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Client Alert Commentary

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FDA's Final Guidance Distinguishes Liquid Dietary Supplements from Beverages

Two new FDA guidance documents can assist both conventional beverage and liquid dietary supplement manufacturers to avoid costly mischaracterization and enforcement action.

The US Food and Drug Administration (FDA or Agency) has raised concerns regarding the increase in the marketing of liquid products with a variety of ingredients and intended uses, some of which are marketed as dietary supplements and others as conventional foods. To assist members of the dietary supplement and beverage industries in distinguishing between these two product categories and complying with the regulatory requirements applicable to each, FDA issued draft guidance in 2009 and, most recently, in January 2014 issued two final guidance documents. These documents, entitled, "Distinguishing Liquid Dietary Supplements from Beverages"[1] and "Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements,"[2] together update the Agency's December 2009 draft guidance entitled, "Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods."[3] The final guidance documents are consistent with the 2009 Draft Guidance, but provide greater detail with respect to distinguishing dietary supplements and beverages. Thus, they are valuable resources for beverage and liquid dietary supplement companies navigating the often muddy food and dietary supplement regulations.

Distinguishing Liquid Dietary Supplements From Beverages

FDA stated in the 2009 Draft Guidance that it intended to assist the dietary supplement and beverage industries in determining whether a liquid product could be labeled and marketed as a dietary supplement. Similarly, the 2014 Liquid Supplement Guidance aims to assist in classifying a liquid product as a beverage or dietary supplement. The distinction between beverages (which are foods) and dietary supplements is critical, as their labeling, advertising, manufacturing, and composition requirements and restrictions differ. Notably, dietary supplements are subject to distinct good manufacturing practice regulations, ingredient compliance requirements, and labeling requirements, just to name a few differences. Thus, misclassification of a liquid product can expose a company to risk of significant enforcement action.

In the 2009 Draft Guidance, FDA very briefly listed factors, such a as liquid product's name, packaging, serving size, and recommended conditions of use, as important determinants of whether the product is represented as a conventional food and thus may not be marketed as a dietary supplement.[4] However, the 2009 Draft Guidance does not provide significant detail regarding the application of these factors in making such a determination.

The 2014 Liquid Supplement Guidance provides a more in-depth analysis of these factors, including specific examples of situations in which a liquid product will or will not be deemed to be appropriately marketed as a dietary supplement, as follows.

Characteristics suggesting that a product is a conventional food that cannot be marketed as a dietary supplement:

- ***Labelling, advertising, and marketing*** that bears (i) statements that indicate that the product is intended to "refresh," "rehydrate," or "quench thirst," or (ii) graphics representative of a conventional food.

- ***Product or brand names*** that use terms that are generally associated with conventional foods, such as "beverage," "drink," "water," "soda" and so forth.

- ***Product packaging characteristics*** that are similar to packaging for common beverages.

- ***Serving size and recommended daily intake*** amounting to a significant part of average daily drinking fluid intake. Notably, however, powdered premix products and liquid concentrates are not necessarily conventional foods.

- ***Marketing practices*** such as comparing the product to a beverage, use of metatags[5] resulting in the product's appearance in the results of an electronic search for beverages, or payment of fees for the product to be displayed in the beverage section of retail stores.

- ***Composition*** where the product is essentially a copy of a common beverage with a dietary ingredient added. In other words, the addition of an ingredient that falls within the definition of a "dietary ingredient" will not necessarily convert a beverage to a dietary supplement.

- ***Other representations*** in publicly-available documents, such as SEC or trademark filings indicative of a conventional food.

FDA notes that it intends to consider all relevant factors in context when making a determination that a product is represented as a conventional food rather than a dietary supplement. To that end, the analysis requires a fact-specific, case-by-case determination, and apparently no one factor will be dispositive.

As noted above, significant differences exist in the regulatory requirements for conventional food beverages and those for liquid dietary supplements. The 2009 Draft Guidance provided some detail on nutrient labeling requirements for conventional foods and on when health or structure/function claims could result in a conventional food being mislabeled or deemed an unapproved drug. In the 2014 Liquid Supplement Guidance, FDA addresses labeling claims for both conventional foods and dietary supplements. In conjunction with the statute, regulations and other FDA guidance, the 2014 Liquid Supplement Guidance can assist both conventional beverage and liquid dietary supplement manufacturers avoid labeling omissions or claims that could result in a determination of mislabeling.

Application of Food Additive Regulations to Beverages and Liquid Supplements

In addition to elaborating on the factors that FDA uses to distinguish between a dietary supplement and conventional food, the 2014 Liquid Supplement Guidance — together with the 2014 Substances Added to Food Guidance — clarifies the regulatory requirements applicable to substances added to both conventional foods and dietary supplements. With respect to conventional foods, FDA expresses concern

that novel ingredients, such botanical ingredients or extracts, added to beverages or conventional foods might cause the food to be adulterated because they have not undergone food additive premarket approval and are not deemed generally recognized as safe (GRAS). In addition, non-novel additives to conventional foods may be added to foods in excess of the levels traditionally found in the food supply, which may make them unapproved additives. The 2009 Draft Guidance provided a brief overview of the regulatory framework applicable to the substances added to conventional foods, but did not explicitly address the application of this regulatory scheme to substances in dietary supplements.

Both of the 2014 guidance documents clarify that ingredients and other substances *in dietary supplements* that *do not* meet the definition of a "dietary ingredient" under the Federal Food, Drug, and Cosmetic Act (*e.g.,* fillers, excipients and binders that do not qualify as dietary ingredients) must meet the same standards as substances added to conventional foods. That is, these ingredients and substances must comply with the food additive regulatory framework or be deemed GRAS for their intended use. This clarification does not represent a new interpretation of the requirements applicable to the substances in dietary supplements. However, the new guidance documents explicitly set forth FDA's view on this matter.

Next Steps

While the topics addressed in FDA's 2014 Guidance Documents are not novel, the new guidance documents provide manufacturers and other members of the industry with additional clarity on FDA's interpretation of its laws and regulations, and thus some insight into FDA's potential enforcement theories and priorities. To that end, dietary supplement and beverage manufacturers would be well-served to review the guidance and assess the potential impact on their products, operations and businesses. Although FDA deems these newly issued guidance documents as final, the Agency will accept comments at any time. Thus, members of industry could take advantage of the opportunity to raise any concerns regarding FDA's interpretations in the guidances through the public comment process.

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Endnotes

[1] FDA, "Guidance for Industry: Distinguishing Liquid Dietary Supplements from Beverages" (Jan. 2014) [hereinafter, "2014 Liquid Supplement Guidance"], *available at* http://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/UCM381220.pdf.

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

[3] FDA, "Draft Guidance for Industry: Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods" (Dec. 2009) [hereinafter, "2009 Draft Guidance"], *available at* http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/dietarysupplements/ucm192702.htm.

[4] *Id.*

[5] A metatag is an HTML tag that contains descriptive information about a Web page.