ISSUE 74 | OCTOBER 2024

SUBSCRIBE

ARCHIVES

LEGISLATION, REGULATIONS & STANDARDS

Bill Banning Weight Loss Supplement Sales to Minors Passes NJ Assembly

The New Jersey General Assembly has passed a bill that would prohibit the sale of certain diet pills and dietary supplements for weight loss or muscle building to those under 18. AB 1848 would include products containing ingredients approved by the U.S. Food and Drug Administration for weight loss or muscle-building as well as steroids, creatine, green tea extract, raspberry ketone, garcinia cambogia and green coffee bean extract.

Skincare Co. Submits Petition for New Sunscreen Active Ingredient

DSM-Firmenich has submitted the first Over-the-Counter Monograph Order Request Tier 1 application to the U.S. Food and Drug Administration for its sunscreen active ingredient Parsol Shield, known as bemotrizinol. The petition starts FDA's 17.5-month review process to determine whether the ingredient will be classified as Generally Recognized as Safe and Effective for inclusion in the U.S. OTC sunscreen monograph. If approved,

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

Laurie Henry
816.559.2421
lhenry@shb.com

it would become the first new sunscreen active ingredient added to the U.S. OTC monograph in nearly 25 years.

FDA Warns Consumers About Weight Loss Product

The U.S. Food and Drug Administration (FDA) has renewed a 2020 warning against purchasing or using Body Shape Weight Loss System, a product promoted and sold for weight loss. According to FDA, the product contains unlisted ingredients such as sibutramine, a controlled substance removed from the market for safety reasons in 2010, and phenolphthalein, which may increase cancer risk.

LITIGATION

NPA, FDA Ask for Pause in NMN Litigation

The Natural Products Association (NPA) and U.S. Food and Drug Administration (FDA) have filed a joint motion for a stay in NPA's lawsuit concerning whether beta-nicotinamide mononucleotide (NMN) is excluded from the definition of "dietary supplement" under the Federal Food, Drug, and Cosmetic Act. *Natural Products Association v. FDA*, No. 24-2479 (D.D.C., filed October 24, 2024). NPA submitted a citizen petition to the agency in March 2023 requesting FDA to reverse its position that NMN is excluded from its definition of "dietary supplement." According to the motion, FDA is evaluating the petition and expects to answer by July 31, 2025.

"FDA has further represented to NPA that, while it considers the arguments raised in the Citizen Petition, the agency does not intend to prioritize enforcement action related to the sale and distribution of NMN-containing products that are labeled as dietary supplements, provided that they would be lawfully marketed dietary supplements if NMN is not excluded from the definition of 'dietary supplement'; however, if FDA becomes

John Johnson III
202.662.4850
jfjohnson@shb.com

Jennise Stubbs
713.227.8008
jstubbs@shb.com

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.

aware of new safety concerns, the agency would need to reevaluate its enforcement priorities," the motion stated.

Consumer Alleges Supplement Labels Misrepresent Dosages

A California plaintiff has filed a proposed class action alleging Natural Organics Inc. misrepresents product dosages on its NaturesPlus supplement labeling. *Theus v. Natural Organics, Inc.*, No. 24-8780 (C.D. Cal., filed October 11, 2024). The plaintiff alleges that the front labels of the company's products prominently advertise a certain dosage amount, such as "Iron 40mg," leading consumers to believe each capsule, tablet or gummy contains the advertised dosage amount. "The truth, however, is that each capsule does not contain the advertised dosage amount. Instead, each capsule, tablet, or gummy contains only a fraction of the advertised dosage and consumers must ingest two or more capsules to achieve the advertised dosage," she argues. "As a result, consumers grossly overpay for the Products, receiving only half, a third, or a quarter of the advertised value while paying the full purchase price."

Court Dismisses Dry Shampoo Benzene Suit Against John Paul Mitchell Systems

An Illinois federal court has dismissed a proposed class action alleging John Paul Mitchell Systems failed to warn consumers that its Invisiblewear Brunette Dry Shampoo contained benzene. *Nelson v. John Paul Mitchell Sys.*, No. 22-6364 (N.D. Ill., filed September 23, 2024). The lawsuit followed a 2022 report from an independent laboratory purportedly finding the presence of benzene in several brands' dry shampoo products. The plaintiffs alleged that the product was contaminated by benzene in the manufacturing process and that the company violated Illinois law by not listing benzene as an ingredient or including a warning on the possibility of the product containing benzene.

The court held that the plaintiffs failed to sufficiently allege facts to show the injury necessary for damages and injunctive relief. The plaintiffs do not allege the product they purchased contained

benzene, the court found, but instead argued that all lots contained or likely contained benzene because the lab's testing revealed the presence of benzene in three lots of the product. “These allegations support the reasonable inference that, assuming the results of Valisure’s test are true and accurate, there is a general risk that some members of the public may have suffered a financial injury by purchasing the Product,” the court said. “But absent allegations that the Product they purchased was from one of the tested lots, these allegations are not particularized to show that Plaintiffs suffered more than an abstract risk of similar financial injury.” The court granted the plaintiffs leave to amend their complaint.

Consumer Alleges RevitaLash Products Fail to Warn About Key Ingredient

A California woman has filed a proposed class action alleging Athena Cosmetics Inc. failed to indicate to consumers that its RevitaLash products contain a prostaglandin analog (PGA) in the same class of compounds as the active ingredient found in prescription drugs that grow eyelashes. *Rush v. Athena Cosmetics, Inc.*, No. 24-8542 (C.D. Cal., filed October 4, 2024). The plaintiff alleged the products contain dechloro dihdroxy difluoro ethylcloprostenolamide (DDDE), which purportedly aims to improve hair growth but allegedly may cause serious adverse effects to the eye and structure around the eye. The U.S. Food and Drug Administration has warned that lash and brow products containing PGAs are not safe for use except under supervision of a licensed physician, the plaintiff asserts.

Virtual Try-On Suit Against L'Oréal Survives Motion to Dismiss

An Illinois federal court has denied L'Oréal USA's motion to dismiss a proposed class action alleging the company's online "Try It On" feature violates the Illinois Biometric Information Privacy Act. *Kukovec v. L'Oréal USA*, No. 22-03829 (N.D. Ill., filed September 27, 2024). The plaintiff alleged the company fails to inform consumers that the "Try It On" feature collects, scans and uses their geometric facial data to allow them to

virtually try on their products. L'Oréal argued that the plaintiff agreed to the terms of use, which include an arbitration provision, thus expressly consenting to the company's privacy policy. According to *Law360*, in an oral ruling, the court said that the privacy policy does not mention an agreement to arbitrate, and a pop-up window seeking consent did not include a disclosure making clear the plaintiff was bound by the terms of use.

Court Denies Bid to Dismiss Proposed 'Target Clean' Class Action

A Minnesota federal court declined Target Corp.'s motion to dismiss consumer claims that it deliberately misled consumers through its "Target Clean" program. *Boyd v. Target Corp.*, No. 23-2668 (D. Minn., filed September 25, 2024). In the complaint, fourteen plaintiffs alleged Target deliberately misled consumers by labeling certain products it sold in stores as being "Target Clean" when some of the products contained a list of purportedly banned ingredients.

Target moved to dismiss the lawsuit, arguing that plaintiffs failed to sufficiently state their claims. The court noted that the case is not as straightforward as a typical product liability case. "The central allegation presented is that the Target Clean program itself is inherently deceptive, not merely any one claim about any one product," the court said. "In other words, by representing Target Clean as a neutral tool to help consumers, Target is alleged to have used an imprimatur of authority, as a retailer, to point health-conscious consumers toward purchasing certain products."

In seeking to dismiss most of the plaintiff's case on the pleadings alone, the court said that "Target asks too much." "Given the breadth of Target's arguments, to grant its motion would amount to this Court declaring, as a matter of law, that the Target Clean program alleged in the Complaint is incapable of deceiving a reasonable consumer," the court said. "Doing so would require this Court to invert the presumptions that govern at the pleading

stage by resolving considerable factual ambiguity and complexity in Target's favor. This the Court cannot do."