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Claim Litigation in the Food Industry

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Not all substances contained in packaged foods and dietary supplements need to be disclosed in the products' ingredient statements. But can the presence of those substances impact claims and "romance language" included elsewhere on the products' labeling?

Plaintiffs' lawyers are increasingly answering that question "yes."

"Natural flavors" is one recent example. When propylene glycol (a synthetic) is used as a solvent to create flavoring agents made with natural ingredients, the resulting product can meet FDA's definition of "natural flavoring" (21 CFR § 101.22(a)(3)). And if the amount of propylene glycol in the final product is insignificant and has no technical or functional effect, the propylene glycol does not need to be disclosed on the ingredient panel (21 CFR §§ 101.22(h)(2), 101.100(a)(3)).

Nonetheless, in the recent case of Madrigal v. Hint Inc., the plaintiff asserted that defendants falsely advertised its fruit-flavored water products—which allegedly contain natural flavoring created with propylene glycol—by claiming that they are "all natural," and "100% natural." While the flavoring created from propylene glycol may well be "natural flavoring" according to FDA, the plaintiff argued, consumers do not view "all natural" products as containing synthetic substances like propylene glycol. It is yet to be seen whether a judge will agree with the plaintiff's assessment. The defendant's response is due later this month.

Another recent example is the use of "no preservatives" in products containing citric acid. FDA regulations require the ingredients panel of a food containing a chemical preservative to "bear … a separate description of its function, e.g., 'preservative' …." 21 CFR § 101.22(j). However, citric acid, while it can function as a preservative, is often used as a flavoring agent—it can be used in place of lemon juice to impart a sour flavor—or as an emulsifying agent. When used for these alternative purposes, it need not be designated as a preservative on the ingredients statement.

In a spate of recent cases, however, plaintiffs have argued it is a step too far to claim that products using citric acid for these alternative functions have "no preservatives." Thus, in Park v. Welch Foods Inc., filed in the Northern District of California, the complaint recognized that citric acid can be used to "impart tart flavor to products that lack such flavor naturally." Nonetheless, plaintiff asserted that defendant's claims that its fruit spreads and fruit juices contained "no preservatives" were misleading since those products contained citric acid. Similarly, in Hu v. Golden Orchid, Ltd., filed in the Eastern District of New York, plaintiffs asserted that the "no preservatives added" claim included on the defendant's pickled vegetable products was misleading despite recognizing that "the acidic pH of citric acid would most certainly provide tartness to the products." Other similar cases have been filed, but the courts have not yet had an opportunity to address these allegations.

Similar issues can arise in the dietary supplements space. For example, vitamins and herbal supplements from green foods or herbs often contain trace amounts of naturally occurring lead. These traces of lead are generally many times less than the safe levels of daily lead intake determined by FDA, and there is no requirement that they be disclosed on product labeling. Nonetheless, some plaintiffs have asserted that

the presence of such trace amounts of lead renders claims about the purity or quality of supplements misleading. One example is Hoffman v. Nutraceutical, where the plaintiff asserted that Nutraceutical's claim that one of its supplements was "pure, unadulterated and of the highest quality" was false because it contained 1/44 of FDA's safe daily exposure levels of lead. Nutraceutical shed this case at the motion-to-dismiss stage, with the court concluding that the presence of such safe levels of lead did not contradict its claims. But plaintiffs' lawyers have persisted with such claims in other cases.

The bottom line is that industry participants assessing their litigation risk should consider the effect of all substances contained in their products when formulating their advertising and marketing strategies, even when those substances need not be affirmatively listed on the product labeling. Plaintiffs' lawyers have made plain that they will not ignore unlisted substances, and only time will tell whether their claims gain traction with the courts.

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