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# FDA Law Update

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## Shift in FDA's Regulation of Products Marketed as Dietary Supplements and Functional Foods?

Manufacturers of liquid supplements and energy drinks appear to be in the FDA crosshairs.

On December 3, 2009, FDA's Center for Food Safety and Applied Nutrition (CFSAN) published a draft guidance, "Factors that Distinguish Liquid Dietary Supplements from Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods." The guidance took many industry insiders by surprise. Because the guidance is still in draft form, CFSAN has invited comments from stakeholders.

If the guidance's title seems innocuous, the shift in FDA's thinking that it perhaps signals is not. In distinguishing between supplements and other beverages marketed as foods, the guidance appears to signal an Agency intention to put functional foods under the microscope.

Beverages with "novel ingredients" – including, for example, numerous botanicals and extracts -- have found a vibrant market in recent years. Between 2001 and 2006, the market increased more than 500%, and the growth has shown little indication of weakening.

Labeling these beverages as dietary supplements, manufacturers have included novel ingredients and health claims acceptable for dietary supplements but not necessarily for foods. If strictly regulated as foods, and scrutinized more closely, some of these products may be alleged to include unapproved food additives. A requirement to obtain prior FDA approval to market those ingredients can take a manufacturer down a long toward a "GRAS" declaration – that is, Generally Recognized as Safe.

Traditionally, the distinction in FDA regulatory status – food or supplement – typically comes down to the way a product is labeled. The guidance reiterates the Agency's longstanding position that designators like "drink," "water," "juice," "beverage," signal a conventional food, but it also went further. Under special scrutiny are liquid products packaged to look like conventional beverages, bearing product names that encourage treatment as such, or packaged in a volume suggestive that the product constitutes rather than supplements a diet. The guidance suggests that the Agency will be paying closer attention to liquid products packaged "in bottles or cans similar to those in which single or multiple servings of beverages like soda, bottled water, fruit juices, and iced tea are sold."

The guidance signals further scrutiny, too, of ingredients used at higher levels than traditional. For example, caffeine.

Moreover, FDA imposes significantly tighter controls on the health claims permitted for foods. Claims for foods must be related to nutritive value, taste, or aroma – in other words, very narrowly restricted.

From an industry perspective, of course, so-called liquid supplements deliver dietary supplements to consumers in a palatable and convenient form. Those who market functional foods view FDA as failing to keep up with technological advances and the concomitant evolution of the marketplace.

In sum, products that blend supplements with more conventional foods and drinks has occupied somewhat of a grey area in Agency regulation for some time – but the recent draft Guidance suggests that all may soon change.

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