CLIENT ALERTS & INSIGHTS

Science-Backed But Not FDA-Approved: New Lawsuit Challenges FDA's Rejection of 114 Health-Related Advertising Claims

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Featured Practices: Litigation, False Advertising & Unfair Competition

Featured Industries: Retail & E-Commerce, Food & Beverage

Key Takeaways

- A new lawsuit challenges the FDA's rejection of 114 health-related advertising claims for supplements, arguing that the agency's narrow interpretation of what counts as an "authoritative statement" unfairly blocks science-backed-but not FDA-approved-claims from appearing on product labels.
- If successful, the case could significantly loosen FDA restrictions on health claims, giving supplement and food companies broader ability to market disease-risk benefits-while raising legal and reputational risks around claim substantiation, consumer expectations, and potential enforcement uncertainty.
- Companies in the supplement and nutrition space should closely monitor the outcome of this case. If the court rules in favor of the plaintiffs, businesses should be prepared to review and potentially update their marketing strategies and product labeling to take advantage of new opportunities-while also ensuring claims remain truthful and substantiated to avoid regulatory or legal challenges.

The FDA may soon stop serving as a roadblock for supplement manufacturers seeking to market their products as capable of reducing disease risks.

Last fall, the Alliance for Natural Health USA and three dietary-supplement manufacturers asked the FDA for permission to include 118 distinct health-related claims on their supplement labels without proceeding through the full petition process. By way of example, they sought to market supplements like Vitamin D, Zinc, and Turmeric as reducing the risk for disease and other ailments:

- "Vitamin D reduces the risk of rickets in children"
- "Zinc may reduce the duration of the common cold"

- “Turmeric extracts may reduce the risk of osteoarthritis”

The full FDA petition process is ordinarily rigorous and demanding. Companies must submit extensive scientific documentation demonstrating “significant scientific agreement” among qualified experts. Specifically, they must show that a claimed relationship between a nutrient and disease is supported by the totality of publicly available scientific evidence. 21 U.S.C. § 343(r)(3)(B). The FDA must issue a final decision on any such petition within 100 days of the petition’s filing and will approve the health claim only if this rigorous scientific standard is met. This process is expensive, time-consuming, and often results in denial-to date, the FDA has approved only 12 health claims through this pathway.

There is an alternative-the “authoritative statement” pathway, codified at 21 U.S.C. § 343(r)(3)(C). This pathway permits manufacturers to make health claims on food labels based on an “authoritative statement” from a scientific body of the U.S. government-such as the National Institutes of Health or the Centers for Disease Control-or the National Academy of Sciences. Such an authoritative statement allows companies to bypass the standard petition process, provided they notify the FDA at least 120 days before marketing the product with the claim.

The supplement manufacturers pursued the “authoritative statement” pathway; the FDA shot them down, categorically rejecting 114 of their 118 proposed health claims. The agency’s reasoning raised alarm bells in the minds of supplement manufacturers. In its denial letter, the FDA conceded that though the operative statute does not define “authoritative,” the FDA adopts a narrow reading that requires that any health-based claims be grounded in “official” or “consensus” positions.

In response, on April 29, 2026, the Alliance for Natural Health USA sued to challenge the FDA’s blanket rejection of their disease-risk-reduction claims. Their complaint contends that the FDA adopted an unlawful and unconstitutional reading of 21 U.S.C. § 343(r)(3)(C). Specifically, they contend that the FDA’s newly adopted definition of “authoritative” imposes additional hurdles that the statute’s plain language does not support. Overall, according to these entities, the FDA’s interpretation raises serious First Amendment concerns because it imposes a blanket ban on science-backed claims without considering other, less-restrictive alternatives.

The Complaint seeks a declaratory judgment that would set aside the denial letter issued by the FDA and categorize it as unlawful, and also an order allowing the previously rejected health-based claims to enter the market.

If successful, this lawsuit could reshape how supplement, food, and beverage companies market their health and nutrition-related products. Specifically, it could:

1. Open the “authoritative statement” pathway for supplement manufacturers, allowing them to market disease risk reduction claims without the expense and delay of a full petition with the FDA;

2. Lead to broader latitude with regard to qualified health claims on nutrition labels and in marketing materials; and

3. Have an industry-wide impact by allowing other companies to issue marketing statements concerning verified vitamin, mineral, and botanical ingredients.

The case’s potential for widespread impact across relevant industries makes it one to watch.

Benesch's Retail & E-Commerce Industry Group is actively monitoring developments in this area. For questions about how these developments may affect your business, please contact Michael D. Meuti, Allyson Cady, or Hannah Laubach.