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LEGISLATION, REGULATIONS & STANDARDS

Congresswomen Press FDA on Ban on Formaldehyde in Hair Products

U.S. Representatives Ayanna Pressley (D-Mass.), Nydia M. Velázquez (D-N.Y.) and Shontel Brown (D-Ohio) have sent a letter to U.S. Food and Drug Administration (FDA) Commissioner Robert Califf seeking an update on the agency's delay in implementing a rule to ban formaldehyde and other formaldehyde-releasing chemicals in hair products. The congresswomen have asked for information on the factors causing the delay and whether the agency has clear timelines and milestones for moving forward with the ban, whether FDA shares their concerns about the health effects of the delay, and what steps the agency has taken to proactively mitigate disruptions to businesses once the ban is implemented. "As the FDA works to address these pressing issues, it is essential to continue to highlight the gravity of formaldehyde exposure, as highlighted by both epidemiological data and laboratory research," they said. "Ensuring that regulatory actions align with

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the best interests of public health remains the goal and we encourage promptly finalizing a proposed rule."

FDA Deputy Commissioner Supports Legislation Requiring Supplement Makers to List Products, Ingredients

In remarks before the U.S. House of Representatives Subcommittee on Health, U.S. Food and Drug Administration (FDA) Deputy Commissioner for Human Foods Jim Jones indicated the agency's support for legislation that would give FDA more authority to require dietary supplement manufacturers to register products—including product ingredients—with FDA. Jones said that the dietary supplement market has grown to more than 10 times its size when the Dietary Supplement Health and Education Act was enacted, and FDA has not kept up the pace with it. "There are virtually no barriers to entry to the dietary supplement market," he said. "Bad actors have continued to exploit the halo created by the quality work of legitimate manufacturers by continuing to distribute and sell dangerous products that put customers at risk." Jones' remarks prompted criticism from the dietary supplement industry, including from Natural Products Association President and CEO Daniel Fabricant, who said in a statement that "it's disappointing to see new leadership hold the same antiquated views on the dietary supplement industry. The notion that the industry's size somehow impedes the agency from doing its job is irresponsible."

FDA Warns Against Use of Umary, Amazy Products

The U.S. Food and Drug Administration (FDA) has warned consumers not to purchase or use products marketed as dietary supplements sold under variations of the name Umary and Amazy, alerting the public to potentially unlisted drug ingredients. In a statement, FDA said it has seen an increase in adverse event reports associated with the products and its own testing has shown the presence of diclofenac, a non-steroidal

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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.

anti-inflammatory drug, and omeprazole, a proton pump inhibitor. In August, FDA issued a warning letter to manufacturer SoloVital for selling Umary; SoloVital and another company, Main Products, Inc., issued a recall for the affected products in July.

NAD Refers Toothpaste Company to FTC for Review

BBB National Programs' National Advertising Division has referred HiSmile PTY to the Federal Trade Commission (FTC) and other regulatory bodies after the company declined to say it will comply with NAD recommendations regarding its marketing claims for tooth concealer products and tooth whitening products. Oral Essentials, Inc. challenged certain HiSmile claims, and NAD determined that the studies and research HiSmile submitted did not provide a reasonable basis for its marketing claims, including claims of its tooth concealers providing "instant brightening" and claims surrounding tooth sensitivity. NAD recommended HiSmile discontinue such claims. Oral Essentials also challenged HiSmile's product demonstrations and endorsements on social media, asserting that HiSmile failed to fully disclose material connections between endorsers and the company. NAD recommended HiSmile modify any video endorsement to include a material connection disclosure that is clear and conspicuous in audio and video. While HiSmile permanently discontinued certain claims for its products during the proceeding, the company did not provide an advertiser statement confirming it will comply with all of NAD's recommendations, prompting NAD to refer the matter to FTC.

Happy Mammoth Agrees to Discontinue Menopause Supplement Health Claims

BBB National Programs' National Advertising Division (NAD) has recommended that dietary supplement manufacturer Happy Mammoth stop making certain claims about its Hormone Harmony supplement, including "Relieves symptoms of Menopause," "Relieves hot flashes," "Improve sleep quality" and "Reduces bloating and gas." NAD found the company could not substantiate its claims about the challenged benefits because there was no testing on the product itself. The company sought to qualify the claims regarding specific ingredients, but NAD said the studies the company submitted "had limitations that rendered them insufficient to support the challenged claims as well as the qualified claims and, therefore, recommended the claims be discontinued." Happy Mammoth agreed to discontinue certain claims and agreed to comply with NAD's recommendations. In July, a social media ad for the same product drew scrutiny from the United Kingdom's Advertising Standards Authority. The ASA banned the ad for making unauthorized health and weight loss claims.

FDA Finds Prescription Drug, Kava Compounds in Recalled Mushroom Products

U.S. Food and Drug Administration (FDA) testing of recalled Diamond Shruumz chocolate-bar and infused-cone samples has reportedly shown the presence of compounds including psilocin, the prescription drug pregabalin, and kavalactones found in the kava plant, the agency has reported. In June, FDA and the Centers for Disease Control and Prevention (CDC) began an investigation into illnesses associated with Diamond Shruumz Microdosing Chocolate Bars manufactured by Prophet Premium Blends, LLC. Later that month, the company recalled its infused cones, chocolate bars and gummies because they contained muscimol, a compound found in some mushrooms. According to FDA, as of August 30, 2024, 158 illnesses linked to the products have been reported from 32 states. Of those, 63 people have been

hospitalized, and there are two deaths potentially associated with the products.

LITIGATION

NPA Seeks Declaratory Judgment, Injunction For FDA's NMN Decision

The Natural Products Association (NPA) has filed a lawsuit against the U.S. Food and Drug Administration (FDA) and Department of Health and Human Services (HHS) and their respective leaders seeking a court ruling that ß-Nicotinamide Mononucleotide (NMN) should not be excluded from the definition of a dietary supplement. *Natural Products Association v. FDA*, No. 24-2479 (D.D.C., filed August 28, 2024). NPA alleged that FDA's conclusion that NMN is subject to the Drug Exclusion Clause of the Dietary Supplement Health and Education Act (DSHEA) harms both its members and members of the public. "Under this misapplication of the law, FDA has created an unprecedented power for itself to reverse the status of dietary supplement ingredients that were previously reviewed by the agency," the organization said. "This has never happened in the thirty years of DSHEA." NPA seeks declaratory judgment and injunctive relief.