

## COURTS SPLIT ON THE VIABILITY OF CLAIMS CHALLENGING “HYPOALLERGENIC” LABELING

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As is often the case with labeling for cosmetic and personal care products, there is no federal standard or definition governing the use of the term “hypoallergenic.” In the 1970s, FDA proposed regulations requiring cosmetic manufacturers to conduct tests to back up any claim that a product is “hypoallergenic”; however, those regulations were struck down in court and, today, according to [FDA Guidance](#), the term means either products that produce “fewer allergic reactions than other cosmetic products” or “whatever a particular company wants it to mean.”

One California law firm has filed two class actions seeking to capitalize on the lack of a firm definition of “hypoallergenic.”

1. In *Rugg v. Johnson & Johnson*, a case pending in the District Court of San Jose, California, plaintiffs claim that Johnson & Johnson’s use of the term “hypoallergenic” to describe dozens of personal care products was false and misleading because they contain known skin sensitizers and known skin or eye irritants and other substances that have not adequately been assessed for safety or skin sensitization potential. According to plaintiffs, reasonable consumers believe and expect that products “labeled as hypoallergenic contain no ingredients known to produce a negative reaction – skin irritation, skin corrosion, eye damage, birth defects, cancer, genetic mutations, etc.” Johnson & Johnson challenged plaintiffs’ definition and argued the term is actually commonly defined as “having little likelihood of causing an allergic reaction” or “[h]aving a decreased tendency to provoke an allergic reaction.” The court agreed with Johnson & Johnson, finding it “completely implausible that a reasonable consumer would understand the use of the term ‘hypoallergenic’ on a product’s label to mean that the product does not contain *any* ingredients, in any concentration, which could ‘sensitize’ the skin, cause cancer, or have *any* other negative effect, regardless of whether such effect constitutes a negative reaction.” The court granted plaintiffs leave to amend their complaint, but expressed skepticism that they will be able to allege facts showing the products are not hypoallergenic under a plausible definition of the term.
2. The San Francisco District Court reached the opposite conclusion in another case, *Kellman v. Whole Foods Market*. The plaintiffs in this case allege a dozen Whole Foods 365-branded products are falsely labeled “hypoallergenic” because, as was asserted in the Johnson & Johnson case, they contain known skin sensitizers. Plaintiffs elaborated on the definition, claiming “[t]he scientific and regulatory definition of a ‘skin sensitizer’ is a substance that causes sensitization by skin contact in a substantial number of persons based on human evidence or appropriate animal testing. If a skin sensitizer makes up 0.1% or more of a product, or if the product contains a sensitizer that may elicit an allergic response at concentrations smaller than 0.1% in individuals who are already sensitized to the chemical, the entire product mixture is classified as a skin sensitizer.” Following Johnson & Johnson’s lead, Whole Foods challenged plaintiffs’ definition of “hypoallergenic” and argued the term has other meanings, including that the products “produce fewer allergic reactions than other products” and, under that definition, Whole Foods’ use of the term was not false. Notwithstanding the striking similarity between plaintiffs’ definition and the definition advanced in the Johnson & Johnson case, the court was not prepared to conclude that plaintiffs’ interpretation was simply “implausible.” Instead, it found plaintiffs’ use of the term, that the products contained

enough skin sensitizers to cause possible reactions in a substantial number of people, more palatable and concluded that how a reasonable consumer would interpret the term “hypoallergenic” was not a question that could be resolved based on the limited record before it. The Whole Foods case now proceeds.

Companies that use the term “hypoallergenic” to describe their products should keep a close eye on these cases.

#### ADDITIONAL INFORMATION

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