



February 2, 2010

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. FDA-2009-D-0542. Draft Guidance for Industry: Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods.

The Council for Responsible Nutrition (CRN)¹ is a Washington, DC-based trade association representing the dietary supplement industry. Our members include some of the largest and most well known ingredient suppliers, manufacturers, direct sellers and retailers of dietary supplements. These products include, but are not limited to liquids and powders or effervescent tablets, to which water must be added prior to consumption – some of the same products that appear to be the subject of the recently issued FDA Draft Guidance.² The purpose of a guidance document should be to provide the public with clarity around FDA’s thinking of a particular regulatory issue(s). In contrast, this Draft Guidance provides little clarity and may actually add further to the confusion. This document also inappropriately attempts to address two, completely unrelated issues – segregation of conventional foods from dietary supplements, and label claims. CRN would like to take this opportunity to provide FDA with comments on the Draft Guidance.

¹ The Council for Responsible Nutrition (CRN), founded in 1973 and based in Washington, D.C., is the leading trade association representing dietary supplement manufacturers and ingredient suppliers. CRN companies produce a large portion of the dietary supplements marketed in the United States and globally. Our member companies manufacture popular national brands as well as the store brands marketed by major supermarkets, drug store and discount chains. These products also include those marketed through natural food stores and mainstream direct selling companies. In addition to complying with a host of federal and state regulations governing dietary supplements, our 70+ manufacturer and supplier members also agree to adhere to voluntary guidelines for manufacturing, marketing and CRN’s Code of Ethics. Learn more about us at www.crnusa.org.

² Docket No. FDA-2009-D-0542, CFSAN 200944. Draft Guidance for Industry: Factors That Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods; December 2009.

Since the passage of DSHEA³, FDA has made its position known on the misrepresentation of conventional foods as dietary supplements through the issuance of numerous warning letters. Many of these warning letters have been aimed at addressing overt violations, e.g.⁴ CRN is aware of the increased practice of marketing what are otherwise conventional foods (e.g. beverages) as dietary supplements. This trend appears to be driven primarily by manufacturers' desire to provide consumers with novel delivery systems along with consumer demand, but may also be motivated by the desire to avoid the process of affirming that added ingredients are generally recognized as safe (GRAS) for their intended use in conventional foods. We recognize the agency's concern regarding this trend and appreciate the issuance of this Draft Guidance.

However, the Draft Guidance, as written, uses flawed logic and fails to address a key product category, and hence has created more confusion than clarity around this issue. In the Draft Guidance FDA maintains "...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* (emphasis added) of the entire daily drinking fluid intake of an average person in the U.S., are represented as beverages...", citing NHANES data⁵ as the reference for a consumer's typical daily fluid intake (1200 ml or roughly 40 fluid oz). This appears to contradict an earlier position taken by the agency.⁶ It is also unclear from this text what "a significant part" represents in the agency's opinion. Furthermore, it is unclear whether FDA has considered the full array of products that may be considered "liquid products". Effervescent tablets or powders (e.g. presented in sachet packets) have increased in utility and popularity in recent years. These products are clearly and appropriately labeled as dietary supplements, yet must be dissolved in water or other liquid, in what may amount to a "significant" volume in FDA's view, prior to ingestion. These products are not addressed in the

³ Dietary Supplement Health and Education Act of 1994; provided a formal definition for dietary supplement, including that a dietary supplement is a product that is labeled as a dietary supplement and is not represented for use as a conventional food or as a sole item of a meal or the diet.

⁴ FDA warning letter issued to Hain Celestial Group, August 17, 2007

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2007/ucm076475.htm>

⁵ Foods Analysis and Residue Evaluation Program (FARE), Version 8.50, Consumption Analysis: Distribution and Means Analysis based on NHANES 2005-2006.

⁶ Shapiro, S. Differentiating Liquid Supplements and Beverages. *Natural Products Insider Magazine*. Dec 16, 2009. <http://www.naturalproductsinsider.com/articles/2009/12/differentiating-liquid-supplements-and-beverages.aspx>

current Draft Guidance, but collectively represent a substantial portion of dietary supplements sold in the US. The assertion that addition of water to these products instantly alters their regulatory status to one with very different standards for manufacturing and labeling seems at the very least impractical.

In CRN's opinion, the volume contributed by a product should not be the sole determining factor in whether it is deemed a dietary supplement or conventional food. Additionally, basing a limit on consumers' typical or recommended daily consumption sets a troubling precedent. Should products be categorized by the percent of energy they provide on a daily basis (e.g. % calories vs. 2000 calorie/day diet)? Or the percent of the Daily Value for a given essential nutrient(s)? This represents a slippery slope that presumably FDA did not intend. No single factor can be the basis for determining whether a product is a dietary supplement or conventional food. Rather, it must be the net impression from a combination of factors that determines such status. CRN believes that FDA more than adequately addresses the issue with the clear statement "...FDA considers a liquid product's name, packaging, serving size, and recommended conditions of use...to be important determinants of whether the product is represented as a conventional food and may not be marketed as a dietary supplement", and we recommend eliminating volume as a sole determinant of whether a product is a beverage or dietary supplement.

It is unclear why FDA chose to address label claims in this Draft Guidance, when it is a completely separate issue requiring, at a minimum, a separate guidance document. Although identical language already appears in existing statutes, regulations, court decisions, or some combination thereof, CRN acknowledges that some aspects of label claims may remain somewhat controversial, in particular the use of structure-function claims with conventional foods. However, the Draft Guidance does not provide a better understanding of the issue. FDA states, "...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..."⁷ Clearly, FDA's position depends substantially on the definition of "nutritive value", and the agency has

⁷ *Nutrilab v. Schweiker*, 713 F.2d 335 (7th Cir. 1983)

historically applied a broad definition to this term: Nutritive value “...means a value in sustaining human existence by such processes as promoting growth, replacing loss of essential nutrients, or providing energy.”⁸ By definition, foods or food components that are the subject of FDA-approved health claims must provide nutritive value. Based on the decisions for approved health claims to date, this would include substances such as plant stanol and sterol esters which are the subject of a FDA-approved claim for reduction of coronary heart disease risk⁹. The claim is based on data demonstrating the ability of these substances to lower LDL-cholesterol, a recognized risk factor and surrogate endpoint for coronary heart disease. The consideration of the LDL-cholesterol lowering effect of stanol and sterol esters as providing nutritive value is an example of FDA’s already broad application of the term. Other FDA-approved health claims and letters of enforcement discretion for qualified health claims provide similar examples. Given this historically broad approach taken by the agency, it is unclear why FDA is attempting to address this issue in this particular guidance document. As written, the Draft Guidance adds little clarity on the agency’s thinking beyond what is already known. The decision to address the issue may be warranted, but CRN recommends at a minimum that FDA address this in a separate guidance document aimed at label claims for conventional foods. If FDA’s objective is to more narrowly define nutritive value, then CRN recommends this be undertaken through notice and comment rulemaking.

Thank you.

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⁸ 21CFR Part 101 §101.14 (a)(3)

⁹ 21 CFR Part 101 §101.83 Health Claims; Plant Sterol/Stanol Esters and Coronary Heart Disease