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ARCHIVES

LEGISLATION, REGULATIONS & STANDARDS

Lawmaker Introduces Dietary Supplement Listing Act

U.S. Senate Majority Whip Dick Durbin (D-Ill.) has introduced the Dietary Supplement Listing Act of 2024, which would require companies to provide the U.S. Food and Drug Administration with information such as product names, a list of ingredients, an electronic copy of the label, allergen statements, health claims and structure/function claims. The information would be made available to the public through an electronic database. The Consumer Healthcare Products Association called for more comprehensive reforms in a statement arguing that the bill would not address the issue of tianeptine, which Durbin has previously highlighted.

Group Presses FDA for Action on Hair Relaxers

The Clean Beauty Action Network (CBAN) is calling on the U.S. Food and Drug Administration (FDA) to take action on its promise to ban hair relaxers containing formaldehyde. In an

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. For additional information about Shook's capabilities, please contact

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open letter, CBAN President Daphne Nguyen urged FDA Commissioner Robert Califf to immediately prioritize the agency rule-making process on the use of formaldehyde. She cited reporting in late 2023 that a proposed rule would be issued in Spring 2024. “There was a lot of good press about this impending development, but for some reason, the proposed rule is languishing,” she said in the letter.

Final FTC Rule Bans Fake Reviews and Testimonials

The U.S. Federal Trade Commission (FTC) has issued a final rule prohibiting false consumer reviews and testimonials, company-controlled review websites, review suppression and misuse of fake social media indicators. The rule, which takes effect in October 2024, gives FTC the authority to seek penalties against knowing violators. In a statement, FTC Chair Lina Khan said the final rule “will protect Americans from getting cheated, put businesses that unlawfully game the system on notice, and promote markets that are fair, honest, and competitive.”

FDA Announces Feature Updates to Cosmetics Direct Portal

The U.S. Food and Drug Administration (FDA) has announced two new feature updates to Cosmetics Direct, the electronic submission portal for companies to register and list product facilities and product requirements established by the Modernization of Cosmetics Regulation Act of 2022 (MoCRA). In a constituent update, the agency said it now offers features that allow for the discontinuation and relisting of cosmetic products. The former provides responsible parties the option to discontinue products that are no longer on the market, while the latter allows them to relist products that were previously discontinued and are being brought back to the market.

FDA Warns of Adverse Events Associated with Kratom Product

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.

has warned consumers to avoid Optimized Plant Mediated Solutions Black Liquid Kratom after the product was linked to a person's death. FDA said the death was one of many serious adverse events individuals have reported to the agency regarding the product, and products containing kratom have been marketed as dietary supplements with claims of therapeutic benefits, "however, the FDA has not approved any prescription or over-the-counter drug products containing kratom or associated compounds."

ASA Bans Ads for Menopause, Anxiety Dietary Supplements

The United Kingdom's Advertising Standards Authority (ASA) has upheld challenges to a series of dietary supplement social media ads. ASA banned ads from two companies—Feel Holdings LTD and Happy Koala LLC. ASA said the ads made prohibited claims about the prevention, treatment and cure of menopause symptoms. ASA also ruled against five companies for claims relating to anxiety: Innocent Health Ltd, Nutriburst Ltd, Nowt Ventures Ltd, Ejec Ventures LLC and Well Gummies.

LITIGATION

Consumers Allege Cosmetics Brands Use 'Fake Imitation of Collagen'

Two cosmetics companies face proposed class actions alleging they misrepresent their products as containing collagen when they contain acacia seyal gum extract. *Kelly v. Pixi, Inc.*, No. 24-05635 (E.D.N.Y., filed August 12, 2024) and *Kouyate v. Lanocorp USA Inc.*, No. 24-05872 (S.D.N.Y., filed August 1, 2024). The consumers allege that Pixi Inc. and Lanocorp USA Inc. misrepresent their products as containing collagen when they actually contain "a fake imitation of collagen derived from a synthetic extract of the bark and stems of the Acacia seyal tree."

Court Vacates Awards in Joint Juice Class Action

The U.S. Court of Appeals for the Ninth Circuit has vacated an $8.3 million statutory damages award and $4.5 million prejudgment interest award to a class of consumers that sued the maker of Joint Juice. *Montera v. Premier Nutrition Corp.*, No. 22-16375 (N.D. Cal., filed Aug. 6, 2024). The plaintiff alleged the company misled consumers about the product's ability to relieve joint pain. In addition to the jury awarding the plaintiff actual damages, the trial court awarded statutory damages of $50 per unit sold in statutory damages, totaling $8.3 million. The court reduced that amount from $550 per unit, or $91 million, after Premier argued it was substantively unreasonable and violated its due process rights. The court also approved an award of $4.5 million in prejudgment interest. Both parties appealed; the plaintiff challenged the court's reduction of the statutory damages award and Premier argued that the district court erred in calculating statutory damages and prejudgment interest.

The panel upheld the lower court order on all issues except the award of prejudgment interest, which it vacated. Citing an intervening decision in *Wakefield v. ViSalus, Inc.*, the court also vacated and remanded the district court's reduction of the award for reconsideration in light of the new authority.

Dry Shampoo Maker Settles Benzene Suit for $850k

A federal court has given preliminary approval to an $850,000 settlement to resolve putative class claims that Luxury Brand Partners' IGK dry shampoo products contained unsafe levels of benzene without warning to consumers. *Henning v. Luxury Brand Partners, LLC*, No. 22-7011 (N.D. Cal., filed April 23,

2024). Consumers who purchased IGK dry shampoos will receive a cash payment based on the number of products purchased and whether they have proof of purchase. Luxury Brand Partners did not admit liability.

Skincare Company Settles Collagen Claims for $9.2M

A federal court has preliminarily approved a $9.2 million settlement to resolve consumer claims that Dr. Dennis Gross Skincare LLC sold skincare products deceptively labeled as containing "C+ Collagen" without collagen. *Kandel v. Dr. Dennis Gross Skincare LLC*, No. 23-1967 (S.D.N.Y., filed June 28, 2024). As part of the settlement, the defendant agreed to stop using the challenged "C+ Collagen" labeling on its products. Class members who submit an approved claim will receive $50 per unit of product purchased. Consumers who do not have proof of purchase can claim up to two units, or $100; those with proof of purchase may claim up to 10 units, or $500.

SCIENTIFIC / TECHNICAL

Dietary Supplement Study Authors Call for More Oversight of Botanicals

The authors of a study published in *JAMA Network Open* have called for governmental authorities to increase regulatory oversight over how botanical products are produced, marketed, tested and monitored in the general population. The study sought to assess the prevalence and clinical characteristics of consumers of the six most frequently reported potentially hepatoxic botanicals—turmeric or curcumin, green tea extract, *Garcinia cambogia*, black cohosh, red yeast rice and

ashwagandha. The authors estimated that at least 15.6 million U.S. adults used at least one of the six within the past 30 days.