main labeling statements required to be displayed on the PDP:

1. the statement of identity (name of the dietary supplement);[7]
2. the net quantity of contents statement (amount of the dietary supplement);[8]
3. the nutrition labeling;[9]
4. the ingredient list;[10] and
5. the name and place of business of the manufacturer, packer, or distributor.[11]

The above statements must be placed either on the principal display panel or on the information panel. In order to clarify, the PDP is that part of the package that the consumer is most likely to see, and you'll find the above information there.[12]The statement of identity and the net quantity of contents statement must also be placed on the PDP.[13]

A product cannot include any other information, therefore only the essential information is presented on the PDP and can then be directly communicated to consumers. When creating a PDP label, the type style is as important as the information included so the label is easily readable.

What is the Statement of Identity?

A statement of identity is used to recognize a common name which describes a single item and this must be placed on the PDP. Within the statement of identity, there are multiple requirements for identifying dietary supplements. These include: use of the term "dietary supplement" or, manufacturers can replace the word "dietary" and use an ingredient name in its place. For example, "calcium supplement" or "vitamin B12 supplement" are common supplements seen on the shelves of stores. The statement of identity must be one of the most important features on the PDP and its bold type size must be more prominent than other features on the front panel of the label, located parallel to the base of the package.

What is the Net Quantity of Contents?

The net quantity of contents is defined as the amount of supplement in the container or package and can be expressed either in weight, measure, numerical or in both. If a net quantity is being defined in weight, it must be expressed in the metric or the US customary system. The weight is defined as the weight of the supplement itself. The weight of the container isn't included in this measurement, except in cases where the supplement is designed to deliver results under pressure.

The net quantity of contents must be located on the product label as a distinct item on the PDP, parallel with the base of the container.

What is the Supplement Facts Panel?

The "Supplement Facts" panel, the ingredient list, and the name and place of business of the manufacturer, packer, or distributor must be placed on the information panel.[14]

The required information on a Supplement Facts label includes:

- Serving size information
- Names and quantities of each ingredient

- Total calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, protein, vitamin A, vitamin C, calcium and iron
- Dietary ingredients with no daily value must be listed by common name
- Amount per serving (this can be worded as: amount per capsule, packet, per 2 tablets, etc.)
- Percent daily value must be declared on all dietary ingredients

This information panel is located immediately to the right of the principal display panel as the product is displayed to the consumer. The information panel may be any adjacent panel when the top of a container is the PDP.[15]

What to put in the ingredient list?

Any compound used in the manufacture of a dietary supplement is considered an ingredient. An ingredient statement is needed unless the product ingredients are listed under the supplement facts label. Ingredients are required to be listed in descending order of prominence by weight. Ingredient listings should also include the use of spices, natural and artificial flavors.

What other information is required?

The street address must be listed if it is not listed in a current city directory or telephone book, the city or town, the state, and zip code. The address of the principal place of business in lieu of the actual address must be listed accordingly.

What is the required format on a Dietary Supplement Label?

It is a requirement to use a print or type size that is prominent, conspicuous and easy to read. The letters must be at least one-sixteenth (1/16) inch in height based on the lower case letter “o,” and not be more than three times as high as they are wide. The lettering must contrast sufficiently (it does not need to be black and white) with the background so as to be easy to read.[16]

Unless excepted by law, the Tariff Act requires that every article of foreign origin (or its container) imported into the United States conspicuously indicate the English name of the country of origin of the article.[17]

Do I need to put Warning Statements as well?

Dietary supplements must also include a warning statement on their packaging. This statement must be placed prominently on the information panel located on the product’s immediate container. By way of example: *“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.”*

FDA labeling requirements may be difficult to decipher however if you keep these five (5) labeling statements in mind, it could help you avoid the numerous FDA hurdles. 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.

Always ask yourself: Does this dietary supplement contain enough information for me to purchase it?

Be sure to contact an experienced FDA lawyer who understands the ins and outs of dietary supplement labeling. FDA can take a variety of enforcement measures, not limited to warning letters. It’s a jungle out there—or as some say, comply or die. Well, on the bright side, beef up your compliance and mitigate enforcement risk.

[1]Source accessed 06/09/2017.

[2] Ibid no. 8.

3Sourrce

[4]Source accessed 06/09/2017

[5]Source accessed 06/09/2017

[6] 21 U.S.C. 321

[7] 21 CFR 101.3(a),

[8] 21 CFR 101.105(a),

[9] 21 CFR 101.36

[10] CFR 101.4(a)(1)

[11] 21 CFR 101.5

[12] 21 CFR 101.2(b) and (d), 21 CFR 101.9(j)(13) and (j)(17), 21 CFR 101.36(g), (i)(2) and (i)(5)

[13] 21 CFR 101.1, 21 CFR 101.3(a) and 21 CFR 101.105(a)

[14] 21 CFR 101.2(b) and (d), 101.36(i)(2)(iii) and (i)(5), 101.5, 101.9(j)(13)(i)(A) and (j)(17). If such information does not appear on the principal display panel, except that if space is insufficient, you may use the special provisions on the “Supplement Facts” panel in 21 CFR 101.36(i)(2)(iii) and (i)(5). See questions 46 and 56 in Chapter IV for more details.

[15] 21 CFR 101.5

[16] 21 CFR 101.2(c) and (f), 21 CFR 101.15, and 21 CFR 101.105(h)

[17] Section 304, Tariff Act of 1930, as amended (19 U.S.C. 304)