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Regulatory responsibilities and best practices for manufacturing and marketing dietary supplements containing proprietary blends

INTRODUCTION

In the United States (U.S.), proprietary blends are expressly provided for dietary supplements by the Food, Drug & Cosmetic Act (FDCA). Like all dietary supplements, those containing proprietary blends are subject to federal and state requirements for safety, quality, and proper labeling. All requirements for listing ingredients in dietary supplements are applicable to proprietary blends, with one exception allowed in the law to protect formulators' intellectual property. While all dietary ingredients in a proprietary blend and the total quantity of all ingredients in the blend must be listed on the product label, the quantities of each dietary ingredient in the blend are not required to be disclosed on the label. This allowance in the law is intended to protect trade secrets such as the exact ingredient amounts in a product. Trade secrets are common in many industries, including food and beverage.

Manufacturers and marketers of dietary supplements containing proprietary blends are responsible for meeting all regulatory requirements in the U.S., including but not limited to those pertaining to listing ingredients on the Supplement Facts label and label claims as outlined below. Beyond the regulatory requirements, including Good Manufacturing Practices (GMPs), manufacturers and marketers in the dietary supplement industry may adopt best practices towards enhancing transparency to consumers.

This document is intended for manufacturers and marketers of dietary supplements containing proprietary blends who have familiarity with dietary supplement labeling regulations including nutrition labeling in 21 CFR 101.36 and the FDCA in general. This document serves to remind firms of some regulatory obligations specific to labeling proprietary blends but is not intended to serve as a comprehensive description of all regulatory requirements or procedures for compliance. It also presents best practices that may enhance regulatory requirements.

A. REGULATORY RESPONSIBILITIES

1. Listing Dietary Ingredients

a. All dietary ingredients contained in a proprietary blend shall be listed by their common or usual name (21 CFR 101.36(b)(3)(i)) and plant part, if applicable (21 CFR 101.36(d)(1).
b. Dietary ingredients in a proprietary blend that have a Reference Daily Intake (RDI) or a Daily Reference Value (DRV) (referred to in regulation as "(b)(2)-dietary ingredients") shall be listed in a column in the order specified in 21 CFR 101.36(b)(2)(B).
c. Dietary ingredients other than (b)(2) dietary ingredients in the blend shall be listed in order of input from most-to-least by weight, in a column or linear fashion, and indented under the term "Proprietary Blend" or other appropriately descriptive term or fanciful name (21 CFR 101.36(c)(2)). [1]

2. Disclosing Proprietary Blend Quantity

a. The quantitative amount of the proprietary blend, that is the weight of all dietary ingredients other than (b)(2) dietary ingredients contained in the proprietary blend, shall be listed ((21 CFR 101.36(c)(3)).[1]
b. In determining the weight of the proprietary blend, sum the weight of each "other dietary ingredient" listed and not the weight of any component, or the source, of that dietary ingredient ((21 CFR 101.36(b)(3(ii)).
c. Dietary ingredients contained in the blend that are (b)(2) dietary ingredients shall be listed according to 21 CFR 101.36 (b)(2) with a quantitative amount and percent Daily Value ((21 CFR 101.36(c)(1)).

3. Label Claims: Structure/Function Claims

a. All claims made on the product label, including any descriptive or fanciful name used to identify a proprietary blend that represents a product claim, shall:
    i. Be truthful and not misleading ((21 USC 343(r)(6)).
    ii. Not represent express or implied disease claims ((21 CFR 101.93(f)).
    iii. Be substantiated ((21 CFR 101.93(a)(3)).[2]
b. If a claim is made on the product label for the proprietary blend or a dietary ingredient in the proprietary blend, the product should contain

[1] See CRN's Best Practices for Probiotics for information about listing probiotics. Available from: https://www.crnusa.org/sites/default/files/Probiotics/CRN-IPA-Best-Practices-Probiotics-revised-11-12-20FINAL.pdf.
[2] See Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.

the dietary ingredient or proprietary blend in a quantity equivalent to the substantiated quantity.

B. BEST PRACTICES

Industry best practices are recommendations intended to complement regulatory requirements. Companies may voluntarily adopt best practices with the goal of enhancing transparency to consumers.

What qualifies as a proprietary blend?

There are two ways to make a proprietary blend. Manufacturers may simply group individual dietary ingredients together on a label listing and create a proprietary blend. Alternatively, manufacturers may obtain or create a pre-made mixture of dietary ingredients and declare it as a proprietary blend. Regulations allow for the heading "Proprietary Blend" or other descriptive or fanciful name to be listed on the Supplement Facts label.[3] A variety of terms may be used, but it is recommended that terms used clearly convey a combination of dietary ingredients such as "proprietary blend," "proprietary formulation," "complex," or "matrix."

Dietary ingredients in a proprietary blend

Dietary ingredients contained in a proprietary blend may be of two types of dietary ingredients:

- Dietary ingredients with a Reference Daily Intake (RDI) or a Daily Reference Value (DRV) (referred to in regulation as "(b)(2)-dietary ingredients"). These are also commonly referred to as "essential vitamins or minerals."
- Dietary ingredient without an RDI or DRV, referred to in regulation as "other dietary ingredients." Examples include curcuminoids, lutein, omega-3 fatty acids, etc.

Regulations require "(b)(2) dietary ingredients" and "other dietary ingredients" to be listed in separate sections of the Supplement Facts label.[4] All "(b)(2) dietary ingredients" must be listed with a quantitative amount and percent Daily Value. Other dietary ingredients in a proprietary blend are listed under the heading "Proprietary Blend" (or other descriptive name) with a quantitative weight representing the cumulative weight of all other dietary ingredients.[5] Thus, it may be difficult for consumers to identify (b)(2) dietary ingredients that are included in a proprietary blend as they are listed separately. It may not be practical for manufacturers to include (b)(2) dietary ingredients in a proprietary blend for the same reason.

[3] 21 CFR 101.36(c).
[4] 21 CFR 101.36(c)(1) (for (b)(2) dietary ingredients) and 21 CFR 101.36(c)(2) (for other dietary ingredients).
[5] 21 CFR 101.36(c)(2)

Ingredients in a dietary supplement containing a proprietary blend that are not dietary ingredients are required to be declared in the "Ingredient" list in accordance with 21 CFR 101.4(g) unless they qualify as processing aids or incidental additives exempt from label declaration under 21 CFR 101.100. Non-dietary ingredients include excipients, fillers, colors, sweeteners, flavors, or binders.

Product claims pertaining to proprietary blends

Like all dietary supplement claims, product claims including structure/function claims made for dietary supplements containing proprietary blends must be substantiated. Regulations do not define "substantiation," however, FDA guidance for industry exists.[6] In general, claims made for a proprietary blend should reflect relevant data and whether the data support claims for the entire blend or specific dietary ingredients contained in the blend.

Good manufacturing practices (GMPs)

Like all dietary supplements, supplements containing proprietary blends must be produced under good manufacturing practices (GMPs) established in 21 CFR 111. Manufacturers should be mindful that the expectation of consistent product quality is no different for proprietary blends formulated in-house compared to those obtained as a premade mixture; thus, appropriate specifications should always be set and verified to ensure the finished product has the intended dietary ingredients, purity, strength, composition, and minimal levels of contaminants.[7]

Best Practices for Proprietary Blends

1. Listing Dietary Ingredients
   - Avoid including (b)(2) dietary ingredients in proprietary blends.
   - Proprietary blend name should contain the word "Blend" or other synonymous term, indicating a mixture of multiple dietary ingredients.
   - Probiotic dietary ingredients should be identified by genus, species, and strain[8]

2. Disclosing Proprietary Blend Quantity
   - Include the weight of all dietary ingredients in the proprietary blend when declaring the blend quantity. [9] Where practical, the weight of non-dietary

[6] See Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act.
[7] 21 CFR 111.70(b) and 21 CFR 111.75(c).
[8] See CRN's Best Practices for Probiotics for information about listing probiotics. Available from: https://www.crnusa.org/sites/default/files/Probiotics/CRN-IPA-Best-Practices-Probiotics-revised-11-12-20FINAL.pdf.
[9] See CRN's Best Practices for Probiotics for information about declaring probiotic quantity. Available from: https://www.crnusa.org/sites/default/files/Probiotics/CRN-IPA-Best-Practices-Probiotics-revised-11-12-20FINAL.pdf.

ingredients such as excipients should not be included in the declared quantity of the proprietary blend.[10]

3. Label Claims: Structure/Function Claims
   - Claims pertaining to the proprietary blend should be substantiated by data on the entire blend. Claims substantiated by data on individual ingredients in the blend should identify the ingredient(s) associated with the claim(s).

4. Good Manufacturing Practices (GMPs)
   - Where practical, standard reference materials should be utilized to verify the identity of dietary ingredients in the proprietary blend.

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[10] The matter of dietary ingredients that are inextricable from their subcomponents, including carriers and other excipients, will be addressed separately.