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LEGISLATION, REGULATIONS & STANDARDS

California Passes Professional-Cosmetics, Animal-Testing Laws

California Governor Jerry Brown has signed a law that will bring labeling for professional cosmetics in line with regulations in place for consumer-facing product lines. According to the bill, "Existing federal law does not regulate professional cosmetics in the same manner as cosmetics sold to consumers. Information on the ingredients in professional salon products is essential to ensuring that workers and owners can make safer product choices and take steps to protect themselves and their customers against harmful exposures." The law affects professional cosmetics manufactured on or after July 1, 2020.

The California legislature has also passed a bill that would ban animal testing for cosmetics. "Notwithstanding any other law, it is unlawful for a manufacturer to import for profit, sell, or offer for sale in this state, any cosmetic, if the cosmetic was developed or manufactured using an animal test that was conducted or contracted by the manufacturer, or any supplier of the manufacturer, on or after January 1, 2020," the bill states. The law enumerates several exceptions, including one for animal testing conducted to comply with foreign regulatory authorities if the manufacturer can support the safety of the cosmetic without the animal-testing evidence. The bill would also exempt ingredients that are "in wide use and cannot be replaced by another ingredient capable of performing a similar function," subject to some limitations. The bill was presented to Governor Brown on September 12, 2018.

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FDA Warns of Kratom Risks Again

U.S. Food and Drug Administration (FDA) Commissioner Scott Gottlieb has issued a statement warning consumers against the use of kratom, echoing an agency statement issued in February 2018. Gottlieb indicated that FDA warned "two more unscrupulous vendors, Chillin Mix Kratom and Mitra Distributing, for marketing kratom products with scientifically unsubstantiated claims."

"In support of the public health, we continue to urge consumers not to consume kratom and to seek appropriate medical care from their health care provider," Gottlieb states. "We will also continue to take action against those who put the safety of Americans at risk and who violate federal law by making unsubstantiated health claims about products that they seek to sell."

Ad Board Refers Sunscreen Products to FTC, FDA

The National Advertising Division (NAD) has referred Cross Brands Manufacturing's marketing for Sea & Ski sun care products to the U.S. Food and Drug Administration (FDA) and Federal Trade Commission (FTC). The company advertises its products as protecting against infrared solar radiation, but a NAD review purportedly found that it was unable to substantiate the claims based on the one study submitted. "The results provided were from a single product test and did not include any of the analysis or graphs that, based on the sample report, were likely part of the original document," NAD stated. "Generally, incomplete study information, whether in the form of abstracts, informal summaries, or, in this case, highly redacted information, do not impart enough information to constitute competent and reliable scientific evidence." Cross Brands did not indicate whether it intended to comply with NAD's recommendations of discontinuing use of the infrared claims, so the board referred the information to FDA and FTC for review.

Draft Guidance on Probiotic Dietary Supplements Issued

The U.S. Food and Drug Administration (FDA) has issued draft guidance on the declaration of live microbials in dietary supplements. The guidance provides information on labeling

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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.

probiotics in terms of colony forming units. FDA may consider comments submitted by November 6, 2018, in revising and finalizing the guidance.

GLOBAL

EU Adopts Micro-Plastics Resolution

The European Commission has adopted a strategy aiming to ensure that the use of micro-plastics—which "can be deliberately manufactured and intentionally added to products such as rinse-off cosmetics (for example facial or body scrubs)"—is reduced across all industries by 2030. Members of European Parliament specifically "called for a ban on intentionally added micro-plastics in cosmetics, personal care products, detergents and cleaning products by 2020."

LITIGATION

Most Claims Dismissed From MMA Fighter's Dietary Supplement Lawsuit

A mixed martial art (MMA) fighter's lawsuit against Vitamin Shoppe, Millennium Sport Technologies, Gaspari Nutrition and Hi-Tech Pharmaceuticals will continue with some claims dismissed. *In re Lyman Good Dietary Supplements Litig.*, No. 17-8047 (S.D.N.Y., entered August 6, 2018). The plaintiff alleged that the defendants sold him supplements containing androstenedione, an anabolic-androgenic steroid, causing him to test positive for illegal substances under his MMA organization's rules.

The court dismissed a claim for fraud, finding the allegations "threadbare, conclusory assertions" that were "insufficient to raise a strong inference of fraudulent intent." The court also dismissed the claim for "assault and battery," noting that the claims are "distinct torts with distinct elements" and finding the plaintiff's argument that the defendant "intended to inflict personal injury on Plaintiff without his consent" was conclusory. The plaintiff's claim of reckless or intentional infliction of emotional distress was likewise dismissed, with the court finding that the cases cited in support of the claim focused on a different cause of action.

The court allowed allegations of breach of implied warranty of merchantability to continue and granted leave to amend some of the claims it dismissed, including an allegation for breach of implied warranty of fitness for a particular purpose.

Court Declines Certification in Weight-Loss Crystals Suit

A California federal court has denied a motion to certify a class alleging Sensa Products misled consumers into believing its "tastant crystals" caused weight loss. *Conde v. Sensa*, No. 14-0051 (S.D. Cal., entered September 10, 2018). The products were marketed as able to "trigger the user's 'I feel full' signal and the user would therefore eat less food." Following a Federal Trade Commission complaint, several consumers filed lawsuits, which were later consolidated.

The court first dismissed the defendants' argument that the plaintiff did not have standing because she used the products for five years and was satisfied, finding that the plaintiff's satisfaction had no bearing on the false-advertising allegation. Turning to the predominance standard, the court found that Sensa's website contained an arbitration agreement stating that "any controversy" related to the products "shall be governed by the laws of your home state of residence." "If the proposed class is certified, the Court will be forced to determine which of the class members may be subject to the arbitration provision (*i.e.*, those who purchased online), and those who are not (*i.e.*, all others). The Court also may have to analyze the legality of the arbitration clause and whether it binds some, all, or none of the purchasers." Finding that this reasoning challenged both the predominance of issues and the ascertainability of the class, the court declined to certify the class.

Court Enters Permanent Injunction Against Sellers of Male-Enhancement Supplements

The U.S. Department of Justice (DOJ) obtained a permanent injunction banning S Hackett Marketing, R Thomas Marketing and their owners from continuing to distribute male-enhancement supplements containing sildenafil, a drug regulated by the U.S. Food and Drug Administration. *U.S. v. S Hackett Marketing*, No. 17-4911 (D.N.J., entered August 30, 2018). DOJ alleged that the companies and their owners used more than 100 websites to promote and distribute male-enhancement supplements with pharmaceutical ingredients. The defendants "failed to respond or even appear in the action," so a New Jersey federal court entered a permanent injunction.

Protein Products' Lead, Cadmium Levels Exceed Prop. 65 Limits, Lawsuit Alleges

A plaintiff has filed a putative class action alleging that Sequel Natural Ltd.'s Vega Protein Powders and Protein Shakes contain levels of lead and cadmium exceeding the limits set by California's Safe Drinking Water and Toxic Enforcement Act (Prop. 65). *Bland v. Sequel Natural Ltd.*, No. 18-4767 (N.D. Cal., filed August 7, 2018). The complaint asserts that one serving of Vega's products exceeds the lead limit set by Prop. 65, while some products would exceed Prop. 65 cadmium limits with two servings. For allegations of strict liability failure to warn, fraud, unjust enrichment and violations of California's consumer-protection statutes, the plaintiff seeks class certification, corrective advertising, an injunction, damages and attorney's fees.

Biolage Class Granted Partial Certification

A New York federal court has granted certification to a class of consumers alleging L'Oréal USA Inc. and Matrix Essentials misled consumers into believing that Biolage hair products contain keratin. *Price v. L'Oréal USA Inc.*, No. 17-0614 (S.D.N.Y., entered August 15, 2018). The plaintiffs moved to certify a New York, California and nationwide class, and the court denied certification to the nationwide class but granted it to the New York and California classes on two of the plaintiffs' asserted claims.

The court distinguished between claims that required reliance on the product's labels and those that did not. "Plaintiffs argue that the misrepresentations in this case are 'so fundamental that it is reasonable to infer . . . that plaintiffs in fact relied on those representations in becoming Customers,'" the court noted. "Such an inference is not warranted here. Customers may have had many reasons for purchasing the Products apart from their purported keratin content. For instance, customers may have been drawn to the Products' smell, color, consistency, the aesthetics of their packaging, or their ability to clean and condition hair." Whether a potential class member relied upon the product's packaging claims would be a different determination for each class member, the court found, and the issue of the reliance was central to the fraud, breach of warranty and unjust enrichment claims. Accordingly, the court denied certification for those claims but granted certification on the consumer-protection claims under New York and California law.

Plaintiff Challenges Efficacy of Prevagen

A consumer has filed a putative class action alleging Quincy Bioscience's Prevagen supplement does not provide "the stated brain and memory support." *Spath v. Quincy Bioscience Holding Co.*, No. 18-12416 (D.N.J., filed August 2, 2018). The plaintiff alleges that Prevagen is represented as "'clinically tested' to 'improve memory within 90 days,'" as its marketing asserts. "Specifically, Defendants are representing that they have conducted high quality, randomized clinical trials, which have been subjected to peer review. In fact, Defendants have conducted no such testing," the complaint argues. "The only test sponsored by Defendants that may have been randomized [] is unreliable and flawed. Based on the data presented, Defendants primarily relied on one double-blind, placebo-controlled human clinical study using objective measures of cognitive function. … The study shows that Prevagen does not improve memory."

The plaintiff alleges that the researchers "conducted more than 30 post hoc analyses of the results, examining data broken down by several variations of smaller subgroups for each of the nine computerized cognitive tasks. This methodology greatly increased the probability that some statistically significant differences would occur by chance alone." For allegations of unjust enrichment and violations of New Jersey consumer-protection statutes, the plaintiff seeks class certification, damages, attorney's fees and injunctions preventing the defendants from selling their products and mandating corrective action.

PowerBar Maker Settles One Lawsuit, Faces Another

Premier Nutrition Corp. has agreed to pay $9 million to settle a class action alleging that its ready-to-drink (RTD) protein products did not contain 30 grams of protein as advertised. *Gregorio v. Premier Nutrition Corp.*, No. 17-5987 (S.D.N.Y., motion filed September 13, 2018). Under the agreement, class members with a proof of purchase can receive up to $40 and those without can receive up to $20. Premier Nutrition has also agreed to "reevaluate and refresh its formulations for Premier Protein RTD shakes, review its manufacturing specifications and protocols for co-manufacturers producing Premier Protein RTD shakes, and work with its co-manufacturers on best practices to implement those specifications and manufacturing protocols in order to minimize the variability of the protein content contained in the Premier Protein RTD shakes."

The company also faces a putative class action alleging it misleads consumers as to the source of protein in the PowerBar Clean Whey Protein Bar. *Ransom v. Premier Nutrition Corp.*, No. 18-4617 (E.D.N.Y., filed August 16, 2018). The plaintiff alleges that the name of the product "gives the impression the protein source is only the most concentrated form of whey – whey protein isolate – and free from fat and lactose," but the products allegedly contain milk protein isolate in amounts that would compose almost half of the protein in the bar. Further, the complaint challenges Premier Nutrition's "No Artificial Colors, Flavors or Sweeteners" marketing, alleging that the product's sweetener, erythritol, is synthetic, "a synonym for 'artificial.'" For allegations of fraud, unjust enrichment and negligent misrepresentation, the plaintiff seeks class certification, an injunction, damages and attorney's fees.

Lawsuit Alleges Jeunesse Is "Illegal Pyramid Scheme"

A woman has filed a putative class action alleging Jeunesse Global misrepresented the likelihood of success selling the company's skin care and wellness products in a multilevel marketing scheme. *Xiong v. Jeunesse Global*, No. 18-1430 (C.D. Cal., S. Div., filed August 10, 2018). The plaintiff is a former seller of Jeunesse products who failed to earn money "because she was doomed from the start by a Jeunesse marketing plan that systematically rewards recruiting distributors over retail sales of product." The complaint asserts that Jeunesse misclassifies its sellers as independent contractors "when they are, in fact, employees" because it "exerts significant control over its representatives. For example, representatives must adhere to rules regarding their conduct, their sales pitches, their performance, and the method by which they complete sales." The plaintiff seeks class certification, rescission of contracts, damages, injunctive relief and attorney's fees for allegations of an "endless chain scheme," false advertising and labor violations under California law.