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LEGISLATION, REGULATIONS & STANDARDS

Personal Care Products Legislation Introduced in Congress

Rep. Janice Schakowsky (D-Ill.) has introduced the Safe Cosmetics and Personal Care Products Act of 2018, which would require the disclosure of ingredients—including "nanomaterials" and "contaminants"— in cosmetics on product packaging. The proposed legislation would also require the registration of entities and products and establish a recall process for adulterated or misbranded cosmetics.

"This bill not only calls for full disclosure of the many chemicals in our products but would ban toxic ingredients, including carcinogens, in them," Schakowsky said in a press release. "This bill takes a step that should have already been taken – consumers, families, and workers have been at risk for far too long. We need to ban toxic beauty and personal care products and give the Food and Drug Administration the resources it needs to keep Americans safe, including recall ability."

Lead Acetate Banned From Hair-Color Products

The U.S. Food and Drug Administration (FDA) has announced an amendment to color-additive regulations removing the approval of lead acetate for use in cosmetics that color hair, finding that "there is no longer a reasonable certainty of no harm from the use of this color additive." The announcement responds to a petition filed by several advocacy groups, including Environmental

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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Working Group, Earthjustice and Center for Environmental Health.

In a press release, FDA Commissioner Scott Gottlieb stated, "In the nearly 40 years since lead acetate was initially approved as a color additive, our understanding of the hazards of lead exposure has evolved significantly. We now know that the approved use of lead acetate in adult hair dyes no longer meets our safety standard. Lead exposure can have serious adverse effects on human health, including for children who may be particularly vulnerable. Moreover, there are alternative color additives for hair coloring products that consumers can use that do not contain lead as an ingredient."

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JAMA Focuses on Supplements

JAMA has published several articles calling for increased scrutiny of dietary supplements and their ingredients. An October 2, 2018, op-ed describes a study on supplement use among children that purportedly found that one-third of minors who participated in the study used supplements regularly. A *JAMA* original investigation examined the identification of active pharmaceuticals in supplements using data from the U.S. Food and Drug Administration, which reportedly found 776 adulterated supplements from 2007 to 2016. An invited commentary on the investigation argues that the agency has failed "to aggressively use all available tools to remove pharmaceutically adulterated supplements from commerce" and calls for changes to the Dietary Supplement Health and Education Act of 1994. In addition, a pair of October 22, 2018, articles—an editor's note and a research letter—published in *JAMA Internal Medicine* also focused on dietary supplement ingredients, focusing on stimulants in the products.

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.

VitaminVape Told to Modify Ad Claims

The Electronic Retailing Self-Regulation Program (ERSP) has recommended that VitaminVape Inc. modify its marketing claims about its Vitamin B12 Vaporizer. The product is marketed as providing "100s of puffs of natural energy" by distributing vitamin B12 through inhalation, which could purportedly improve cell health and nerve function. VitaminVape submitted studies to support its claims, but ERSP found that the studies did not test the administration of vitamin B through a vaporizer or test the formula of the product. ERSP also determined that VitaminVape's tagline "A better way to B" "could reasonably be interpreted by

consumers as meaning that VitaminVape is superior to shots or pills based on cost, convenience, or effectiveness," an assertion "not supported by the evidence in the case record."

GLOBAL

EFSA Releases Guidance on Muscle-Function and Physical-Performance Heath Claims

The European Food Safety Authority has updated "Guidance on the scientific requirements for health claims related to muscle function and physical performance" by incorporating changes resulting from a public consultation that concluded in October 2018. The guidance, which applies to products marketed as having "beneficial physiological effects" on physical performance and muscle functions, provides information on acceptable study characteristics that can provide evidence to support the marketed claims.

ASA Requires Ad Changes from Feelunique, Warpaint Cosmetics

The U.K. Advertising Standards Authority (ASA) has upheld consumer complaints about Feelunique International and Warpaint Cosmetics.

Feelunique, a retailer, advertised several products intended for use in combatting acne and its effects, and a consumer challenged the ad as featuring "medicinal claims for unlicensed products." After seeking an opinion from the U.K. Medicines and Healthcare products Regulatory Agency, ASA agreed. "They considered that acne was an adverse medical condition and that claims that stated or implied that a product could prevent or treat acne were medicinal claims. In their view, 'spots' would most commonly be associated in public perception with acne, and therefore claims to prevent or treat them would also likely be seen as medicinal." With that counsel under consideration, ASA determined that "consumers' understanding of 'spots' would be highly dependent on the context of the claim" because the phrase could mean the medical condition acne or individual instances of "clogged sebum ducts." In Feelunique's ads, ASA found, "consumers would understand the combination of claims, in the context of the page, to mean that the products listed could prevent and/or treat acne" and accordingly upheld the complaint.

Warpaint Cosmetics received a complaint about its brand-ambassador partnership with a social media influencer who advertised an eyeshadow palette on her Instagram account. ASA agreed with Warpaint's argument that the woman's followers were likely to know about the commercial relationship because of her previous posts announcing the partnership and her profile's biography indicating that she was a brand ambassador for the company. However, because her profile "was visible to the public, any posts she published could appear in search results and those posts could be viewed in isolation to her profile," removing the context that would make the connection clear. "Therefore in the absence of a clear identifier, such as '#ad', we concluded that the post was not obviously identifiable as a marketing communication and that it breached the Code," ASA ruled.

LITIGATION

Ninth Circuit Reverses FDCA Preemption Dismissal

The U.S. Court of Appeals for the Ninth Circuit has revived a putative class action against MusclePharm Corp., holding that the federal Food, Drug and Cosmetic Act (FDCA) does not preempt state-law allegations that the company misled consumers as to the protein sources in its supplement. *Durnford v. MusclePharm Corp.*, No. 16-15374 (9th Cir., entered October 12, 2018). A lower court had dismissed the lawsuit, finding the FDCA preempted the claims and that the plaintiff could not use state law to create liability for a measurement that complies with the U.S. Food and Drug Administration's (FDA's) regulations.

The appeals court distinguished the plaintiff's claims about the amount of protein—which the company allegedly boosted with nitrogen spiking—from the company's representations about the sources of protein in the product. The lower court correctly found the nitrogen-spiking allegation to be preempted, the appeals court held, because "FDA regulations approve of the use of nitrogen as a proxy" in complying with the requirement to disclose "the 'amount' of 'total protein' in the nutrition panel."

In contrast, the plaintiff's allegation about the source of the protein—MusclePharm marketed it as sourced from hydrolyzed beef protein and lactoferrin rather than nitrogen-spiking agents—was not preempted. "The district concluded, however, that [the plaintiff's] claims were nonetheless preempted because he did not allege that he had any independent study contradicting the label that used the FDA's elaborate 12-sample testing protocol," the court stated. "This reasoning misapprehends [the plaintiff's]

protein composition theory. That theory rests not on the misleading nature of nitrogen spiking but on the label's misleading suggestion that all of the protein in the Supplement, in whatever amount it exists, comes from specific protein sources." The composition allegation, the court held, was not preempted by the FDCA, and it reversed the district court's dismissal.

FTC Obtains Summary Judgment Against Roca Labs

A Florida federal court has granted the Federal Trade Commission (FTC) summary judgment in a lawsuit alleging Roca Labs made deceptive claims about its weight-loss products and unfairly enforced "gag clauses" aimed at stopping negative online reviews. *FTC v. Roca Labs Inc.*, No. 15-2231 (M.D. Fla., Tampa Div., entered September 14, 2018). Roca Labs, which represented its products as providing "a natural gastric bypass effect in the stomach," made false or unsubstantiated claims about the products, FTC argued. Further, the court determined that Roca Labs and its executives "deceptively failed to disclose their financial relationship to testimonialists who worked for them, and their control of a supposedly independent and objective information website that they used to promote their products; misrepresented the nature of that site; misrepresented that they would keep their customers' private health information confidential; and misrepresented that consumers had agreed to non-disparagement clauses in exchange for a substantial discount on the products," according to an FTC press release.

Bang Products Lack Advertised Nutrients, Lawsuit Alleges

A consumer has filed a putative class action alleging Bang's energy supplements and energy drinks do not contain the promised levels of creatine, CoQ10 and branched-chain amino acids. *Barker v. Vital Pharmaceuticals Inc.*, No. 18-6898 (N.D. Ill., filed October 12, 2018). The complaint asserts that testing showed no creatine or CoQ10 and "only .09g of the single Branched Chain Amino Acid Leucine. Isoleucine and Valine, the other Branched Chain Amino Acids, were not found." For allegations of fraud, unjust enrichment and breach of express warranty, the plaintiff seeks class certification, restitution, damages and attorney's fees.

Sexy Hair Concepts to Settle “Sulfate-Free” Class Action

Sexy Hair Concepts and Ulta Salon Cosmetics & Fragrance have moved to settle a lawsuit alleging that Sexy Hair Concepts' shampoos were falsely labeled as free of sulfates. *Crane v. Sexy Hair Concepts (*No. 17-10300, motion filed October 19, 2018). Under the agreement, Sexy Hair Concepts will pay $2.33 million to a settlement fund, which will pay $6 to the projected 900,000 class members who purchased the shampoo since 2002. Ulta's customer database will contribute contact information for potential class members. Details on Ulta and Sexy Hair Concepts’ failed motion to dismiss appear in Issue 54 of this *Bulletin*.