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DIETARY SUPPLEMENT & COSMETICS LEGAL BULLETIN

ISSUE 39 | JULY 1, 2015

SHOOK HARDY & BACON

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SPOTLIGHT

Amid Mounting Pressure from Environmentalists, California State Assembly Passes Bill to Ban Microbeads

The California State Assembly recently passed legislation (**A.B. 888**) that would prohibit the use of microbeads in many personal care products as of January 1, 2020. If enacted into law, the ban would prohibit the use of both synthetic plastic and biodegradable plastic microbeads. Violators of the law would also face civil penalties not to exceed $2,500 per day. The proposal is now winding through the California Senate where similar legislation failed last year.

Microbeads are commonly found in facial scrubs, moisturizers and toothpaste, and environmentalists increasingly caution that because treatment plants cannot filter them, microbeads are contaminating waterways and marine environments in large concentrations. Among other things, environmental advocates further contend that microbeads are not only dangerous to the fish who ingest them, but potentially dangerous to people who consume those fish. Personal care product manufacturers such as Johnson & Johnson and Proctor & Gamble have vowed to phase out microbeads from their formulations.

California would join Colorado, Illinois, Maine, New Jersey, Indiana and Maryland, which have all enacted similar laws. But the California legislation raises the bar and is widely deemed the toughest microbead ban to date. Similar bills are pending in New York, Michigan, Minnesota, Washington, and Oregon.

In March 2015, U.S. Reps. Fred Upton (R-Mich.) and Frank Pallone (D-N.J.) introduced legislation (H.R. 1321) to ban synthetic plastic microbeads effective in January 2018. In addition to prohibiting the sale and distribution of microbead-containing personal care products, the **Microbead-Free Waters Act of 2015** would establish a national standard to avoid a "patchwork of state laws."

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The U.N. Environment Program (UNEP) also issued a comprehensive June **report** about microplastics advocating collaboration among all stakeholders to address their alleged risks and decrease their influx into the environment.

LITIGATION

Regulators Target Supplement Manufacturer over "Clinically Proven" Weight-Loss Claims

The Federal Trade Commission (FTC) has sued Lunada Biomedical, Inc. and its owners over the dietary supplement Amberen®, alleging that the manufacturer falsely claimed the supplement was clinically proven to cause weight loss in women. *FTC v. Lunada Biomedical Inc.*, No. 15-3380 (C.D. Cal., complaint filed May 12, 2015). Lunada marketed the product through radio and TV commercials, websites, email, and other promotional materials and reportedly sold nearly $65 million's worth of the supplement between 2010 and 2013. FTC's complaint alleges that the company's clinical trials failed to demonstrate that the supplement caused weight loss and that the company falsely claimed that consumers could try the supplement at no cost for a month. Customers, however, received a 90-day supply and were required to return any unused product at their own expense to request a refund.

Court Dismisses Dietary Supplement Suit and Questions Attorneys' Diligence

A California court has dismissed with prejudice a putative class action suit filed against Natural-Immunogenics Corp. over its Sovereign Silver dietary supplements. *Nilon v. Natural-Immunogenics Corp.*, No. 12-0930 (S.D. Cal., order entered May 22, 2015; sanctions memorandum filed June 24, 2015). Natural-Immunogenics advertised its colloidal silver hydrosol supplement as boosting immunity, which the plaintiff had alleged violated California's unfair competition and false advertising laws. In dismissing the case, the court rebuked the attorneys for the lead plaintiff, saying that "the slightest amount of diligence" would have been enough to learn that the lead plaintiff did not live in California and was not a member of the class. The court further noted that the plaintiff's publicly available criminal history showing his Arizona address contradicted the complaint's claims that he had lived in San Diego County and

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

Debra Dunne
215.575.3112
ddunne@shb.com

Laurie Henry
816.559.2421
lhenry@shb.com

Madeleine McDonough
816.559.2342
202.783.8400
mmcdonough@shb.com

If you have questions about this issue of the *Bulletin* or would like to receive supporting documentation, please contact Mary Boyd at mboyd@shb.com.

purchased the product there. In June 2015, Natural-Immunogenics filed a request for $91,863.96 in monetary sanctions against the plaintiff's attorney, arguing that he hid information about the class representative.

False Advertising Claims Move Forward over Revlon Foundation and Concealer

A New York federal court has dismissed the majority of claims in a putative class action alleging that Revlon Age Defying with DNA Advantage® foundation and concealer were falsely advertised under state law. *Elkind v. Revlon Consumer Prods. Corp.*, No. 14-2484 (E.D.N.Y., order entered May 14, 2015). The plaintiffs alleged that the marketing for the DNA Advantage® line of products misleads consumers with claims that they slow the aging process by affecting skin and DNA on a molecular or cellular level. The court rejected the claims lodged against the powder product for lack of standing, refused to grant an injunction and dismissed the women's mislabeling claims as preempted by the federal Food, Drug, and Cosmetic Act. The plaintiffs' deceptive advertising claims against the DNA Advantage® line's foundation and concealer products will continue. Details on the May 2014 complaint appear in Issue **24** of this *Report*.

FTC Refunds $3 Million to Consumers for Cactus Juice Drink

Nearly 500,000 consumers will receive refunds totaling almost $3 million after the Federal Trade Commission (FTC) settled charges against dietary supplement maker TriVita, Inc. for claiming that its cactus juice fruit drink would treat health problems. *FTC v. TriVita*, No. 14-1557 (D. Ariz., stipulation approval order entered July 11, 2014). The beverage, Nopalea®, was advertised with infomercials that included unsupported product claims, including anti-inflammatory properties, and featured testimonials from consumers who were compensated for selling the product. TriVita did not admit liability as part of the settlement but did agree to fund the $3.5 million for consumer reimbursement and to cease making claims that the drink could alleviate a variety of health problems. Details on the 2014 settlement appear in Issue **29** of this *Report*. *See FTC Press Release,* May 15, 2015.

Court Stops Short of Finding Liability Against Organic Cosmetics Brand

A California federal court has announced a favorable ruling for plaintiffs seeking to establish that Hain's Avalon Organics® line violated California's consumer protection laws by labeling its products "organic" when they contained less than 70 percent organic ingredients. *Brown v. Hain Celestial Grp.*, No. 11-3082 (N.D. Cal., order entered May 26, 2015). The court found that the alleged misrepresentations, if true, would violate the California Organic Products Act (COPA), which would create a presumption of classwide reliance under the state consumer protection act; further, as a matter of law, "violations of COPA are 'material' misrepresentations under the UCL." Additional information on previous rulings in the case appear in Issues **16** and **20** of this *Report*.

LEGISLATION, REGULATIONS AND STANDARDS

FTC Targets Skincare Marketers' Allegedly False "Risk-Free Trials"

A California federal court has **granted** the U.S. Federal Trade Commission's (FTC's) request for a temporary restraining order prohibiting seven individuals and 15 companies from advertising or selling Auravie, Dellure, LéOR Skincare and Miracle Face Kit products after FTC alleged that the defendants offer false "risk-free trials." *FTC v. Bunzai Media Grp., Inc.*, No. 15-4527 (C.D. Cal., temporary restraining order entered June 16, 2015).

The complaint asserts that the defendants (i) hide pricing terms in fine print or fail to disclose them altogether, (ii) falsely represent that customers can test the products without incurring costs, (iii) fail to provide a simple method of canceling the recurring charges, and (iv) misrepresent the companies as accredited by the Better Business Bureau with an "A-" rating when they have actually received an "F" rating. Several of the defendant companies, including BunZai Media Group, Pinnacle Logistics, DSA Holdings, Lifestyle Media Brands, and Agoa Holdings are registered in California with the same primary and secondary addresses and list many of the same directors. "The sellers of AuraVie tricked people into paying a lot of extra money for skin care products," Bureau of Consumer Protection Director Jessica Rich said in a June 25, 2015, press release. "Companies need to give clear, honest

information about charges. If a company advertises a 'risk free trial,' then that's what it must provide."

Regulators Take Aim at Stimulant Included in Workout Supplements

The U.S. Food and Drug Administration (FDA) recently sent several warning letters to manufacturers of over-the-counter supplement products that include AMP citrate, a stimulant also known as DMBA. The companies were ordered to halt sales because the agency said it was not aware of evidence establishing AMP citrate as safe to use as a dietary ingredient. The companies that received letters include 1ViZN LLC, Beta Labs, Blackstone Labs LLC, Brand New Energy LLC, Core Nutritionals, Genomyx LLC, Iron Forged Nutrition, Nutrex Research LLC, Powder City LLC, RPM Nutrition LLC, and VPX Sports. FDA has recently targeted stimulant ingredients in weight-loss and workout supplements, including warning letters sent in April 2015 over BMPEA.

Industry Self-Regulator Recommends Modification to Shampoo Name

The National Advertising Division (NAD), the self-regulatory body of the advertising industry administered by the Council of Better Business Bureaus, has asked Vogue International, Inc. to change the names of some of its shampoos and conditioners so that consumers will not misconstrue their claimed benefits. The products' names, which include "Renewing Argan Oil of Morocco Shampoo," "Anti-Breakage Keratin Oil Shampoo," "Nourishing Coconut Milk Shampoo," and "Thick & Full Biotin & Collagen Shampoo," faced a complaint from Unilever United States that the names could imply the exotic ingredients provided a certain benefit. NAD, through an independent review of the product packaging, found that the product names were themselves unsupported claims. NAD recommended that Vogue revise its packaging to clarify that the overall product – rather than the named ingredient – provided the claimed benefit. Vogue disagreed with NAD's determination, but agreed to revise the packaging. *See ACSR News Release*, May 20, 2015.

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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.

Shook is widely recognized as a premier litigation firm in the United States and abroad. The firm's clients include large multinational companies in the tobacco, pharmaceutical, medical device, automotive, chemical, food and beverage, cosmetics, oil and gas, telecommunications, agricultural, and retail industries.

GLOBAL TRENDS

Infused Water Maker Censored by U.K. Advertising Standards Authority

The U.K. Advertising Standards Authority (ASA) has upheld complaints filed by the Nightingale Collaboration against Scotland-based Water for Health Ltd., ruling that advertisements for certain food supplements and infused water products violated EC Regulation 1924/2006 on Nutrition and Health Claims made on Foods. At issue were website advertisements touting general health benefits and reduced disease risk associated with chlorella, chia seeds, organic flax seed oil, alkaline water, and other products.

"Because the ad made general health claims which were not accompanied by a related specific authorized health claim, and included specific health claims, and a reduction of disease risk claim, for which evidence had not been provided that they were authorized on the EU Register, and because it included prohibited claims that the advertised foods could prevent, treat or cure human disease, we concluded that it breached the Code," stated ASA in its May 27, 2015, ruling. "We told Water for Health Ltd to ensure they did not make general health claims that were not accompanied by a relevant authorized health claim, or to include specific health claims or reduction of disease risk claims that were not authorized on the EU Register, or to make claims for food to prevent, treat or cure human disease."