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Perspectives

Perspectives on the Use of Proprietary Blends in Dietary Supplements

Leila G. Saldanha [1,*], Johanna T. Dwyer [1], Constance J. Hardy [2], Douglas J. MacKay [3]

[1] *Office of Dietary Supplements, National Institutes of Health, Bethesda, MD, United States;* [2] *Office of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition, Food and Drug Administration, College Park, MD, United States;* [3] *Consumer Healthcare Products Association (CHPA), Washington, DC, United States*

A B S T R A C T

This paper discusses the rationale for use of proprietary blends on dietary supplement labels, and their implications for researchers and consumers. The Dietary Supplement Health Education Act of 1994 allows the listing of nonnutrient dietary ingredients as proprietary blends on dietary supplement labels for companies to protect their unique formulas. The weight of the blend and names of the ingredients within the blends must be declared, but not the amounts of the individual ingredients within the proprietary blend. Thus, from label information, the amount of a dietary ingredient in a proprietary blend is not available for calculating exposures in assessments of intakes or for determining doses in clinical trials.

Keywords: proprietary blends, dietary supplements, dietary ingredients, labeling

Historical Perspective

The Dietary Supplement Health Education Act of 1994 (DSHEA) created dietary supplements as a category of consumer products that were to be regulated as a subset of foods [1]. Although most food labeling regulations also apply to dietary supplements, DSHEA included several exceptions to these food regulations that are specific to dietary supplements [2,3]. For example, a new category for ingredients named "dietary ingredients" was designated, with 6 classes of dietary ingredients specified: vitamins and minerals; herbs and other botanicals; amino acids; "dietary substances" that are part of the food supply, such as enzymes and live microbials (commonly referred to as "probiotics"); and concentrates, metabolites, constituents, extracts; or combinations of any dietary ingredient from the preceding categories [4]. Only 35 of these dietary ingredients have Daily Values (DVs) (Table 1). DVs are reference amounts of nutrients to consume or not to exceed each day expressed in a form suitable for labeling purposes [5]. In section (b)(2) of the regulation 21 CFR 101.36 Nutrition Labeling of Dietary Supplements, the ingredients with DVs are listed and are thus commonly called "(b)(2) ingredients" [6]. Most dietary ingredients are without DVs, and they are referred to as "other dietary ingredients" in section (b)(3) of 21 CFR 101.36. In addition, the "other dietary ingredients" are sometimes referred to as the "(b)(3) dietary ingredients," although this term is not noted in 21 CFR 101.36.

DSHEA also allowed expanded use of "structure/function" claims on dietary supplement labels [7]. These claims describe the role of a dietary ingredient that is intended to affect the structure or function of the human body. DSHEA also permitted the listing of dietary ingredients without DVs as "proprietary blends" on the label, ie, the weight of the blend and every ingredient within the blend was required to be disclosed, but not the amount of each ingredient within the blend [1]. According to data available in January 2023 on the NIH's Dietary Supplement Label Database (DSLD) [8], only 13% of >155,000 labels available listed only vitamins and minerals, 34% did not list any ingredient with a DV, whereas the remaining 54% of labels listed at least 1 ingredient with a DV in addition to other dietary ingredients. Thus, up to 87% of the labels in the DSLD contain dietary ingredients that could be listed as proprietary blends within the Supplement Facts box. There is little published information and supporting literature on proprietary blends in dietary supplements. This

Abbreviations: CRO, contract research organization; DSHEA, Dietary Supplement Health Education Act of 1994; DSLD, NIH's Dietary Supplement Label Database; DV, Daily Value; FTC, Federal Trade Commission; FDA, Food and Drug Administration; NLEA, Nutrition Labeling and Education Act of 1990.

* Corresponding author. *E-mail address:* leilags2016@gmail.com (L.G. Saldanha).

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TABLE 1
Categories of dietary ingredients[1]

Dietary ingredient categories	Contain a Daily Value (DV) ingredient
1) Vitamins	14 have DVs
2) Minerals (or elements)[2]	14 have DVs
3) Amino acids (and protein)[2]	1, only protein has a DV
4) Dietary substance used by man to supplement the diet by increasing the total dietary intake (all other nutrients)[2]	6 have DVs (eg, fiber, fats, carbohydrates, sugars)
5) Herb or botanical	None have DVs
6) Metabolite, constituent, extract, isolate, or combination of any of these (nonnutrient/nonbotanical ingredients)[2]	Do not have DVs

[1] Only 35 have daily values.
[2] Describes how these dietary ingredients are coded in the Dietary Supplement Label Database (DSLD).

paper presents research on the use of these blends on dietary supplement labels and perspectives about them in these products.

Prevalence of Proprietary Blends on Dietary Supplement Labels and Trends in Use

The DSLD contains information on products marketed in the United States since 2011 [8]. Overall, 34% of labels available in the database, as of April 2022, listed dietary ingredients in blends and 21% listed them in proprietary blends (Table 2). We compared the use of proprietary blends over two time points to see if their use had changed over time and there were no significant differences in prevalence (Table 2). Labels entered in the database between October 2011 (when labels were first listed in the DSLD) and December 2018 were compared with labels entered between January 2019 (when changes to the food label were scheduled to take effect) and April 2022 using a paired Student's t test assuming unequal sample sizes.

In the DSLD database, labels are coded under 11 product types on the basis of their composition. They are based on the dietary ingredients listed within the Supplement Facts box on the label. The 11 product types are amino acid/protein; botanical; fiber and other nutrients; omega 3 and other fatty acids; vitamin; mineral; single vitamin and mineral; multivitamin and mineral; botanicals with nutrients; nonnutrient/nonbotanical; and all other combinations. The definitions for these codes can be found under the glossary section in the DSLD. Labels are not categorized on the basis of their use or intended use, ie, weight loss, sports, and bodybuilding products, because there is no logical or generally accepted way to do so.

To determine if the use of blends and proprietary blends varied by product type, we further examined the use within 5 product types (botanical; multivitamin and mineral; botanicals with nutrients; nonnutrient/nonbotanical; and all other combinations) that represented 79% of the labels in the database. We selected these product types as they contained mainly "other dietary ingredients," ie, those without DVs that can be listed as proprietary blends. Labels containing multivitamins and a mineral were also included in the analysis for comparison purposes. The highest use of blends was in products containing combinations of ingredients that were not included in the other 10 defined product types, i.e. all other combinations (Table 2). By regulation, a proprietary blend is a blend that does not list the amounts of the individual dietary ingredients within the blend but does list the quantitative amount of the blend. The labels in the DSLD are not always coded to be consistent with the regulations because the NIH is not a regulatory agency. The contractor for the DSLD, TRC Healthcare codes a blend as a proprietary blend if the blend name includes the words "proprietary blend" or if there is an intellectual property symbol used in association with the blend title name, but not if the amounts of the individual dietary ingredients within the blend are not listed as per the regulations.

Rationale for the Use of Proprietary Blends and Intellectual Property Symbols

The use of proprietary blends on dietary supplement labels was granted by Congress in DSHEA presumably to protect intellectual property, especially that of small herb companies from having their traditional formulas copied and marketed by competitors with larger resources, and this intellectual property rationale continues to drive current use. Unlike new drugs that are granted a protection period by law, there is no such protection of intellectual property for new dietary supplements to prevent third parties from using their invention. Using

TABLE 2
Frequency of listing blends on dietary supplement labels by product type in the DSLD

Product type[2]	Labels listed 2011–2018 (N = 86,336)[1]			Labels listed 2019–2022 (N = 60,128)[1]		
	Number[3]	Blends %[4]	Proprietary blends %	Number	Blends %	Proprietary blends %
Botanicals only	16,171[5]	21[5]	18	14,462	21	17
Multivitamin and mineral only	1557	3	1	1024	2	0
Botanical with nutrients	4995	36	23	2745	35	20
Nonnutrient/nonbotanical	10,832	19	9	7607	17	7
All other combinations	34,743	48	29	21,856	47	27
Total	68,298[6]	35[6]	22	47,694	33	20

[1] Available in the Dietary Supplement Label Database (DSLD) as of April 2022.
[2] As coded in the DSLD. Products are coded on the basis of their composition.
[3] Number of labels used in the analysis.
[4] Percentage includes proprietary blends.
[5] Percentage is calculated as a percentage for that product type.
[6] Percentage of the number sampled.

proprietary blends is one way that companies can use to protect their trade secrets. The use of proprietary blends is also allowed by regulation in conventional foods and beverages to protect secret recipes and trade secrets.

Using intellectual property symbols for proprietary blend names is another way companies use to protect proprietary blends. However, trademarking the unique names does not necessarily translate to the protection of companies' unique ingredients or formulations. This is because the United States Patent and Trademark Office grants a trademark if a name is unique within a given application or use, and thus the decision is not based on chemical differences in the composition of blends or products [9]. The unique and fanciful blend names that are used to distinguish a product from competing products in the marketplace are attractive to consumers and often imply the benefit of the blend. Examples include "keto weight loss blend," "probiotic blend," "phytochemical complex blend," "weight loss + blend," "full body cleansing blend," "pain T4 proprietary blend," "nerve relief herbal formula," "urinary tract blend," and so on [8].

Regulations Related to Proprietary Blend Claims

Good Manufacturing Practices for dietary supplements require that the manufacturing process ensures that a dietary supplement contains what it is labeled to contain and that it is not contaminated. Furthermore, United States Food and Drug Administration (FDA) requires that the Master Manufacturing Record and Batch Record list the amounts of each ingredient in a proprietary blend and that such records must be made available to the FDA during plant inspections.

Companies are not required to notify the FDA or to seek preapproval for proprietary blend names. However, if the unique and fanciful blend names used in product labeling imply a health benefit, they can be viewed as health claims or structure/function claims by the regulatory agency. Examples are "nerve relief herbal formula," "weight loss + blend," and "urinary tract blend." Health claims, first allowed under the Nutrition Labeling and Education Act of 1990 (NLEA), require premarket approval. Health claims describe a relationship between a food substance (a food, food component, or dietary supplement ingredient) and reduced risk of a disease or health-related condition. Thus, a health claim has 2 essential components: *1*) a substance (whether a food, food component, or dietary ingredient) and *2*) a disease or health-related condition. A statement lacking either one of these components does not meet the regulatory definition of a health claim [7]. All health claims must be substantiated by published literature. Structure/function claims are claims that do not meet the definition of a health claim. They describe the role of a dietary ingredient intended to affect the structure or function of the human body. Premarket approval is not required for these types of claims; however, companies must notify the FDA of structure/function claims that appear in the labeling of a dietary supplement. Because structure/function claims are not reviewed by the FDA, to caution consumers that dietary supplements bearing such claims are not for therapeutic uses, they must be accompanied by the label statement "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." Additional information on the different types of claims that can be printed on supplement labels can be found on the FDA website [7].

Although both the FDA and the Federal Trade Commission (FTC) [10] require the marketing of dietary supplements to be truthful and accurate (not misleading), there are substantial differences in the legal frameworks and approaches these agencies use in regulating claims. Unlike the FDA, the FTC [10] makes no distinction between how it regulates the different types of health and nutrition claims used in advertising. The FTC requires that "before disseminating an ad, advertisers must have adequate substantiation for all objective product claims conveyed, expressly or by implication, to consumers acting reasonably." Although all claims used in advertising must be adequately substantiated, the FTC does not require that substantiation of these claims, such as clinical studies of efficacy, are made available in the public domain. Thus, companies that conduct studies to substantiate advertising claims through contractual agreements with contract research organizations (CROs) can opt not to publish them to protect their intellectual property.

Implications for Researchers

The use of proprietary blends with unknown amounts of various bioactives that are dietary ingredients and the lack of publicly available scientific evidence to support the effectiveness or claims about these unique formulations have implications for researchers and consumers. When the amount of a dietary ingredient listed within a proprietary blend is not declared, it is not possible to accurately calculate exposures and intakes of that ingredient or determine doses used in clinical trials from label information. Researchers must use alternative ways to arrive at amounts, either by chemically analyzing the product, arriving at default values calculated from similar products where the amounts are declared, or by contacting the manufacturer to request the amounts (although they are not required to supply it).

Calculating exposures for some dietary supplements may be more challenging than others [11]. Some botanicals, especially those used in formulating weight loss or bodybuilding dietary supplement products, are more likely to be listed in proprietary blends. For example, if a researcher is interested in calculating total caffeine intakes for safety assessments, the sources of caffeine (coffee beans, cocoa beans, kola nuts, tea leaves, yerba mate, and guarana) in addition to the synthetic form can be listed in proprietary blends. Many companies are now opting to declare caffeine amounts on dietary supplement labels. However, these are for caffeine added as anhydrous caffeine and not from all sources, because the declaration of anhydrous caffeine is required on supplement labels. However, if a label makes a general statement about the caffeine content that does not accurately reflect the quantitative amount of caffeine from all sources, that label may be considered by the regulatory agency to be false or misleading by failing to reveal a material fact of the actual total caffeine content per serving. Caffeine and the sources of caffeine (typically botanicals) are dietary ingredients and can be listed within the Supplement Facts box; however, they cannot be listed within Nutrition Facts box on conventional food labels as these bioactives are non-DV ingredients. Thus, calculating total exposures from foods and dietary supplements from

declared label information for non-DV ingredients can be difficult for researchers.

Not having access to all proprietary unpublished studies can also be difficult for researchers who are conducting literature reviews to design clinical trials. According to some estimates, there are 2760 CROs in the United States [12]; however, the percentage of dietary supplement studies funded by dietary supplement companies to support proprietary blends conducted at CROs is not known. From the scientific standpoint, if the studies are not in the public domain, they do not exist.

Future Trends of Proprietary Blends

Although there have been challenges to DSHEA, the Act has remained relatively unchanged since it was passed in 1994. In the 117th Congress, in 2022, there were several proposed bills in the House and Senate calling for the mandatory listing of dietary supplements to provide the FDA with better oversight of dietary supplement products sold in the United States market. One proposed Senate bill called for the listing of all ingredients used in formulating the products and their amounts. However, none of these bills were passed in the 117th Congress.

The current use of proprietary blends on dietary supplement labels complicates the quantification of bioactives listed as dietary ingredients for accurately estimating exposures. If the proposed legislation is introduced in the current Congress, it could create the needed transparency for researchers.

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Disclaimers

The opinions expressed in this article are the authors' own and do not reflect the views of the National Institutes of Health, the Department of Health and Human Services, the United States government, or their organizations.

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