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FIRM NEWS

Shook Attorney Discusses First Circuit Supplement Labeling Case in FDLI

The First Circuit is the latest federal appeals court to weigh in on appropriateness of labeling claims that emphasize the health benefits of nutrients contained in dietary supplements, according to an article by Shook Partner Jennifer Hill.

Hill discussed the First Circuit's ruling in *Ferrari v. Vitamin Shoppe* for the Food and Drug Law Institute (FDLI) in her article titled "Ferrari v. Vitamin Shoppe: A Favorable Ruling for a Manufacturer Facing a Challenge to Its Dietary Supplement Structure/Function Claims."

In the piece, Hill discusses the U.S. Food and Drug Administration's history of regulating dietary supplement labeling, dives into the First Circuit's ruling, and provides takeaways for dietary supplement makers. One such takeaway, she says, is that *Ferrari* shows manufacturers can face aggressive legal attacks from consumers, yet still prevail.

"As new products emerge, so too will new theories for challenges under state law," she said. "Courts will continue to be called on to define the parameters of acceptable structure/function claims and the corresponding substantiation required by federal law. *Ferrari* adds to that body of law and illustrates the need for manufacturers to be vigilant of the legal requirements for making a structure/function claim."

Read the article at the Food and Drug Law Institute >>

Shook offers expert, efficient and innovative representation to clients targeted by plaintiffs' lawyers and regulators. We know that the successful resolution of health, wellness and personal care product-related matters requires a comprehensive strategy developed in partnership with our clients.

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LEGISLATION, REGULATIONS & STANDARDS

FDA Issues Draft Guidance on Cosmetic Product Facility Registrations and Product Listings

The U.S. Food and Drug Administration (FDA) has issued draft guidance on cosmetic product facility registrations and product listings, which are required by the Modernization of Cosmetics Regulation Act of 2022 (MoCRA).

Under MoCRA, cosmetic product manufacturers and processes are required to register their facilities with FDA, update content within 60 days of any changes, and renew their registration every two years. Additionally, a responsible person must list each marketed cosmetic product with FDA, including product ingredients, and provide annual updates. Certain small businesses are exempted from these requirements, and exemptions also exist for certain products and facilities that are subject to requirements for drugs and devices.

When the draft guidance is finalized, it will help stakeholders with cosmetic product facility registration and product listing submissions to FDA, by describing who is responsible for making the registration and listing submissions, what information to include, how to submit and when to submit, as well as certain exemptions to the registration and listing requirements.

The draft guidance includes information about an electronic registration and listing submission portal. FDA said it intends to make the portal available in October 2023. The draft guidance also discusses FDA's intention to use the FDA Establishment Identifier (FEI) as the required facility registration number.

FDA said in an August 7 Constituent Update that stakeholders should plan to register and list well in advance of the December 29, 2023, statutory deadline. The deadline to submit comments on the draft guidance is September 7, 2023.

Study Calls Attention to Inaccurate Sports Dietary Supplement Labels

A review of 57 sports dietary supplements published in *JAMA Network Open* found that 89% of product labels did not accurately declare the products' ingredients, and 12% contained ingredients prohibited by the U.S. Food and Drug Administration (FDA).

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ABOUT SHOOK

Shook, Hardy & Bacon attorneys counsel consumer product manufacturers on FDA, USDA and FTC regulatory compliance and risk management issues, ranging from recalls and antitrust matters to facility inspections, labeling, marketing, advertising, and consumer safety. We help these industries develop early legal risk assessments to evaluate potential liability and develop appropriate policies and responses to threats of litigation or product disparagement.

The firm's lawyers also counsel manufacturers on labeling audits and a full range of legal matters such as U.S. and foreign patent procurement; licensing and technology transfer; venture capital and private financing arrangements; joint venture agreements; patent portfolio management; research and development; risk assessment and management; records and information management issues and regulations; and employment matters, including confidentiality and non-compete agreements.

The study's authors said that since FDA banned ephedra from dietary supplements in 2004, supplement manufacturers have promoted a complex variety of alternative botanical compounds for sports enhancement. They sought to determine the accuracy of dietary supplement labels declaring *Rauwolfia vomitoria*, methylliberine, halostachine, octopamine and turkesterone.

Of 57 products containing one of the above five ingredients, 40% did not contain a detectable amount of the labeled ingredient. Of the products that contained detectable amounts of the listed ingredients, the actual quantity ranged from 0.02% to 334% of the labeled quantity. Additionally, the authors found that seven of the 57 products contained at least one FDA-prohibited ingredient.

The authors noted the study's limitations: the sample size was small, only one sample of each brand was analyzed, and only supplements containing one of five targeted ingredients were analyzed.

“It is not known whether the results are generalizable to other botanical ingredients in sports supplements or whether quantities might also vary among batches within a given brand,” they said. “Given these findings, clinicians should advise consumers that supplements listing botanical ingredients with purported stimulant or anabolic effects may not be accurately labeled and may contain FDA-prohibited drugs.”

Dietary Supplement Industry Groups Raise Concerns About Proposed FDA Reorganization

Dietary supplement industry groups are expressing concerns about the U.S. Food and Drug Administration's (FDA) recently announced plans to reorganize its Human Foods Program. The updated proposal, announced June 27, relocates the functions of the Office of Dietary Supplement Programs (ODSP) within a new Office of Food Chemical Safety, Dietary Supplements, and Innovation.

The American Herbal Products Association (AHPA) issued a statement on the proposed change, saying FDA created the current office in 2015, elevating the program from its former status as a division under a parent office.

“Removing ODSP's separate status and combining it with these other functions would unwind a structure that has ensured dedicated funding and attention to programs for the growing market for these health-promoting products,” said Robert Marriott, director of regulatory affairs for AHPA.

The Consumer Healthcare Products Association (CHPA) has also weighed in, saying it was seeking a meeting with FDA officials to discuss the proposed reorganization.

“With three out of every four American consumers taking a dietary supplement on a regular basis, a rate which rises to four in five for older Americans, it’s essential that this growing consumer healthcare category receive appropriate attention, authority, and resources within the FDA, its primary regulatory authority,” CHPA president Scott Melville said in a statement.

He added that CHPA has requested a meeting with FDA leaders “to ensure the proposed structure would in no way dilute the prioritization of dietary supplements.”

In statements to *Natural Product Insider*, United Natural Products Alliance President Loren Israelsen questioned why dietary supplements are being placed in the same office as food additives. “A primary objective in the passage of [the Dietary Supplement Health and Education Act of 1994] was to—once and for all—stop FDA's use of the food additive provision to remove dietary supplements from the market,” he said. “We now find ourselves in the same company as food additives. This is unsettling.”

Trade Group Calls on FDA to Reconsider Stance on Drug Preclusion Clause

The Council for Responsible Nutrition (CRN) has submitted a citizen petition to the U.S. Food and Drug Administration (FDA), urging the agency to reconsider its interpretation of the Drug Preclusion Clause, which CRN asserts has been misapplied to dietary supplement ingredients FDA has previously acknowledged as lawfully marketed.

CRN is asking FDA to reconsider its positions with respect to section 201(ff)(3)(B) of the Federal Food, Drug, and Cosmetic Act, which were recently stated in connection to the legality of beta-nicotinamide mononucleotide (NMN); acknowledge that agency prior statements and actions affirming the legal use of an ingredient as a dietary supplement cannot be reversed on the grounds of drug preclusion; and issue guidance clarifying the agency's rulemaking authority.

The group said FDA’s positions “have the effect of diminishing the purpose of that provision, and the careful balance Congress intended between drug and dietary supplement interests, as well as the plain reading of the words.”

“These positions have the potential to inject significant uncertainty and inequities into the supplement marketplace and to upend the intended balance in the law between pharmaceutical and dietary supplement interests,” the group said in its petition. “The totality of FDA’s various viewpoints on the application of the statute – with respect to pyridoxamine, vinpocetine, NAC, other ingredients, and now NMN – unfairly promotes pharmaceutical research at the expense of dietary supplements, consumer access, and public health.”

Mushroom Powder Supplement Ads Made Unlawful Claims, UK Ad Authority Finds

The United Kingdom's Advertising Standards Authority (ASA) has upheld a series of complaints that Dirtea, which makes mushroom powder supplements, made unlawful claims in a series of social media ads that stated or implied that a food prevented, treated or cured human disease.

According to ASA, one of the ads, which appeared on Instagram, included text stating the benefits of Lion's man, asserting that the ingredient “can even help with repairing and regenerating nerves and support dementia and Alzheimer's.” Another ad included text about the Cordyceps mushroom, calling it “a powerhouse for all things energy, endurance, stamina and hormones” that can help users balance their hormones and increase libido.

"We considered the claims in the ads relating to anxiety, dementia, attention deficit hyperactivity disorder (ADHD), Alzheimer’s, pre-menstrual syndrome, menopause, acne, rosacea, eczema, flu, and the anti-inflammatory, analgesic, antipyretic, hepatoprotective, and sedative properties of the products were likely to be interpreted as claims to prevent, treat or cure human disease,” ASA said in its ruling, determining the ads breached the UK’s CAP Code.

ASA said the ads must not appear again in similar form, and instructed the company to ensure its future advertising did not make claims that their products could prevent, treat or cure human illness. Dirtea told ASA it had removed all of the ads and it would not use them again.

Mushroom Wholesale Supplier Petitions FDA for New Fungi Labeling Requirements

A wholesale supplier of premium, organic mushroom extracts to U.S. food and dietary supplement manufacturers and distributors has petitioned the U.S. Food and Drug Administration (FDA) to tighten its regulations surrounding the labeling of fungi in dietary supplements and other food products.

In June, North American Reishi Ltd., doing business as NAMMEX, submitted a citizen petition urging the FDA Commissioner to take actions to ensure dietary supplements and other food products containing ingredients from fungi are properly labeled to identify the fungal part/growth stage of the ingredient, and disclose the presence of any substrate on which the fungal ingredient is grown.

NAMMEX said that it is seeking to address a significant problem in the dietary supplement and functional food industries: the misbranding and/or adulteration of products labeled as "mushroom" or "containing mushroom(s)" that do not contain "mushroom(s)" as claimed and/or contain the "mycelium" stage of the fungal organism, including the grain substrate it is grown on, and fail to identify the fungal ingredient(s) as "mycelium," and/or fail to list grain as an ingredient in the finished product.

"Such labeling deceives consumers into thinking they are purchasing a 'mushroom' supplement, or supplement that consists primarily of 'mushrooms,' when in fact, the product is completely or predominantly mycelium on grain," NAMMEX said in the petition. "This results in unfair competition in the marketplace, and economic and other harms insofar as consumers may not be getting genuine mushroom products that offer nutritive and other health benefits–benefits they are paying for."

FDA Issues Consumer Warnings for Apetamin, SARMs

The U.S. Food and Drug Administration (FDA) has issued consumer warnings about products containing selective androgen receptor modulators (SARMs) and a product used for weight gain and figure augmentation. The warnings demonstrate the agency's continued monitoring of unapproved drugs.

In April, FDA warned that it continues to receive adverse event reports related to SARMs, chemical substances that mimic the effects of testosterone and anabolic steroids. SARMs are not FDA-approved, but, according to the agency, online vendors and social media influencers are using social media to make them seem safe and effective.

"The reality is SARMs are potentially dangerous," FDA said in its warning, adding that serious adverse incidents are likely underreported. FDA said SARMs cannot be legally marketed in the United States as a dietary supplement or drug. In June, the agency sent a warning letter to Warrior Labz SARMS, identifying several products as unapproved new drugs.

FDA also warned consumers that it had reviewed several serious adverse event incidents associated with the use of Apetamin, which it says is being marketed illegally for weight gain and figure augumentation.

"Apetamin is not an FDA-approved product," the agency said in the warning. "It is manufactured overseas and illegally imported into the U.S. Although the FDA restricted importation of Apetamin, the product continues to find its way into the U.S. market, often via online marketing and in some retail stores. Apetamin is heavily promoted and sold through social media, targeting people seeking to gain weight and achieve a certain physique."

Oklahoma Dietary Supplements Company Faces Product Seizure, Putative Class Action for Kratom

Federal law enforcement officials seized more than 250,000 units of dietary supplements and bulk dietary ingredients that are or contain kratom, including over 1,000 kilograms of bulk kratom, the U.S. Food and Drug Administration (FDA) announced in late April.

The dietary supplements—which include liquid and capsule formulations marketed under the brand "Feel Free Plant Based Herbal Supplement"—are manufactured by Botanic Tonics LLC, of Broken Arrow, Oklahoma. According to an FDA release, the seized products are worth approximately $3 million.

The U.S. Department of Justice filed a complaint against the manufacturer in the U.S. District Court for the Northern District of Oklahoma alleging that kratom is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that it does not present a significant or unreasonable risk or injury, and as such, dietary supplements or bulk dietary ingredients that are or contain kratom are adulterated under the Federal Food, Drug and Cosmetic Act.

In a separate action, a California man has filed a putative class action against Botanic Tonics, alleging that the company marketed its wellness tonic as kava-based when its primary

ingredient is kratom. *Torres v. Botanic Tonics LLC*, No. 23-1460 (N.D. Cal., filed March 28, 2023).

The consumer further argues that Botanic Tonics "manipulated the formula of Feel Free to magnify the effects of kratom and induce a quicker, longer-lasting, and greater high." For allegations of false advertising, fraud, breach of warranty and unjust enrichment, the plaintiff seeks class certification, damages, restitution, costs and attorney's fees.

Washington Governor Signs Toxic-Free Cosmetics Act into Law

Washington State Governor Jay Inslee has signed into law the state's Toxic-Free Cosmetic Act, House Bill 1047. The law is the first state law on cosmetics and personal care products to ban ortho-phthalates, all formaldehyde-releasing agents and triclosan; restrict lead; require state agencies to assess the hazards of chemicals used in products that can impact vulnerable populations; and provide support for small businesses and independent cosmetologists to transition to safer products. The bans take effect in 2025, except for formaldehyde releasers, which have a phased-in approach beginning in 2026.

The bill was sponsored by State Rep. Sharlett Mena (D-Tacoma), who said in a statement that consumers should not have to be toxicologists to shop for personal care products. "When products are on the shelf, we assume they are safe to use, but this is not always the case. In fact, Ecology found that many cosmetics contain toxic chemicals and that those with the highest concentrations are often marketed to women of color," she said. "We regulate the use of toxics in other products, but the law allowed products that we apply to our bodies to use harmful chemicals. With this new law, we will no longer allow these harmful chemicals to be added to personal care products and sold to unsuspecting people."

Study Finds 88% of Melatonin Gummy Products Inaccurately Labeled

A study of 25 melatonin gummy products found that 88% were inaccurately labeled as to the amount of melatonin in the products, according to data printed in a JAMA research letter in April.

Researchers from the University of Mississippi and the Cambridge Health Alliance note in the letter that during the COVID-19 pandemic, pediatric use of melatonin products has increased.

They cited U.S. Poison Control Centers data showing a 530% rise in calls for pediatric melatonin ingestions from 2012 to 2021.

The researchers found that one of the 25 products studied did not contain detectable levels of melatonin but did contain CBD. Of the products containing melatonin, the actual amount of melatonin in the products ranged from 74% to 347% of the labeled quantity. The researchers determined that 88% of the products, or 22 of the 25 products, were inaccurately labeled, and only three products contained a quantity of melatonin that was within 10% of the declared quantity.

"Administration of as little as 0.1 mg to 0.3 mg of melatonin to young adults can increase plasma concentrations into the normal nighttime range," the authors said. "Consuming melatonin gummies as directed could expose children to between 40 and 130 times higher quantities of melatonin. Unintentional ingestions could lead to consumption that greatly exceeds these dosages of melatonin."

They said clinicians should advise parents that pediatric use of melatonin gummies may result in ingestion of unpredictable quantities of melatonin and CBD, which is not approved by the U.S. Food and Drug Administration for any use in healthy children.

The Council for Responsible Nutrition (CRN), a supplement industry group, said in a statement that the authors of the report wrongly conflate their findings with pediatric data although most of the products sampled contained adult servings and are expressly labeled for use in adults.

"This report does a complete disservice to a safe product when it is used according to manufacturer's instructions," Steve Mister, president and CEO of CRN, said in a statement. "Parents know how to take care of their own kids, and, often in consultation with their health care providers, have been safely giving the pediatric versions of these melatonin products to their children for years."

LITIGATION

Ninth Circuit Affirms Ruling in Dietary Supplement Labeling Suit

A federal appeals court has upheld a lower-court ruling throwing out a class action alleging that Walmart's Spring Valley-branded Glucosamine Sulfate was mislabeled. *Hollins v. Walmart Inc.*, No. 21-56031 (9th Cir., entered May 11, 2023)

The plaintiffs alleged that the product was mislabeled because it contained glucosamine hydrochloride, not glucosamine sulfate or glucosamine sulfate potassium chloride. The plaintiffs based their assertions on tests of 13 bottles of the product using a test method called Fourier-transform infrared spectroscopy (FTIR). Walmart moved for summary judgment, arguing that the plaintiffs' testing methodology was different from the one required by federal law.

The lower court granted Walmart's motion, finding that the plaintiff's expert witness' methods raised *Daubert* concerns and were not "reliable and appropriate" under FDA regulations. The court concluded that Walmart met its burden of showing the plaintiffs' state-law claims were preempted by federal law.

The plaintiffs appealed, contending that their state-law mislabeling claim would not impose a different labeling requirement on the product than is imposed by federal law. They argued that a blended version of glucosamine sulfate potassium chloride may not be identified on the label as glucosamine sulfate because the label does not meet regulatory requirements that the ingredients be declared by their "common or usual name."

The Ninth Circuit disagreed, holding that a product's common or usual name is determined by testing using an AOAC method or "by other reliable and appropriate procedures." The court found that the plaintiffs' expert witness "used test methods … that he conceded were not validated or accepted by the FDA for use in this context," the court said in its opinion. The court also disagreed with the plaintiffs' argument that their claim would not allow the state to impose a labeling requirement different from federal law.

"[The expert witness's] testing and concessions indicated that under federal law, glucosamine sulfate or glucosamine sulfate potassium chloride are common or usual names for the blended formulation of glucosamine sulfate," the court said. "Logically, using the 'common or usual' name of a product to identify the product on the label does not constitute offering that product for sale 'under the name of another food,' in violation of § 343(b). [The plaintiff] cites nothing contrary to this common-sense conclusion."

The Ninth Circuit concluded that the plaintiffs' claims are preempted by federal law and that Walmart is entitled to judgment as a matter of law.

Appeals Court Vacates $8M Supplement Settlement

The U.S. Court of Appeals for the Eleventh Circuit vacated an $8 million class action settlement involving the manufacturer of the supplement Neuriva, holding the class did not have standing to seek the requested injunctive relief. *Williams v. Reckitt Benckiser LLC, No. 22-11232* (11th Cir., entered April 12, 2023).

The class alleged the defendants, including Reckitt Benckiser LLC and RB Health LLC, used false and misleading statements to sell their brain performance supplements under the brand name Neuriva.

The class alleged the statements falsely gave consumers the impression that Neuriva and its active ingredients had been clinically tested and proven to improve brain function. The district court approved a settlement of up to $8 million as well as injunctive relief that enjoined the defendants from using the terms “Clinically Proven,” “Science Proved,” “Clinically Tested and Shown,” “clinical studies have shown,” or similar “shown” claims on Neuriva’s labeling.

One person objected to the settlement, arguing the parties inflated the perceived value of the settlement because it knew that few class members would complete the process of submitting claims to receive payment, which allowed the plaintiffs’ counsel to secure a disproportionately large fee award of approximately $2.9 million.

The court did not address the merits of the objector’s arguments because it found the class lacked standing to pursue the injunctive relief because none of the named plaintiffs alleged that they planned to purchase any of the Neuriva products again in the future; in fact, the operative complaint gave every indication that they would not again purchase any of the Neuriva products because the class members claimed they were “worthless.”

Court Denies Grande Cosmetics’ $6.25M Serum Suit Settlement

A federal court has denied a proposed $6.25 million class action settlement to resolve a California woman’s claims that Grande Cosmetics unlawfully sold its eyebrow, eyelash and hair serums without warning consumers about active ingredients that could potentially have adverse effects. *Mandel v. Grande Cosmetics, LLC*, No. 22-0071 (N.D. Cal., entered July 27, 2023).

The plaintiff alleged that Grande Cosmetics unlawfully sold products containing the active ingredient isopropyl cloprostenate (ICP) without identifying it as an active ingredient or warning consumers of potential serious side effects. She alleged that ICP is

in the same class of compounds as the active ingredient found in prescription drugs that grow eyelashes, such as Latisse, which is only approved by the U.S. Food and Drug Administration for use under physician supervision.

The parties in April submitted a motion seeking preliminary approval of a $6.25 million settlement, which would have established a $5 million cash settlement fund and a $1.25 credit voucher settlement fund. Grande also agreed to make changes to packaging and marketing highlighting warning statements and new ingredient declarations.

At a July 27 hearing, the court denied the settlement. According to the hearing's minutes, the court held that the proposed credit voucher is unfair and unreasonable to the class. The court additionally said that the parties did not establish that the cash settlement fund is enough to support a class of 2.5 to 3 million class members, nor did they adequately explain why they expected a claims rate below 3%. The court directed the parties to return to mediation and to file a status report in November.

Second Circuit Partially Revives False Advertising Suit Against Essential Oils Company

The U.S. Court of Appeals for the Second Circuit has reinstated part of a lawsuit alleging an essential oils company falsely advertises its products as being "therapeutic-grade" and imparting certain physical or mental health benefits. *MacNaughton v. Young Living Essential Oils, LC*, No. 22-0344 (2d Cir., entered May 2, 2023).

In July 2020, the National Advertising Division ruled that Young Living Essential Oils, LC's claims that its products are "therapeutic-grade" and impart physical and mental health benefits are "unsupported," and recommended that the company stop making the claims. The plaintiff purchased Young Living's products prior to the decision, including lavender oil the company advertised could "promote[] [a] feeling of calm and fight[] occasional nervous tension" and peppermint oil that allegedly "helps to maintain energy levels."

The plaintiff filed suit against Young Living, asserting claims under common law and state consumer protection statutes. The district court dismissed her suit, finding that Young Living's claims were run-of-the-mill puffery.

The Second Circuit said its 2022 decision in *Int'l Code Council, Inc. v. UpCodes Inc.* provides a "critical distinction between

subjective statements that are non-actionable puffery as a matter of law, and objective statements that are provable and not so facially implausible that no reasonable buyer could justifiably rely on them."

The court said that any potential puffery in the plaintiff's case is in the latter category, which requires a fact-intensive inquiry to assess how a reasonable buyer would react to the relevant statements. The appeals court vacated the lower court's dismissal of the plaintiff's New York General Business Law claims and dismissal of her unjust enrichment claim, and it affirmed the lower court's dismissal of the plaintiff's breach of warranty claims.

Extra Strength Vitamin C Claims Allowed to Proceed in Part

A federal court is allowing some claims to proceed against the maker of NatureMade Extra Strength Chewable Vitamin C tablets. *Whitaker v. Pharmavite LLC*, No. 22-04732 (C.D. Cal., entered May 9, 2023). The plaintiffs, a California woman and a New York man, argue that they purchased NatureMade Extra Strength Chewable Vitamin C tablets, understanding the products to contain a higher dose of vitamin C than NatureMade's Regular Strength product. Both products, however, contain 500 mg of vitamin C per tablet, with the Extra Strength product merely containing an instruction on the back label for consumers to take two tablets per day. Their putative class action alleges violations of California's Consumer Legal Remedies Act and False Advertising Law, as well as New York's General Business Law sections 349 and 350.

Pharmavite moved for dismissal, asserting that the plaintiffs' claims fail to satisfy the "reasonable consumer" standard and that the California plaintiff cannot seek restitution because she has an adequate remedy at law. The court agreed with the latter, dismissing the plaintiff's restitution claim with leave to amend her petition, but disagreed with Pharmavite on the former.

The court found that the Extra Strength product label could mislead a reasonable consumer to believe that each unit has greater potency. "It is at least plausible that a reasonable consumer would expect that the 'Extra Strength' label would describe the product's potency, and not merely reflect a higher dosage," the court said, pointing to a similar ruling in the U.S. District Court for the Northern District of Illinois. "Plaintiffs have therefore stated a claim under California and New York law."

Lume Deodorant Odor-Blocking Claims are Misleading, Consumer Alleges

A New York woman has filed a putative class action against Lume Deodorant, alleging the company's odor-blocking claims and claims that its deodorants are "aluminum free" are misleading. *Nelson v. Lume Deoderant, LLC*, No. 23-3629 (E.D.N.Y., filed May 15, 2023).

The plaintiff said in her complaint that she bought Lume's deodorants after seeing marketing that they are "clinically proven to block body odor all day, and continue to control odor for 72 hours." She claims the statement is false and misleading because the study upon which Lume relies for its claim only evaluated the product in comparison to competitors, concluding it was superior to them, not that it blocked odor all day, nor continued to control odor for 72 hours.

"The sample sizes were neither large nor diverse enough to prove the Product blocked odor all day nor continued to control odor for 72 hours, notwithstanding the results only could establish relative claims," she said in her suit. "Consumers expect a 'clinically proven' claim to mean a significant degree of scientific consensus and/or that the relied upon study was subject to peer-review, even though neither exists here." She also alleges the company's claim that its deodorants are "aluminum free" is misleading, because aluminum is not found in any deodorant products.

The plaintiff is alleging violations of New York General Business Law Sections 349 and 350 and other state consumer fraud acts, as well as unjust enrichment and fraud. She seeks class certification, and an award of damages and costs and expenses including attorneys' fees.