FDAGuidancesPoseRegulatoryChallengesforFunctionalFoods

The Food and Drug Administration recently finalized two guidance documents for dietary supplement manufacturers, one focused on Distinguishing Liquid Dietary Supplements from Beverages and the other on Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements. These were ostensibly issued to clarify the types of food in which certain ingredients may be used, with some permitted only in dietary supplements and not in conventional food like beverages, and the resulting claims and promotional statements which could be made depending on product category. More broadly, they reflect an aggressive view of limitations that apply to any functional food and articulate principles related to the concept of “intended use” that have ramifications for all product types regulated by FDA, including drugs, biological products, and medical devices.

Congress included liquid products in the definition of dietary supplements, but also made clear that they could not be represented as conventional foods or meal replacements/sole items in the diet. Manufacturers of supplements and conventional foods should review the final documents carefully to understand the factors involved in assessing whether a product is a beverage or a dietary supplement, as well as the implications of this assessment for determining the ingredients and claims that should be used for any particular product. One of the most important factors relates to the claims made in labeling and promotional materials, but the guidance also discusses the relevance of product name, product packaging, serving size and recommended daily intake, recommendations and directions for use, marketing practices, composition, and “other representations” about a product.

All FDA-regulated companies should also note aspects of the guidance documents that reflect a expansive view of the ways in which FDA may determine how a manufacturer intends that its product be used. This is critical because “intended use” dictates whether these products will be regulated as a food or drug. The guidance includes several assertions about the types of evidence which may establish product classification, all of which have implications far beyond the specific context of distinguishing beverages and supplements. For example, according to the guidance, such evidence may include:

- Website metatags that cause a product to appear in the results of an electronic search, such as tags that cause a product to appear in results of an electronic search for sodas, juices, or other beverages; and,
• Payments for product placement, such as payment to have a product displayed in the beverage section of retail stores

Importantly, public companies and patent-holding entities should also be aware that FDA, despite an absence of legal authority to do so, includes as one factor representations in filings with the Securities Exchange Commission or US Patent and Trademark Office, such as a filing describing a product as a type of “bottled water” or “coffee drink.” While this factor may not support an FDA enforcement action, it could pose difficulties in other arenas and thus requires careful cross-functional company consideration.

The guidance confirms that teas can be supplements. It also specifically classifies powdered premix products and liquid concentrates that are intended to be added to water or other liquids and marketed as dietary supplements, as supplements. FDA finds that these products are unlikely to be confused with, or used as a substitute for, beverage mixes. Additionally, FDA states that consumption of a product primarily for taste – a purely subjective consideration - rather than for nutrition or health-related purposes, will render the product a conventional food.

Finally, while the claims discussion is mostly a review of the law, FDA does restate its controversial position that structure-function claims for a conventional food may not promote a use other than providing taste, aroma, or nutritive value, even though a broader set of structure-function claims may be made for supplements. FDA states that “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 a drug under section 201(g)(1)(C) of the FD&C Act 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”.

CONTACTS
For more information regarding the content of this Sidley Update, please contact:

Scott Bass
212.839.5613
202.736.8684
sbass@sidley.com

Diane McEnroe
212.839.5621
dmcenroe@sidley.com

Torrey Cope
202.736.8803
tcope@sidley.com

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