Portfolio Media. Inc. | 111 West 19th Street, 5th Floor | New York, NY 10011 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

FDA Leaves Beverage-Labeling Questions Unanswered

Law360, New York (January 29, 2014, 4:54 PM ET) --

Angela C. Agrusa

On Jan. 13, 2014, the U.S. Food and Drug Administration released a new guidance to assist in determining whether a liquid product should be classified as a dietary supplement or a conventional beverage.[1] Proper categorization of liquid products may be important in some circumstances because the regulatory requirements for labeling ingredients of beverages and dietary supplements can differ. This article summarizes the FDA's nonbinding recommendations, including the list of factors the agency may consider if it is called upon to categorize a liquid product.

The labeling of conventional beverages and liquid dietary supplements can both include health claims and nutrient content claims, but the FDA states that the mandatory labeling requirements for beverages differ in some respects from the mandatory labeling requirements for dietary supplements, as do the rules governing certain structure/function claims (i.e., claims about the effects of the product on the structure or function of the body). The FDA's guidance states that it might deem a product misbranded if the labeling or other representations made about the product are inconsistent with the product category under which it is being marketed.

In addition, an ingredient that can be added to a dietary supplement might not be proper to add to a conventional beverage. In conventional beverages, the FDA states that an ingredient should be used in conformity with a food or color additive regulation prescribing the conditions of its use in food, be generally recognized as safe for its intended use or qualify for one of the other exceptions to the food additive definition.[2] Dietary ingredients, as opposed to nondietary ingredients such as binders and fillers, used in dietary supplements are exempt from the food additive definition.

In general, the FDA defines dietary supplements as products that are intended to supplement the diet, among other requirements. Conventional beverages, on the other hand, are products intended to quench thirst, provide fluids, provide nutritive value and/or provide taste and aroma. The following is the FDA's list of factors it may consider[3] in assessing whether a liquid product should be categorized as a conventional beverage or a dietary supplement. Although in some circumstances a single factor may be determinative, in most cases the FDA will review a combination of factors.

- It is the FDA's view that the most obvious representations about a product's use are made in its labeling and advertising. Consider the statements and graphics (e.g., symbols and pictorial serving suggestions) on the product's label, labeling, and advertising — including social media — when evaluating the intended use

of the product. Words such as “refresh” or “rehydrate” may suggest the product for use as a beverage.

- The FDA states that, in some instances, product or brand name alone may be sufficient to establish that a product is represented for use as a conventional beverage. Product or brand names that use terms such as “beverage” or “water” may be viewed by the FDA as a representation that the product is a conventional beverage.

- The FDA may view the packaging of a product as conveying a message about how it is to be used — considering the size, shape, color and design of the packaging, the volume of liquid it holds, whether it is designed to be consumed in a single serving and the similarity of the packaging to common beverages.

- Consider whether the practical result of the labeled serving size and/or total recommended daily intake is that the product will be used as a beverage to replace ordinary sources of drinking fluid.

- Are the recommendations and directions for use consistent with a dietary supplement or a conventional beverage? For example, a recommendation or direction that one tablespoon be taken three times per day could be consistent with a dietary supplement, even if the product’s packaging is similar to that of a common beverage.

- Examples of marketing practices identified by the FDA that may represent a liquid product as a conventional beverage 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” and the use of metatags that cause the product to appear in the results of electronic searches for sodas or juices. However, recommending that a product be taken with a meal or promoting a product as a substitute for a beverage would not always represent the product as a conventional beverage.

- Does the product consist mostly of conventional beverage components unrelated to its claimed nutritional or health benefit? The FDA recognizes that

there are areas of overlap between the ingredients of some dietary supplements and conventional beverages, but indicates that it intends to consider whether the composition of a liquid product — along with other factors — represents the product as a conventional beverage. As an example, the FDA states that adding an ingredient such as ginkgo to Kool-Aid or nonalcoholic eggnog would not automatically create a dietary supplement.

- Other representations that the FDA might consider include those made in publicly-available documents such as filings with the U.S. Securities and Exchange Commission or Patent and Trademark Office.

The FDA's guidance addresses two specific product types: powdered premix products and liquid concentrates. Products in both of these categories often include directions recommending that the product be added to water or other liquids. But the FDA states that it generally does not view these products as beverages when they are labeled as dietary supplements — provided they are not otherwise represented for beverage use or as alternatives to beverages.

Finally, it is important to note that the FDA's guidance reflects nonbinding recommendations; it does not establish legally-enforceable responsibilities, but rather describes the agency's current thinking. The FDA states that manufacturers may "use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations."

—By Angela C. Agrusa and Wendy S. Dowse, Liner LLP

Angela Agrusa is a partner and Wendy Dowse is senior counsel in Liner's Los Angeles office.

The opinions expressed are those of the author(s) and do not necessarily reflect the views of the firm, its clients, or Portfolio Media Inc., or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.

[1] Food and Drug Administration, Guidance for Industry: Distinguishing Liquid Dietary Supplements from Beverages (2014), available at http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/UCM381220.pdf.

[2] See Food and Drug Administration, Guidance for Industry: Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements (2014), available at http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/UCM381316.pdf.

[3] This information is only a summary and is not exhaustive of the FDA's rules, regulations, or guidance. This document is not legal advice and should not be relied upon in making decisions that may have legal consequences. If you have questions or need legal advice, seek the advice of counsel licensed to practice in the jurisdiction in which your question arises.