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COSMETICS . COSMECEUTICALS . DIETARY SUPPLEMENTS . NUTRACEUTICALS DIETARY SUPPLEMENT & COSMETICS LEGAL BULLETIN

LEGISLATION, REGULATIONS & STANDARDS

NAD Recommends Drunk Elephant **Modify Influencer Posts**

BBB National Programs' National Advertising Division (NAD) has found claims by skincare company Drunk Elephant, LLC that its products are "safe for kids and tweens to use" to be supported but recommended the company modify its influencer posts to sufficiently disclose the material connection between the company and influencers. According to an NAD press release, NAD determined that while the claims had a reasonable basis, two TikTok videos involving influencers reviewing the company's B-Goldi Bright Drops should be modified.

In one of the paid partnership videos, NAD found that in part because the disclosure "#drunkelephantpartner" was on the fifth line of the post and only viewable after clicking on the hyperlink "more," the hashtag was not clear and conspicuous as a material connection disclosure. NAD recommended Drunk Elephant seek modification of the post to ensure the hashtag appears clearly and conspicuously on influencer posts without requiring a click

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and as separate words, and to ensure influencers include a clear and conspicuous material connection disclosure within the video. Drunk Elephant told NAD it reached out to the influencer to edit or delete the post.

NAD also found that a video involving an unpaid influencer did not feature a material connection disclosure despite the influencer receiving free product. Drunk Elephant advised it will take reasonable steps to instruct influencers on required disclosure practices and ensure influencers receiving free product make appropriate disclosures.

Texas, New Hampshire Lawmakers Pre-File Bills Restricting Minor Supplement Sales

Lawmakers in Texas and New Hampshire have pre-filed legislation to restrict sales of certain dietary supplements to minors, bringing the total of states that have introduced similar legislation to 11, SupplySide Supplement Journal reported.

According to the publication, Texas' HB 1474 would restrict the sale to minors of supplements marketed or otherwise represented for weight loss or muscle building. The law would impose a \$500 civil penalty per violation and mirrors legislation that took effect earlier this year in New York. New Hampshire's HB 0516 will be titled "Prohibiting the sale of over-the-counter weight loss and muscle building supplements to minors."

Codex Committee Declines to Approve New Guidelines for Probiotics

The Codex Committee on Nutrition and Foods for Special
Dietary Uses declined to approve a proposal that would establish
a new regulatory definition for probiotics, *Nutraceuticals*World reported. The proposal was reportedly developed by
Argentina, Malaysia and China and would have relied upon the
Food and Agriculture Organization and World Health
Organization to take part in a scientific review and systematic
analysis to develop proposed Codex-owned guidelines in
probiotics.

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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 noncompete agreements.

LITIGATION

Suit Alleges 'Natural' Dr. Squatch Products Contain Synthetic Ingredients

A New York consumer has filed a proposed class action alleging Dr. Squatch LLC's "natural" labeling is misleading because the products contain synthetic ingredients. *Napolitano v. Dr. Squatch LLC*, No. 24-7490 (E.D.N.Y., filed October 26, 2024). "The Products are 'misbranded' and misleading, because despite the labeling and marketing as 'Men's Natural Shampoo' and 'Men's Natural Conditioner,' at least fifteen of the twenty-four ingredients are not "natural," as this term is understood by consumers," the plaintiff asserted, pointing to ingredients such as glycerin, fragrance and xanthan gum.

Court Stays NMN Suit, Denies Pharmaceutical Co. Intervention

A federal court has stayed the Natural Products Association's (NPA) lawsuit against the U.S. Food and Drug Administration (FDA) concerning whether beta-nicotinamide mononucleotide (NMN) is excluded from the definition of "dietary supplement" under the Federal Food, Drug, and Cosmetic Act. *Natural Products Ass'n v. FDA*, No. 24-2479 (D.D.C., filed October 30, 2024). The court ordered that all proceedings are stayed until FDA answers NPA's pending Citizen Petition, which the agency has said it intends to do by July 31, 2025.

The court also denied a bid by a clinical-stage pharmaceutical company that filed a motion to defer its ruling on NPA and FDA's joint motion to stay the case. Metro International Biotech, LLC, argued that it is entitled to intervene because the lawsuit directly threatens its interests, noting it has spent millions of dollars to develop NMN as a drug.

Prevagen Maker Ordered to Stop Memory Claims

A federal court has clarified that its November 18 judgment forbade Quincy Bioscience Holding Co. from making certain memory claims about its supplement Prevagen. *FTC v. Quincy Bioscience Holding Co., Inc.*, No. 17-0124 (S.D.N.Y., December 6, 2024). The court order came in response to motions from the defendants and one of the plaintiffs, New York State Attorney General Letitia James. The defendants sought clarification on the judgment's scope, while James sought to amend the judgment to pursue statutory penalties, disgorgement and statutory costs. The court affirmed that its judgment took effect "forthwith" and applies to Prevagen's national marketing.

The court said the jury in the case found the purported scientific support for eight challenged statements—including claims that Prevagen is clinically shown to improve memory—was lacking, though only two statements were materially misleading under New York state law, and all had the tendency to deceive under state law. The court said it held Quincy violated the Federal Trade Commission (FTC) Act, which forbids false advertising and unfair or deceptive acts. The court said it is appropriate to enjoin all eight of the challenged statements, noting that Quincy continued to use them after trial and the court's order imposing FTC Act liability.

Separately, the court denied James' motion. "Quincy's loss of the use of all eight Challenged Statements in its marketing and public relations, at a single blow, is not a trivial event. It involves years of accumulated goodwill, whose loss must be replaced with costs and effort," the court said.

Consumers Allege Kratom Co. Failed to Disclose Products' Addictive Potential

Two California consumers and an Oregon consumer have filed a proposed class action alleging DBZ Enterprises LLC, doing business as K-Chill and Kryptic Kratom, misleads consumers about the addictive nature of kratom. *D.B. v. DBZ Enterprises LLC*, No. 24-2405 (C.D. Cal., November 4, 2024).

K-Chill sells kratom powder, capsule and liquid extract products. The plaintiffs allege that kratom contains a psychoactive chemical that behaves like opioids and carries the same addiction and dependency risk. "Defendant markets its K-Chill Products as if they are nothing more than over-the-counter supplements," they said in the complaint. "Indeed, the packaging looks more like allergy medication than a dangerously strong opioid, and Defendant's glossy website and design language obfuscates the very real truth that it is selling a strong narcotic to consumers who likely do not fully comprehend the risks associated with consuming the Products."

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