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## Food

### **Draft Guidance for Industry: Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods**

*Contains Nonbinding Recommendations*

*Draft - Not for Implementation*

December 2009

#### **This guidance is being distributed for comment purposes only.**

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers you comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance within 60 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to

<http://www.regulations.gov><sup>1</sup>. All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at [REDACTED] (Updated phone: 240-402-2375) .

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
December 2009**

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#### **Table of Contents**

- I. [Introduction](#)
- II. [Background](#)
- III. [Discussion](#)
- IV. [References](#)

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#### **Guidance for Industry(1)**

### **Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods**

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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 can 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**

FDA is issuing this guidance to assist dietary supplement and beverage manufacturers and distributors in reaching a determination as to whether a liquid product may be labeled and marketed as a dietary supplement. The guidance describes factors that can be used to identify liquid products that are excluded from being dietary supplements because they are represented as conventional foods. Further, this guidance reminds manufacturers and distributors of beverages and other conventional foods, particularly those that contain novel ingredients, about the requirements of the Federal Food, Drug, and Cosmetic Act (the FDCA) regarding ingredients and labeling.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe 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 guidances means that something is suggested or recommended, but not required.

## II. Background

The Food and Drug Administration (FDA) has observed and become concerned about two trends in the marketing of beverages. First, we have seen an increase in the marketing of beverages as dietary supplements, in spite of the fact that the packaging and labeling of many liquid products represent the products as conventional foods. Products that are represented as conventional foods do not meet the statutory definition of a dietary supplement in section 201(ff) of the FFDC (21 U.S.C. 321(ff)) and must meet the regulatory requirements that apply to conventional foods.

Second, FDA has seen a growth in the marketplace of beverages and other conventional foods that contain novel ingredients, such as added botanical ingredients or their extracts. Some of these ingredients have not previously been used in conventional foods and may be unapproved food additives. In addition, ingredients that have been present in the food supply for many years are now being added to beverages and other conventional foods at levels in excess of their traditional use levels or in new beverages or other conventional foods. This trend raises questions regarding whether these ingredients are unapproved food additives when used at higher levels or under other new conditions of use. Some foods with novel ingredients also bear claims that misbrand the product or otherwise violate the FFDC.

## III. Discussion

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

Under section 201(ff)(2)(B) of the FFDC (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 FFDC. Even when the label of a liquid product characterizes it as a dietary supplement, the product may not in fact be a dietary supplement. Liquid products can be represented as conventional foods as a result of factors such as their packaging, the volume in which they are intended to be consumed, their product or brand name, and statements about the product in labeling or advertising. For example, the packaging of liquid products in bottles or cans similar to those in which single or multiple servings of beverages like soda, bottled water, fruit juices, and iced tea are sold, suggests that the liquid product is intended for use as a conventional food.

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, FDA estimates the average total daily drinking fluid intake<sup>[1]</sup> per person to be about 1.1 liters (1200 ml) (Ref. 1). Liquid products that suggest through their serving size, packaging, or recommended daily intake 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 U.S., are represented as beverages. In addition, the name of a product can represent the product as a conventional food. Product or brand names that use conventional food terms such as "beverage," "drink," "water," "juice," or similar terms represent the product as a conventional food.

In sum, FDA considers a liquid product's name, packaging, serving size, and recommended conditions of use, as well as other representations about the product, to be important determinants of whether the product is represented as a conventional food and may not be marketed as a dietary supplement.

### B. Ingredients in Beverages and Other Conventional Foods are Subject to the FFDC's Requirements for Substances Added to Food

Many ingredients intentionally added to beverages and other conventional foods are food additives. Food additives require pre-market approval based on data demonstrating safety submitted to FDA in a food additive petition. The agency issues food additive regulations specifying the conditions under which an additive has been demonstrated to be safe and, therefore, may be lawfully used.

A substance is exempt from the definition of a food additive and thus, from pre-market approval, if, among other reasons, it is generally recognized as safe (GRAS) by qualified experts under the conditions of intended use. 21 U.S.C. 321(s). Accordingly, for a particular use of a substance to be GRAS, there must be both evidence of safety (the "technical element" of the GRAS standard) and a basis to conclude that this evidence is generally known and accepted by qualified experts. The technical element of the GRAS standard requires that the information about the substance establish that the intended use of the substance is safe; i.e., that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under its intended conditions of use. 21 CFR 170.3(i). In addition, the data and information to establish the technical element must be generally available, and there must be a basis to conclude that there is consensus among qualified experts about the safety of the substance for its intended use. See 21 CFR 170.30(a)-(c). Any substance added to a beverage or other conventional food that is an unapproved food additive (e.g., because it is not GRAS for its intended use) causes the food to be adulterated under section 402(a)(2)(C) of the FFDC (21 U.S.C. 342(a)(2)(C)). Adulterated foods cannot be legally imported or marketed in the United States.

FDA is concerned that some of the novel ingredients that are being added to beverages and other conventional foods may cause the food to be adulterated because these added ingredients are not being used in accordance with an approved food additive regulation and may not be GRAS for their intended use. In addition, some ingredients that have been present in the food supply for many years are now being added to beverages and other conventional foods at levels in excess of their traditional use levels or in new beverages or other conventional foods. This trend raises questions regarding whether these higher levels and other new conditions of use are safe.

## C. Beverages and Other Conventional Foods May Not Carry Unauthorized Labeling Claims and Must Carry the Appropriate Mandatory Labeling

### *Labeling Claims*

\* General prohibition on false or misleading labeling. All claims and statements in the labeling of a food are subject to section 403(a)(1) of the FFDCA (21 U.S.C. 343(a)(1)), which provides that a food is misbranded if its labeling is false or misleading in any particular. The FFDCA 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. Rather, 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).

\* Health claims. Health claims characterize the relationship between a substance (food or food component) and a disease or health-related condition. 21 C.F.R. 101.14(a)(1). Health claims are limited to claims about reducing the risk of a disease or health-related condition and do not include claims about treating, mitigating, or curing disease, which are drug claims. See *Whitaker v. Thompson*, 353 F.3d 947 (D.C. Cir.), cert. denied, 125 S. Ct. 310 (2004)). See FDA's website for more information on health claims <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/default.htm><sup>2</sup>.

There are three ways in which FDA exercises its oversight in determining which health claims may be used on a label or in labeling for a food:

- (1) FDA reviews health claim petitions and issues regulations authorizing health claims that meet the significant scientific agreement standard set forth in the Nutrition Labeling and Education Act of 1990 (Pub. L. 101-535).
- (2) FDA reviews health claim notifications under the Food and Drug Administration Modernization Act of 1997, which amended the FFDCA to establish a notification procedure that streamlines the authorization of health claims that are based on an authoritative statement from a scientific body of the United States government with official responsibility for public health protection or research directly related to human nutrition, or from the National Academy of Sciences (now the National Academies) or any of its subdivisions, about the relationship between a nutrient and a disease or health-related condition. Such claims may be used beginning 120 days after submission of a health claim notification to FDA, unless the agency prohibits or modifies the claim by regulation or obtains a court order determining that the statutory requirements for an authoritative statement notification health claim have not been met. See section 403(r)(3)(C)-(D) of the FFDCA (21 U.S.C. 343(r)(3)(C)-(D)).
- (3) As a result of court decisions interpreting the First Amendment to the U.S. Constitution, FDA reviews qualified health claim petitions and issues a letter of enforcement discretion when there is credible scientific evidence supporting the claim, but the strength of the evidence falls below the standard for FDA to issue an authorizing regulation. These claims are referred to as "qualified health claims" because they include qualifying language to describe the limitations in the evidence supporting the claim and to convey any other information necessary to prevent the claim from misleading consumers. Although FDA's enforcement discretion letters are issued to the petitioner who requested the qualified health claim, the qualified health claims are available for use on other products that meet the enforcement discretion conditions specified in the letter. See FDA's website for information on the procedures that FDA uses to evaluate and respond to qualified health claim petitions <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/default.htm><sup>3</sup>.

A beverage or other conventional food bearing a health claim that is not authorized by regulation or by the FFDCA is misbranded under section 403(r)(1)(B) of the FFDCA (21 U.S.C. 343(r)(1)(B)). Currently, the health claims that FDA has authorized by regulation are listed in 21 C.F.R. 101.72 to 101.83. Health claims that have been authorized through the notification procedure are listed on FDA's website at <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/FDAModernizationActFDAMAClaims/default.htm><sup>4</sup>. Qualified health claims for which the agency has issued a letter of enforcement discretion are listed on FDA's website at: <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm073992.htm><sup>5</sup>.

As a legal matter, an unauthorized health claim or a claim that suggests that a beverage or other conventional food is intended to treat, cure or mitigate disease subjects the food to regulation as a drug under section 201(g)(1) of the FFDCA (21 U.S.C. 321(g)(1)). An example of a health claim that meets the significant scientific agreement standard and is authorized by regulation is: "Diets low in sodium may reduce the risk of high blood pressure, a disease associated with many factors" (see 21 C.F.R. 101.74). In comparison, the following are examples of drug claims: "Shrinks tumors, "Kills influenza viruses," and "We've loaded our product with nature's best cold fighters."

\* Nutrient content claims. A nutrient content claim is a claim characterizing the level of a nutrient in a beverage or other conventional food. 21 C.F.R. 101.13(b). Beverages and other foods may bear authorized nutrient content claims on their labels and in other labeling. Nutrient content claims describe the level of a nutrient in a food using terms such as free, high and low, or they compare the level of a nutrient in a food to that of another food, using terms such as more, reduced and lite. There are three ways in which FDA exercises its oversight in determining which nutrient content claims may be used on a label or in labeling for a beverage or other conventional food:

- (1) FDA reviews petitions for new nutrient content claims and, when appropriate, issues a regulation defining the claim and establishing nutritional criteria that a food must meet to use the claim. See 21 C.F.R. 101.69(m).
- (2) FDA reviews petitions to establish a synonym for a nutrient content claim defined by regulation or to authorize the use of an implied nutrient content claim in a brand name and, when appropriate, issues a letter granting the petition. See 21

C.F.R. 101.69(n)-(o).

(3) FDA reviews nutrient content claim notifications under the Food and Drug Administration Modernization Act of 1997, which amended the FFDCA to establish a notification procedure that streamlines the authorization of claims that are based on an authoritative statement from a scientific body of the United States government with official responsibility for public health protection or research directly related to human nutrition, or from the National Academy of Sciences (now the National Academies) or any of its subdivisions, identifying the nutrient level to which the claim refers. Such claims may be used beginning 120 days after submission of a nutrient content claim notification to FDA, unless the agency prohibits or modifies the claim by regulation or obtains a court order determining that the statutory requirements for authorization of the claim have not been met. See section 403(r)(2)(G) of the FFDCA (21 U.S.C. 343(r)(2)(G)).

The requirements that govern the use of nutrient content claims help ensure that descriptive terms, such as high or low, are used consistently for all types of food products and are meaningful to consumers. A beverage or other conventional food bearing an unauthorized nutrient content claim is misbranded under section 403(r)(1)(A) of the FFDCA (21 U.S.C. 343(r)(1)(A)). Currently, the nutrient content claims that FDA has authorized by regulation are listed in 21 C.F.R. 101.13 and 21 C.F.R. 101.54 to 101.67. See FDA's website for information on nutrient claims that have been authorized through the notification procedure. <http://www.fda.gov/>

<http://www.fda.gov/Food/LabelingNutrition/LabelClaims/FDAModernizationActFDAMAClaims/default.htm><sup>6</sup>.

Some nutrient content claims, such as "high" and "more," are defined only for substances with an established Reference Daily Intake (RDI) or Daily Reference Value (DRV). A list of nutrients with RDIs can be found at 21 C.F.R. 101.9(c)(8)(iv); a list of nutrients with DRVs can be found at 21 C.F.R. 101.9(c)(9). A food may bear a statement about a nutrient for which there is no established RDI or DRV as long as the claim specifies only the amount of the substance per serving, does not characterize the level of the substance (e.g., by implying that there is a lot or a little of the substance in the product), and is not otherwise false or misleading. 21 C.F.R. 101.13(i)(3).

\* Structure/function claims. The FFDCA 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 FFDCA (21 U.S.C. 321(g)(1)(C)). "Food" is defined in section 201(f) of the FFDCA (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 as long as 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 drug 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 beverage or other 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 subjects the product to regulation as a drug under section 201(g)(1)(B) of the FFDCA (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 FFDCA (21 U.S.C. 343(a)(1)).

#### Required Labeling for Conventional Foods

Labeling requirements for beverages and other conventional foods differ from those for dietary supplements. For example, beverages and other conventional foods are required to bear nutrition information in the form of Nutrition Facts rather than Supplement Facts, and all ingredients in a beverage and other conventional food must be declared in the ingredient statement by their common and usual names, in descending order of predominance. 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 claim or other claims described in section 403(r)(6)(A) of the FFDCA (21 U.S.C. 343(r)(6)(A)).

Questions regarding the regulatory status of ingredients that you intend to use in your beverage or other conventional food, and about how to file a GRAS Notice or Food Additive Petition, should be directed to the Office of Food Additive Safety, Center for Food Safety and Applied Nutrition, HFS-200, 5100 Paint Branch Parkway, College Park, MD 20740. Questions regarding the labeling requirements for beverages and other conventional foods, and about voluntary labeling claims for these foods, should be directed to the Food Labeling and Standards Staff, Office of Nutrition, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition, HFS-810, 5100 Paint Branch Parkway, College Park, MD 20740.

FDA's general food labeling requirements are located in Title 21 of the Code of Federal Regulations, Part 101, and additional guidance can be obtained from the Food Labeling Guide <http://www.fda.gov/FoodLabelingGuide><sup>7</sup>, which is available on the FDA website.

#### IV. References

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

1. [Foods Analysis and Residue Evaluation Program \(FARE\), Version 8.50, Consumption Analysis: Distribution and Means Analysis based on NHANES 2005-2006.](#)

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**Links on this page:**

1. <http://www.regulations.gov/http://www.regulations.gov/>
2. <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/default.htm>
3. <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/default.htm>
4. <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/FDAModernizationActFDAMAClaims/default.htm>
5. <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/QualifiedHealthClaims/ucm073992.htm>
6. <http://www.fda.gov/Food/LabelingNutrition/LabelClaims/FDAModernizationActFDAMAClaims/default.htm>
7. <http://www.fda.gov/FoodLabelingGuide>