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E-ALERT | Food & Drug

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FDA ISSUES GUIDANCE DOCUMENTS RELATING TO LIQUID DIETARY SUPPLEMENTS AND SUBSTANCES ADDED TO FOODS

On January 14, FDA released guidances for industry entitled "Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements" and "Distinguishing Liquid Dietary Supplements from Beverages."[1] These publications come at a time when FDA faces concerns — from lawmakers and vocal consumer advocacy groups — about the adequacy of its regulatory scheme for food ingredients identified as "generally recognized as safe" (GRAS). While much of what is expressed in the guidance documents is not new, their publication reflects the agency's responsiveness to such concerns. The guidance documents also articulate FDA's views on some issues of importance to the broader food industry, including with respect to structure/function claims for conventional foods and the broad range of documents and materials that may be deemed to reveal a marketer's intended use of its products.

I. GUIDANCE ON DISTINGUISHING LIQUID DIETARY SUPPLEMENTS FROM BEVERAGES

This long-awaited final guidance sets out the factors that FDA considers in determining whether a liquid product should be marketed as a beverage, which constitutes a conventional food, or as a dietary supplement. For purposes of this guidance, the key distinction is that all ingredients in conventional foods must be either FDA-approved food additives or must be GRAS, whereas dietary ingredients in dietary supplements are subject to a different regulatory regime. Before FDA released this final guidance, the most recent iteration of the agency's thinking on this subject was a draft guidance dated December 2009.[2] In the interim time period, this distinction has become a hotly contested issue in the conventional food and dietary supplement industries, such as in the context of marketing energy drinks and enhanced waters.

Unlike the December 2009 draft guidance, which focused on claims and statements made on product labels, the final guidance expands the scope of distinguishing factors. Nevertheless, FDA maintains the position that these claims are the "most obvious representations" of a product's use. The agency also considers a product's name, packaging, serving size, recommended daily intake and other recommended conditions of use, and composition to be factors that distinguish beverages from liquid dietary supplements. For example, FDA states that "conventional food terms" (e.g., "beverage," "drink," "water," or "soda") on a liquid product represent that product as a conventional food. When the term used "is not associated exclusively with conventional foods," however, the term in the product name would be weighed against other factors. The final guidance identifies products described as "teas" as falling in this less certain category.

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[1] These guidance documents are available here ("Distinguishing Liquid Dietary Supplements from Beverages") and here ("Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements").

[2] The 2009 draft guidance is available here.

Notably, the final guidance indicates that marketing practices and representations about the product "outside its labeling and advertising" can also inform the judgment of a product's regulatory category. When evaluating the applicable factors, the agency will consider "all relevant factors in context."

Other highlights of this final guidance have relevance beyond the liquid product category, as they indicate FDA's current thinking on issues of relevance to the broader food industry. These include:

- **Structure/function claims for conventional foods.** FDA reiterates its view that structure/function claims that may be made for conventional foods are limited to those for effects "derive[d] from the product's character as a food — its taste, aroma, or nutritive value." While this has been the agency's longstanding position, FDA had taken a broad view of "nutritive value" in accepting the GRAS status and claims for plant stanol and sterol esters in the 1990's, and the issue had been relatively quiet for nearly two decades. Last fall, FDA articulated a very narrow view of "nutritive value" for food ingredients in its final guidance on when an investigational new drug application (IND) is required for clinical research.[3] If enforced, the agency's constricted view of "nutritive value" potentially could preclude a number of structure/function claims that are widely used for conventional foods today.
- **Statements made in filings with government agencies.** The final guidance states that representations about a product made in publicly available documents, including statements made in filings with government agencies such as the Securities and Exchange Commission and the Patent and Trademark Office, may indicate whether the product is a dietary supplement or conventional food. An "isolated representation," however, generally would not be dispositive. These agency comments serve as a reminder to the food industry that FDA may look to a broad range of materials, not just product labels, to determine a marketer's intended use of its products.
- **Omissions from labeling.** FDA reminds industry that an article may be deemed misbranded because of the omission of material facts or consequences, and not just because of affirmative misrepresentations on labels or in labeling.

II. GUIDANCE ON CONSIDERATIONS REGARDING SUBSTANCES ADDED TO FOODS, INCLUDING BEVERAGES AND DIETARY SUPPLEMENTS

The December 2009 draft guidance on the distinctions between beverages and liquid dietary supplements originally included the material reflected in this guidance, but FDA has now released it as a separate document. In the Federal Register notice announcing the availability of this guidance, the agency explained that the document "merely summarizes" the existing regulatory scheme "without setting forth any new interpretations of those requirements." As such, the guidance reviews and reminds industry of the requirement that substances added to foods, including non-dietary ingredients ("other ingredients") in dietary supplements, must either be FDA-approved food additives or be determined to be GRAS.

Covington & Burling LLP is experienced in legal matters concerning the regulation of conventional foods and dietary supplements and is available to provide individualized compliance counseling concerning the marketing and regulation of these products.

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[3] FDA Guidance for Clinical Investigators, Sponsors, and IRBs, Investigational New Drug Applications (INDs) — Determining Whether Human Research Studies Can Be Conducted Without an IND (September 2013), available here.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food & Drug Practice Group:

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