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The FDA Stance On High-Fructose Corn Syrup

Law360, New York (October 15, 2009) -- A recent ruling by the U.S. Court of Appeals for the Third Circuit calls into question the U.S. Food and Drug Administration's position on use of the term "natural" to describe products that contain high-fructose corn syrup (HFCS).

The ruling has potential implications for all firms that rely on the FDA's policy concerning use of "natural" as it pertains to HFCS, including pending litigation in New Jersey and California alleging that Snapple Beverage Corp. (Snapple) acted inappropriately by claiming its products were "all natural" when HFCS was the primary sweetener in the products.

FDA's Position on "Natural"

The FDA has not established a formal definition for the term "natural." However, in the preamble to a rulemaking for nutrient content claims in 1993, the FDA offered an informal policy regarding use of the term "natural."

The policy states that "natural" means "nothing artificial or synthetic has been included in, or has been added to, a food that would not normally be expected to be in the food." 58 Fed. Reg. 2302, 2407 (Jan. 6, 1993). Except as to "flavors" and "colors," the FDA has not defined or issued guidance regarding the terms "synthetic" or "artificial."[1]

In July 2008, in a letter to the Corn Refiners Association, Geraldine June, Supervisor of the FDA's Product Evaluation and Labeling Team on the Food Labeling and Standards Staff, explained the FDA's position concerning use of the term "natural" to describe HFCS.

In the letter, Ms. June stated that, depending on the process used to manufacture the HFCS, it is possible that the ingredient can be considered "natural."

In particular, the letter stated that the FDA would not object to use of the term "natural" when describing HFCS derived from a manufacturing process whereby the enzymes for making HFCS are fixed to a column by the use of a synthetic fixing agent called glutaraldehyde, but the agent does not come into contact with the high-dextrose equivalent corn starch hydrolysate and so it is not considered to be included or added to the HFCS.

However, Ms. June indicated that the FDA would object to use of the term "natural" on a product containing HFCS that has a synthetic substance such as a synthetic fixing agent included in or added to it.

New Jersey Lawsuit

In early 2007, a class action lawsuit was filed in the U.S. District Court of New Jersey against Snapple alleging that the company misled consumers in violation of the New Jersey Consumer Fraud Act, among other laws, by claiming that its juices were "all natural" when HFCS was the primary sweetener in the products.

Snapple argued that the plantiffs' challenges to the claims on its juice products were preempted by federal law, asserting that the FDA has broad regulatory authority granted to it pursuant to the Federal Food, Drug and Cosmetic Act (FDCA) to issue comprehensive regulations governing the naming and labeling of juice drinks.

In June 2008, the district court, in ruling for Snapple, found that the FDCA and FDA regulations preempt state regulation of beverage and juice labeling.

The court found that the FDA had contemplated the appropriate use of the term as evidenced by the FDA's definition of "natural flavor" and its informal policy regarding use of the term "natural," even though it had not formally adopted a definition for the term.

Furthermore, the court found that it was within the FDA's purview, not the court's, to define "natural."

Third Circuit Ruling

On Aug. 12, 2009, the Third Circuit reversed the district court's ruling and remanded the case back to the district court for further proceedings.

The Third Circuit found that there was no federal preemption of the state's right to regulate, stating that it does not appear that the U.S. Congress has regulated so comprehensively in the areas of food or beverages and juices so as to leave no role for the states.

Further, the Third Circuit found that neither the FDA's policy statement regarding use of the term "natural" nor its letter indicating that some forms of HFCS may be labeled as "natural" have the force of law required to preempt conflicting state law because they

were not issued as part of any formal rulemaking or adjudication and were not subject to the notice and comment process.

California Lawsuit

On Aug. 21, 2009, a class action lawsuit similar to the one filed in New Jersey in 2007 was filed against Snapple in U.S. District Court for the Southern District of California.

Among other things, the complaint alleges that Snapple violated the California Business and Professions Code provisions prohibiting unfair competition by labeling its products as "all natural" when they contain HFCS.

Conclusion

The FDA has declined on several occasions to enact a formal policy regarding use of the term "natural." Instead, the administration has sought to offer guidance through less formal means such as by language in the preamble to the nutrient content claims rulemaking and its 2008 letter issued to the Corn Refiners Association.

However, in light of the Third Circuit's recent ruling that the FDA's policy statements concerning use of the term "natural" do not have the effect of preempting state regulation in this area, the FDA may elect to reconsider its earlier refusal to formally define what constitutes "natural."

Given the widespread use of this claim in national (and international) markets, the FDA is unlikely to want to allow the issue to be settled by the potentially inconsistent actions of individual states or through consumer fraud lawsuits across the country.

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[1] With regard to colors, it is the FDA's position that any added color is an artificial color, even if the added color is from a source considered to be natural. See Compliance Policy Guide No. 7127.01. The FDA defines "natural flavor" by regulation as "the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis ... of a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, ... or fermentation products thereof." 21 C.F.R. § 101.22(a)(3).