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LEGISLATION, REGULATIONS & STANDARDS

Hawaii Bans Two Sunscreen Ingredients

The Hawaii legislature has passed a law that will prohibit the sale or distribution of sunscreen containing oxybenzone and octinoxate after January 1, 2021. The ingredients "have significant harmful impacts on Hawaii's marine environment and residing ecosystems," including "mortality in developing coral," "coral bleaching that indicates extreme stress" and "genetic damage to coral and other marine organisms," according to the bill. The law will exempt prescribed sunscreens as well as "products marketed or intended for use as a cosmetic [] for the face."

CSPI Urges FDA to Act on Ginkgo Biloba

The Center for Science in the Public Interest (CSPI) has sent the U.S. Food and Drug Administration (FDA) a letter to provide the agency with "concerning data regarding the adulteration and marketing of ginkgo biloba supplements." CSPI asserts that "ginkgo has largely been shown in studies to be ineffective in achieving any significant beneficial effects for memory or circulation" and further that it may "increase the risk of bleeding for medical patients." The advocacy group also notes that "ginkgo may be among the most adulterated herbs sold as a supplement" because a supplement-testing organization reportedly found that a majority of samples tested "either didn't contain much ginkgo or showed strong evidence of having been spiked with cheaper plant material." The letter further urges FDA to "closely examine the claims made on labels and in related materials about ginkgo biloba to ascertain whether they are supported by sufficient

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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evidence" and "consider whether requiring a warning on packages for ginkgo biloba products is warranted."

FDA Sends Warning Letters to Kratom, Dietary Supplement Makers

The U.S. Food and Drug Administration (FDA) has issued warning letters to three online sellers of kratom, advising the companies that sales of unapproved new or misbranded drugs violate the Food, Drug and Cosmetic Act. FDA warned Kratom Spot, Revibe, Inc. and Front Range Kratom that they have 15 business days to correct the violations, which include claiming that their products can be used to treat opioid addiction or withdrawal.

FDA also warned five other manufacturers or sellers of dietary supplements after reviewing their websites, facilities and labeling. Baker's Best Health Products Inc. was warned that its Eterni-D, Triple Action Joint Formula, Apple Cider Vinegar + and Colon Formula were unapproved new drugs or misbranded. GliSODin Skin Nutrients was advised that its Advanced Skin Brightening Formula was intended for use as a drug. Napa Valley Bioscience was warned that claiming Sunsafe Rx can protect from UV rays serves as evidence that the product is intended for use as a drug; a similar warning was issued to Sunergized LLC for its Sunergetic supplement.

Chi's Enterprise Inc. was warned that FDA had not received a response to concerns noted during two inspections of its facility in 2017, including failure to establish quality control operations or manufacturing specifications, failure to establish specifications for components, supplement labels or packaging and failure to establish or follow procedures related to product complaints.

Ad Boards Review Carmex, Max Factor Marketing

The National Advertising Division (NAD) has recommended that Carma Laboratories Inc. discontinue advertisements suggesting that Carmex Cold Sore Treatment "speeds healing, shortens symptom duration, prevents cold sores, or stops progression of the [herpes simplex 1] virus." NAD found that while "the competent and reliable scientific evidence required to support health-related claims is a human clinical trial," Carma did not submit clinical studies or other evidence to support its claims. Carma agreed to discontinue the ads along with testimonials,

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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.

reviews and paid reviews that make unsupported claims about the product.

The U.K. Advertising Standards Authority (ASA) rejected seven complaints challenging Coty UK's ads claiming that Max Factor Healthy Skin Harmony Foundation is "better for your skin than no foundation." Coty argued that the claim was directly connected to the benefits shown in text onscreen: SPF 20, hydration, shine control and added vitamins. The company provided ASA with documentary evidence in support of the four claims, and ASA concluded that the evidence supported claims of SPF protection and hydration, although it did not consider whether it supported the other two advertised benefits.

GLOBAL

European Parliament Calls for Global Ban on Animal Testing

The European Parliament has passed a resolution calling on the EU to urge countries worldwide to stop animal testing in the cosmetics industry. The EU banned the practice for finished cosmetics in 2004 and for individual ingredients in 2009; the resolution notes that the degree of compliance with the existing bans is "very high," but products imported into the EU may have been subjected to required or permitted animal testing. The resolution "calls for the EU institutions to guarantee a level playing field for all the products placed on the EU market and to make sure that none of them have been tested on animals in a third country" and urges the European Commission to use diplomatic networks to encourage the end of animal testing globally.

LITIGATION

Ninth Circuit Reverses Dismissal of Pharmavite Vitamin E Putative Class Action

The U.S. Court of Appeals for the Ninth Circuit has reversed a dismissal of a putative class action alleging Pharmavite LLC misled consumers with its Vitamin E product's "heart health" labeling. *Bradach v. Pharmavite, LLC*, Nos. 16-56598, 17-55064 (9th Cir., entered May 17, 2018). The court first held that federal law does not preempt state requirements that structure/function

claims on dietary supplement labels be accurate and not misleading.

The court then turned to the issue of reliance in California putative class actions arising from the state's consumer-protection statutes. Plaintiffs do not have to prove individual reliance on allegedly misleading statements, the court held, because the standard is whether "members of the public are likely to be deceived." These types of claims are "ideal for class certification because they will not require the court to investigate class members' individual interaction with the product," the court noted.

Most Claims to Continue in Church & Dwight Folate Putative Class Action

An Illinois court has ruled that federal law does not preempt mislabeling claims in a putative class action alleging that Church & Dwight Co. Inc.'s Vitafusion B Complex Adult Vitamin Gummies contain three times the amount of folate stated on the label, a level allegedly harmful to human health. *Chavez v. Church & Dwight Co. Inc.*, No. 17-1948 (N.D. Ill., entered May 16, 2018). The court dismissed nationwide and multistate putative class action allegations, ruling that the plaintiff cannot make allegations on behalf of out-of-state residents.

Church & Dwight argued that the plaintiff's mislabeling claims were preempted by the Food, Drug and Cosmetic Act (FDCA) and the Nutritional Labeling and Education Act. The court disagreed, finding that Illinois law was not identical to the federal statutes. The court also dismissed Church & Dwight's request for a stay under the primary jurisdiction doctrine, finding that the company failed to identify "any relevant proceedings to which this court should defer."

HGH Anti-Aging Supplement Maker Exaggerated Benefits, Putative Class Action Alleges

A plaintiff has filed a putative class action alleging Sanmedica International misleads consumers about the benefits of SeroVital-hgh, a supplement touting increased levels of human growth hormone (HGH) that purportedly helps with "wrinkle reduction, decreased body fat, increased lean muscle mass, stronger bones, improved mood, [and] heightened sex drive," according to the complaint. *Pizana v. Sanmedica Int'l LLC*, No. 18-0644 (E.D.

Cal., filed May 9, 2018). Sanmedica's marketing allegedly asserts that the supplement will increase HGH levels by 682 percent, but according to the plaintiff, "if SeroVital were to increase HGH levels as claimed, it would cause significant health risks." The complaint cites two endocrinologists, purported experts on growth hormones, who "each concluded the Product cannot increase HGH levels by 682% nor can the Product lead to the anti-aging benefits claimed by Defendants." Alleging violations of California's consumer-protection statutes, the plaintiff seeks class certification, damages, restitution and attorney's fees.

Court Recommends Denial of Settlement in CVS Lawsuit

A magistrate judge in New York has recommended that a court deny a motion for preliminary approval of a settlement in a lawsuit alleging CVS Pharmacy Inc. mislabels Algal-900 DHA. *Aliano v. CVS Pharmacy, Inc.*, No. 16-2624 (E.D.N.Y., filed May 21, 2018). The plaintiff's adequacy as class representative was challenged by a plaintiff in a similar lawsuit against CVS.

The court found that the plaintiff's attorney had represented him in 36 lawsuits, including pro bono for a matter occurring during the CVS litigation. The plaintiff also offered as an expert witness a physician with a suspended medical license and multiple felony fraud convictions. Finally, the plaintiff asserted that he had purchased the product at a CVS location that recorded no sales of the product on the date in question.

Because of the "appearance of impropriety" of the client-counsel relationship, their attempt to "rush" a settlement before the plaintiffs in the similar suit could conclude their negotiations with CVS, and questions about the plaintiff's credibility, the magistrate judge concluded that the plaintiff was an inadequate representative of the putative class.

Putative Class Action Alleges Garlique Deceptively Marketed as "Natural"

Focus Consumer Healthcare LLC faces a putative class action alleging that it deceptively labeled and marketed Garlique as "natural" despite containing "unnatural, synthetic, and/or artificial ingredients" and does not contain garlic. *Hertel v. Focus Consumer Healthcare, LLC*, No. 18-1176 (E.D. Cal., filed May 10, 2018). The complaint alleges that the product is marketed as "Cholesterol's Natural Enemy" and that its name implies that it

contains garlic. However, the product allegedly contains several artificial ingredients, including titanium dioxide, which can be used as a colorant; the plaintiff asserts that the U.S. Food and Drug Administration (FDA) has stated that "all color additives, regardless of source, are synthetic and thus, not 'natural.' Moreover, the FDA has also explicitly stated that it would be 'inappropriate' to label a product as 'natural' when it includes a color additive as an ingredient."

Claiming violations of California consumer-protection laws, breach of warranty and breach of quasi-contract, the plaintiff seeks class certification, injunctive relief, damages, restitution and attorney's fees.

Glossier Targeted in ADA Putative Class Action

Glossier Inc.'s website is not fully accessible to blind and visually impaired users in violation of the Americans with Disabilities Act (ADA), a putative class action alleges. *Sypert v. Glossier Inc.*, No. 18-4215 (S.D.N.Y., filed May 10, 2018). The complaint alleges that because Glossier's website is not compliant with Web Content Accessibility Guidelines, the plaintiff was unable to buy products online or access information about the location and hours of the New York store to purchase products in person. Claiming violations of the ADA and New York's human-rights laws, the plaintiff seeks injunctive relief, damages, class certification and attorney's fees.

Supplement Powders Allegedly Lack Prop. 65 Warning

A consumer has filed a putative class action alleging Barlean's falsely advertises its Greens Supplement Powders and fails to include a warning about the product's lead levels as required by California's Safe Drinking Water and Toxic Enforcement Act (Prop. 65). *Brannon v. Barlean's*, No. 18-0981 (S.D. Cal., filed May 17, 2018). The plaintiff does not specifically allege a violation of Prop. 65 but asserts that the manufacturer's failure to include a "clear and reasonable warning" about the product's lead content "constitutes a material misrepresentation and/or omission, in violation of California consumer protection law." In addition, Barlean's allegedly makes unsubstantiated representations about the supplement powder's benefits—including "cleansing of organs and tissues," improving digestion and promoting "a healthy immune system"—in violation of the Dietary Supplement Health

& Education Act. Claiming violations of California consumer-protection statutes, breach of express warranty and quasi-contract, the plaintiff seeks class certification, injunctive relief, damages and attorney's fees.