

Guidance for Industry

Distinguishing Liquid Dietary Supplements from Beverages

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Guidance for Industry¹

Distinguishing Liquid Dietary Supplements from Beverages

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You may use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. Introduction

We are issuing this guidance to help dietary supplement and beverage manufacturers and distributors determine whether a product in liquid form is properly classified as a dietary supplement or as a beverage. This guidance describes the factors that distinguish liquid products that are dietary supplements from those that are conventional foods. Further, this guidance reminds manufacturers and distributors of dietary supplements and beverages about the requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) regarding their respective ingredients and labeling.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance describes the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word “should” in Agency guidance means that something is suggested or recommended, but not required.

In this guidance, “we” refers to FDA and “you” refers to manufacturers and distributors of dietary supplements and beverages.

¹ This guidance has been prepared by the Office of Nutrition, Labeling, and Dietary Supplements and the Office of Food Additive Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

II. Background

We have observed an increase in the marketing of liquid products with a wide array of ingredients and intended uses. Some of these products are marketed as dietary supplements, and others as conventional foods. Some products may be misbranded because their labeling or other representations made about them are inconsistent with the product category under which they are being marketed. In addition, products may be excluded from the dietary supplement category because of representations that they are for use as conventional foods. This guidance is intended to describe the factors to consider when determining whether a liquid product should be marketed as a dietary supplement or a conventional food.

III. Discussion

A. Beverages Are Conventional Foods That May Not Be Marketed as Dietary Supplements

Under section 201(ff)(2)(B) of the FD&C Act (21 U.S.C. 321(ff)(2)(B)), the term “dietary supplement” means a product that, among other requirements, “is not represented for use as a conventional food or as a sole item of a meal or the diet.” Beverages are conventional foods under the FD&C Act. Even when the label of a product characterizes it as a dietary supplement, the product may not in fact be a dietary supplement. Products in liquid form can be represented as conventional foods as a result of factors such as their product or brand name, packaging, serving size and total recommended daily intake (i.e., the volume in which they are intended to be consumed), composition, recommendations and directions for use, statements or graphic representations in labeling or advertising, and other marketing practices.

B. Factors that Distinguish Beverages from Liquid Dietary Supplements

The most obvious representations about a product’s use are claims made for the product in its labeling and advertising. However, a product’s name, packaging, serving size, recommended daily intake and other recommended conditions of use, and composition, as well as marketing practices and representations about the product outside its labeling and advertising, can also be important determinants of whether the product is represented as a conventional food (and, thus, may not be marketed as a dietary supplement). Below, we discuss some of these factors in more detail. Although in some circumstances a single factor may be determinative of whether the product is represented as a conventional food (see, e.g., the discussion below regarding product name), in most circumstances a combination of factors would determine whether the product is represented as a conventional food.

- Labeling and advertising. FDA considers statements and graphics on product labels, labeling, and advertising, including Web sites and social media, when the agency evaluates the intended use of the product and how it is represented. For example, a product that bears a Supplement Facts panel may still be a conventional food if it also bears statements that the product is intended to “refresh” or “rehydrate” because such statements represent the product

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for use as a beverage, i.e., a conventional food. Graphics (e.g., symbols, vignettes, pictorial serving suggestions) can also represent a product as a conventional food. For example, an ad or label with a picture of a liquid product being poured onto a green salad would represent the product as a salad dressing.

- **Product name.** Product or brand names that use conventional food terms such as “beverage,” “drink,” “water,” or “soda” represent the product as a conventional food. Examples of other terms that generally would be considered to represent a liquid product as a conventional food when used in the product’s name are beverage names such as “orange juice,” “apple cider,” “bottled water,” “iced tea,” and “coffee.” For example, calling a product “bottled water” represents the product as a conventional food because “bottled water” is a term identifying a specific category of conventional food that is defined in a food standard regulation (see 21 Code of Federal Regulations (CFR) 165.100). In some instances, the mere use of such a term in a product name or brand name may be sufficient to establish that a product is represented for use as a conventional food. However, in other situations (e.g., where the term is not associated exclusively with conventional foods), the use of such a term in the product name likely would be evaluated in the broader context of other factors. This would be the case, for example, for products described as teas.
- **Product packaging.** Packaging is used to market a product as well as to contain, hold, and preserve the product. Packaging can convey messages about how the product is to be used. Packaging characteristics that should be considered include the size, shape, color, and design of the container or other packaging, the volume of liquid it holds, whether it is reclosable or designed to be consumed in a single serving, and the similarity of the packaging to packaging used for common beverages. For example, packaging a liquid product in a red twelve-ounce pop-top aluminum can bearing a silver stripe with the name “cola supplement” printed in script on the can could be considered an implied representation that the product is a cola-flavored soft drink that is intended to be consumed in a single serving like other canned soft drinks. However, there may be situations where other factors (such as labeled serving size and recommended daily intake, discussed in next bullet) support a determination that the product is not represented as a conventional food, even if its container is similar to a beverage container.
- **Serving size and recommended daily intake.** Based on data from the 2005-2006 National Health and Nutrition Examination Survey on daily intake of drinking water and other beverages in the United States, we estimate the average total daily drinking fluid intake per person to be about 1.2 liters (1200 ml) (Ref. 1). Liquid products that suggest through their labeled serving size and/or recommended daily intake (e.g., “Drink up to three 16-ounce bottles per day”) that they are intended to be consumed in amounts that provide all or a significant part of the entire daily drinking fluid intake of an average person in the United States are effectively being represented as conventional foods. Even if a product is not expressly represented as an alternative to a beverage, when the practical result of the labeled serving size and/or total recommended daily intake is that the product is used as a beverage or replaces beverages that serve as ordinary sources of drinking fluid, FDA would generally consider the product to be represented for use as a conventional food.

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- Recommendations and directions for use. Dietary supplements are defined as products that, among other requirements, are intended to supplement the diet. (See section 201(ff)(1) of the FD&C Act [21 U.S.C. 321(ff)(1)].) In contrast, beverages generally are intended, for example, to quench thirst or otherwise provide a source of fluids (e.g., water, soda), provide nutritive value (e.g., milk, orange juice), or provide taste and aroma (e.g., hot cocoa). Recommendations or directions to use a product as a thirst quencher can be considered recommendations or directions to use that product as a beverage, replacing other beverages such as fruit juice, water, or soda, and thus represent the product as a conventional food. In contrast, recommendations or directions to use a liquid product to supplement the diet in a manner consistent with other dietary supplements (e.g., by taking one tablespoon three times a day) could be a factor in determining that the product is not represented as a conventional food, even if the packaging is similar to packaging used for beverages.
- Marketing practices. Examples of marketing practices that may represent a product in liquid form as a conventional food include labeling, advertising, or other promotional activities that favorably compare the product to a category of beverages (e.g., sodas), market the product as an accompaniment to a meal, or market the product based on typical beverage criteria like taste, refreshment, and thirst-quenching ability; the use of metatags² that result in the product's appearing in the results of an electronic search for sodas, juices, or other beverages; and paying for the product to be displayed in the beverage section of retail stores. However, simply recommending that a liquid product be taken with a meal would not generally be considered to represent the product as a conventional food, as many dietary supplements should be taken with food for best absorption. Moreover, promoting a product as a substitute for a beverage would not always represent the product as a conventional food. For example, a labeling or advertising statement promoting a liquid vitamin C supplement as a quick and easy alternative to drinking orange juice would not represent the product as a conventional food because it would be promoting the supplement as a more convenient source of vitamin C, not as a beverage to quench thirst, provide fluids, or wash down a meal.
- Composition. FDA recognizes that there are areas of overlap between the ingredients of some dietary supplements and conventional foods. For example, amino acids, proteins, vitamins, water, and certain plant ingredients are commonly used in both. However, in light of Congress's findings in the Dietary Supplement Health and Education Act of 1994 (DSHEA), which focused on the value of dietary supplements in improving nutrition, promoting long-term health and quality of life, and reducing the risk of chronic diet-related diseases, the agency does not believe that Congress intended the overlap in composition between dietary supplements and conventional foods to be total.³ Moreover, the dietary supplement provisions of the FD&C Act (added by DSHEA) are premised on the concept of dietary supplements as products that are marketed and consumed for nutrition and health benefits, and specifically authorize supplements to be marketed for those purposes (see section 403(r)(6) of the FD&C Act [21 U.S.C. 343(r)(6)]). Given that some conventional foods are consumed primarily for taste rather than for nutrition or health-related purposes, it

² A metatag is an HTML tag that contains descriptive information about a Web page. Although the metatag does not appear when the Web page is displayed in a browser, searching for a word that is one of the Web page's metatags will cause that Web page to turn up in the search results (Ref. 2).

³ Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 2, 108 Stat. 4325, 4325-26.

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would strain common sense to interpret DSHEA as authorizing the creation of a dietary supplement whenever any dietary ingredient is added to any conventional food. Such an interpretation would make the dietary supplement and conventional food universes co-extensive, differentiated only by labeling, advertising, and other marketing practices. In addition, if a manufacturer could create a dietary supplement simply by adding a dietary ingredient to any pre-existing conventional food and labeling the resulting product as a supplement, firms could easily evade the requirement that ingredients in conventional foods be generally recognized as safe (GRAS) or approved for their intended use (see section III.D.1, below).

When a product marketed as a dietary supplement consists in significant part of conventional food components unrelated to its claimed nutritional or health benefit as a supplement and the product is essentially a copy of a common beverage with a dietary ingredient added, FDA intends to consider whether the composition, along with other factors, represents the product as a conventional food. Merely adding an ingredient listed as a dietary ingredient in section 201(ff)(1) of the FD&C Act to a product universally recognized as a beverage does not by itself transform that beverage into a dietary supplement. For example, adding a botanical such as ginkgo to kool-aid or non-alcoholic eggnog would not automatically create a product that could be marketed as a “ginkgo supplement.”

It should be noted that a dietary ingredient that is lawful for addition to dietary supplements may or may not also be lawful for addition to conventional foods. To be lawful for use in a conventional food, the ingredient must be used in conformity with a food or color additive regulation prescribing the conditions of its use in food, be GRAS for its intended use in food, or qualify for one of the other exceptions to the food additive definition. For example, a firm that makes or distributes a liquid dietary supplement containing yohimbe bark extract should not assume that yohimbe bark extract may be added to a carbonated soft drink. Unless the intended use of yohimbe bark extract in the soft drink meets the GRAS eligibility criteria described in the FD&C Act or another exception to the food additive definition applies, this use of yohimbe bark extract would be unlawful without a food or color additive regulation prescribing safe conditions of use.

- Other representations about a product. Other representations about a product include, for example, representations in publicly available documents, such as statements made in filings with government agencies such as the U.S. Securities and Exchange Commission or the U.S. Patent and Trademark Office. For example, a filing describing a product as a type of “bottled water” or “coffee drink” would represent the product as a conventional food. However, an isolated representation of this type generally would not be enough for FDA to conclude that the product is not a dietary supplement. FDA intends to consider all relevant factors in context when determining whether a product is represented as a conventional food.

C. Powdered Premix Products and Liquid Concentrates May Be Dietary Supplements

Powdered premix products that are intended to be added to water or other liquids have long been marketed as dietary supplements. If properly labeled as a dietary supplement, a product of this

type is unlikely to be confused with beverage mixes or used as a substitute for a beverage mix. Powdered premixes may bear directions recommending that the premix be added to a liquid as a convenient delivery system, for other reasons of convenience or stability (e.g., if the ingredients are not stable in aqueous solutions), or to mask the taste of certain ingredients. We generally do not view such products as beverages when they are labeled as dietary supplements, provided that they are not otherwise represented as being for beverage use or as alternatives to beverages. Likewise, we generally would not view liquid concentrates that are added to water or other liquids as beverages when they are labeled as dietary supplements, provided that they are not otherwise represented for beverage use or as alternatives to beverages. An example of a product represented for beverage use would be chocolate syrup labeled with the statement “Delicious in milk or over ice cream.” In addition, a product labeled as a powdered lemonade mix would be considered to be a conventional food because lemonade is a beverage.

D. Regulatory Requirements for Ingredients of Beverages and Liquid Dietary Supplements

It is your responsibility to ensure that any beverage or liquid dietary supplement you market complies with all applicable regulatory requirements for substances added to the product.

1. Substances intentionally added to beverages

Many substances intentionally added to beverages are food additives, which require premarket approval by FDA. (See section 409 of the FD&C Act [21 U.S.C. 348] and 21 CFR Part 171.) A substance is exempt from the definition of a food additive, and thus from pre-market approval, if it is generally recognized as safe by qualified experts under the conditions of its intended use in food (see 21 CFR 170.30), or if it falls under another exception to the food additive definition in section 201(s) of the FD&C Act (21 U.S.C. 321(s)).

The “Ingredients, Packaging & Labeling” Web page on the FDA Web site (Ref. 3) includes links to regulatory requirements and recommendations that apply to substances intentionally added to beverages and other conventional foods. A guidance document entitled “Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements” (Ref. 4) is particularly relevant to beverages containing ingredients that have not previously been used in conventional foods, that are now being added to beverages at levels in excess of their traditional use levels, or that are now being added to new beverages.

2. Dietary ingredients in dietary supplements

Substances that are “dietary ingredients” under section 201(ff)(1) of the FD&C Act (21 U.S.C. 321(ff)(1)) must not adulterate the dietary supplement to which they are added (see section 402 of the FD&C Act [21 U.S.C. 342]). In addition, dietary ingredients that were not marketed in the United States before October 15, 1994, are “new dietary ingredients” subject to the requirements of section 413 of the FD&C Act (21 U.S.C. 350b) and 21 CFR 190.6. Our Web pages entitled “Dietary Supplements” (Ref. 5), “New Dietary Ingredients in Dietary Supplements - Background for Industry” (Ref. 6), and “New Dietary Ingredients Notification Process” (Ref. 7) include links to regulatory requirements and recommendations that apply to new dietary ingredients.

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3. Substances (other than dietary ingredients) intentionally added to dietary supplements

Section 201(s) of the FD&C Act (21 U.S.C. 321(s)) exempts dietary ingredients used in dietary supplements from the food additive definition. Although a dietary ingredient used in a dietary supplement must not adulterate the supplement under section 402(f) of the FD&C Act (21 U.S.C. 342(f)), it does not have to be GRAS for its intended use in the supplement. However, other ingredients intended for use in dietary supplements, such as binders, excipients, and fillers, are not exempt from the food additive definition and must meet the same requirements as substances added to conventional foods. In other words, non-dietary ingredients added to a dietary supplement must be used in accordance with a food additive regulation or be GRAS for their intended use (unless they qualify for another exception to the food additive definition). See the discussion in section III.D.1 of this guidance and References 3 and 4.

E. Regulatory Requirements for the Labeling of Beverages and Liquid Dietary Supplements

It is your responsibility to ensure that your dietary supplement or beverage complies with all applicable labeling requirements.

1. General prohibition on false or misleading labeling

All claims, statements, and graphics in the labeling of foods, including beverages and liquid dietary supplements, are subject to section 403(a)(1) of the FD&C Act (21 U.S.C. 343(a)(1)), which provides that a food is misbranded if its labeling is false or misleading. The FD&C Act further provides in section 201(n) (21 U.S.C. 321(n)) that affirmative representations are not the only factor relevant to whether labeling is misleading. In determining whether the labeling of an article is misleading, “there shall be taken into account (among other things) ... the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.” 21 U.S.C. 321(n).

2. Health claims

Beverages and liquid dietary supplements may bear health claims, which characterize the relationship between a substance (food or food component) and a disease or health-related condition (see 21 CFR 101.14(a)(1)). For more information about health claims, including procedures for our review of health claims and examples of authorized health claims, we refer you to the following:

- Sections 403(r)(1)(B), (r)(3), (r)(4), and (r)(5) of the FD&C Act (21 U.S.C. 343(r)(1)(B), (r)(3), (r)(4), (r)(5));
- 21 CFR 101.14;
- 21 CFR 101.70;
- 21 CFR 101.72–101.83; and
- References from FDA’s Web site

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- “Label Claims. General Information” (Ref. 8)
- “Guidance for Industry: Evidence-Based Review System for the Scientific Evaluation of Health Claims” (Ref. 9)
- “Qualified Health Claims” (Ref. 10)
- “FDA Modernization Act (FDAMA) Claims” (Ref. 11)
- “Summary of Qualified Health Claims Subject to Enforcement Discretion” (Ref. 12).

3. Nutrient content claims

Liquid dietary supplements and beverages may bear nutrient content claims, which characterize the level of a nutrient in a food (see 21 CFR 101.13(b)). For more information about nutrient content claims, including procedures for our review of nutrient content claims and examples of authorized nutrient content claims, we refer you to the following:

- Sections 403(r)(1)(A), (r)(2), (r)(4), and (r)(5) of the FD&C Act (21 U.S.C. 343(r)(1)(A), (r)(2), (r)(4), (r)(5));
- 21 CFR 101.13;
- 21 CFR 101.69;
- 21 CFR 101.54–101.67; and
- References from FDA’s Web site
 - “Label Claims. General Information” (Ref. 8)
 - “FDA Modernization Act (FDAMA) Claims” (Ref. 11).

4. Structure/function claims for conventional foods

Conventional foods, including beverages, may bear certain kinds of claims about effects on the structure or function of the body (structure/function claims). The FD&C Act defines “drug” to include articles intended to affect the structure or function of the body. This provision contains an exception for foods, which affect the structure and function of the body by virtue of providing nutrition to sustain life and health. See section 201(g)(1)(C) of the FD&C Act (21 U.S.C. 321(g)(1)(C)). “Food” is defined in section 201(f) of the FD&C Act (21 U.S.C. 321(f)) as “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.”

Consistent with case law interpreting the “other than food” exception as applying to articles consumed primarily for taste, aroma, or nutritive value, FDA does not intend to regulate conventional foods that bear structure/function claims in their labeling as drugs if the claimed structure/function effect derives from the product’s character as a food—its taste, aroma, or nutritive value. See *Nutrilab v. Schweiker*, 713 F.2d 335 (7th Cir. 1983). However, if a structure/function claim promotes a product for a use other than providing taste, aroma, or nutritive value, such as blocking the absorption of carbohydrates in the gut, the claim may cause the product to be a drug under section 201(g)(1)(C) of the FD&C Act by changing its primary use. In other words, because of the use promoted in the claim, the product may no longer be consumed as a food—primarily for taste, aroma, or nutritive value—but rather as a drug for some other physiological effect. Further, if a labeling claim about the effect of a conventional food on the structure or function of the body also states or implies that the product is useful in treating, mitigating, curing, or diagnosing a disease, the claim causes the product to be a drug

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under section 201(g)(1)(B) of the FD&C Act (21 U.S.C. 321(g)(1)(B)). The same is true for a disease prevention claim in the labeling of a conventional food, unless the claim is an authorized health claim about reducing the risk of a disease or health-related condition.

As with all claims in food labeling, structure/function claims for conventional foods may not be false or misleading. See section 403(a)(1) of the FD&C Act (21 U.S.C. 343(a)(1)).

5. Structure/function claims and related claims for dietary supplements

Structure/function claims in the labeling of dietary supplements are subject to section 403(r)(6) of the FD&C Act (21 U.S.C. 343(r)(6)) and our regulation in 21 CFR 101.93, as are dietary supplement labeling claims about general well-being and benefits related to a classical nutrient deficiency disease. For more information about these claims for dietary supplements, see Ref. 8.

As with conventional foods, if a labeling claim about the effect of a dietary supplement on the structure or function of the body also states or implies that the product is useful in treating, mitigating, curing, or diagnosing a disease, the claim causes the product to be a drug under section 201(g)(1)(B) of the FD&C Act (21 U.S.C. 321(g)(1)(B)); see also 21 CFR 101.93(g). The same is true for a disease prevention claim in the labeling of a dietary supplement, unless the claim is an authorized health claim about reducing the risk of a disease or health-related condition.

6. General food labeling requirements

Mandatory labeling for beverages and other conventional foods differs in many respects from mandatory labeling for dietary supplements. For example, beverages must show nutrition information in the Nutrition Facts format (see 21 CFR 101.9), but dietary supplements must show nutrition information in the Supplement Facts format (see 21 CFR 101.36). Generally, all ingredients in a beverage must be declared in the ingredient statement by their common and usual names,⁴ in descending order of predominance; however, for dietary supplements, only ingredients not listed in Supplement Facts have to be listed in the ingredient statement. In addition, a beverage or other conventional food should not be labeled with the FDA disclaimer that is required on dietary supplement labels that bear structure/function claims or other claims described in section 403(r)(6)(A) of the FD&C Act (21 U.S.C. 343(r)(6)(A)).

FDA's general food labeling requirements, including those that apply to dietary supplements, are in 21 CFR Part 101.

IV. References

We have placed the following references on display in the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. You may see them at that location between 9 a.m. and 4 p.m., Monday through Friday.

⁴ There are a few exceptions for ingredients that are exempt from declaration (e.g., processing aids) or that may be declared collectively (e.g., spices and flavorings). See 21 CFR 101.4(b), 101.22, 101.100(a).

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1. Memorandum from Jannavi Srinivasan, FDA, Center for Food Safety and Applied Nutrition, Office of Food Additive Safety, to Barbara Schneeman, FDA, Center for Food Safety and Applied Nutrition, Office of Nutrition, Labeling, and Dietary Supplements. Daily Drinking Fluid Intake Estimate (Aug. 31, 2009).
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 3. FDA. [Ingredients, Packaging & Labeling](http://www.fda.gov/Food/IngredientsPackagingLabeling/default.htm). Available at <http://www.fda.gov/Food/IngredientsPackagingLabeling/default.htm>
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 11. FDA. [FDA Modernization Act \(FDAMA\) Claims](http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm2006874.htm). Available at <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm2006874.htm>
 12. FDA. [Summary of Qualified Health Claims Subject to Enforcement Discretion](http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm073992.htm). Available at <http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm073992.htm>
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