

**LEGAL TRENDS
REPORT**

COSMETICS • COSMECEUTICALS
• DIETARY SUPPLEMENTS
• NUTRACEUTICALS



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INSIDE GOVERNMENT

New York, California to Ban Products Containing Microbeads

Lawmakers in New York and California have proposed legislation that would prohibit the use of plastic microbeads in personal care products. Found in more than 100 products, including facial scrubs, soaps and toothpaste, microbeads have garnered recent attention as a pervasive form of plastic pollution in the marine environment, with studies reportedly showing that the tiny particles are prevalent in ocean debris piles, the Great Lakes and the Los Angeles River. Too small to be captured by most sewage and water-treatment facilities, the non-biodegradable particles flow directly into rivers and streams where they are ingested or absorbed by marine life and other mammals. Some 350,000 polyethylene or polypropylene microbeads can apparently be contained in a single product.

Proposed by New York State Attorney General Eric Schneiderman and State Assemblyman Robert Sweeney, the Microbead-Free Waters Act (A. [08744](#)) would prohibit, effective December 31, 2015, the production, manufacture, distribution, and sale in New York of any beauty product, cosmetic or other personal care product containing plastic particles smaller than 5 millimeters.

California Assembly Member Richard Bloom’s bill (A.B. [1699](#)) seeks to prohibit, after January 1, 2016, the sale of personal care products that contain microplastic particles. The legislation would impose civil penalties up to \$2,500 per day for each violation. See *Los Angeles Times*, February 12, 2014; *PremierBeautyNews.com*, February 16, 2014.

CRN Says 2015 Dietary Guidelines Should Include Supplements

The Council for Responsible Nutrition (CRN) has urged the U.S. Dietary Guidelines Advisory Committee to adopt a new posture on dietary supplements in the upcoming round of federal dietary guideline revisions that would “encourage the use of multivitamins and supplements as a convenient, safe and affordable” way to fill key nutrient gaps in most American diets.

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For additional information on SHB's Health, Wellness & Personal Care Products capabilities, please contact

Debra Dunne
215-278-2555
ddunne@shb.com



Laurie Henry
816-559-2421
lhenry@shb.com



Madeleine McDonough
816-559-2342
mmcdonough@shb.com



If you have questions about this issue of the Update, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.

According to a CRN news release, maximizing nutrition from calories consumed is a public health goal, yet government research demonstrates that many Americans continue to fall short of their nutrient requirements because consumption of vegetables, fruits, whole grains, dairy products, and seafood is lower than recommended. Citing research showing that "a large portion of Americans fall below the estimated average requirement (EAR) for certain nutrients, specifically vitamins A, C, D, E, magnesium, and calcium," CRN said that intake of some nutrients is low enough to be of "public health concern."

"The use of a multivitamin and other dietary supplements should be carefully considered to ensure adequate intake of essential micronutrients, especially in those at risk for nutrient inadequacies," CRN concluded. *See CRN News Release*, February 3, 2014.

LITIGATION AND REGULATORY ENFORCEMENT

Court Refuses to Dismiss Claims Based on "Organic" Labels

A federal court in California has determined that a state agency decision not to pursue an investigation into the defendant's alleged violations of the California Organic Products Act (COPA) does not pose a bar to a putative class action alleging COPA and other violations against Hain Celestial in the labeling of its "Avalon Organics" and "Jason" branded cosmetic products. *Brown v. The Hain Celestial Group, Inc.*, No. 11-3082 (U.S. Dist. Ct., N.D. Cal., San Francisco Div., order entered February 10, 2014). So ruling, the court denied the company's motion for summary judgment.

Hain Celestial argued that the agency ruling extinguished the plaintiffs' COPA claims, the plaintiffs were estopped from arguing otherwise because they likely initiated the agency's complaint and were "deeply involved" in the investigation, and the agency's determination is dispositive of the remaining claims because they are predicated on a COPA violation. The court ruled that the agency simply conducted an informal inquiry, obtaining only *ex parte* submissions from the company, "that resulted only in a decision not to pursue the matter further." This, the court determined, did not decide the COPA claim. The court also found that while the agency asked the plaintiffs, including former plaintiff Center for Environmental Health, for copies of the center's COPA lawsuits against the manufacturers of personal care products, this was the only involvement the plaintiffs had in the informal inquiry. The court disagreed that the remaining claims were predicated on the alleged COPA violation.

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Court Rules in FTC's Favor on False Supplement Ads; Awards \$2.2 Million

A federal court in California has determined that the Federal Trade Commission (FTC) is entitled to prevail on its claims that Wellness Support Network Inc. violated the Federal Trade Commission Act by advertising its diabetes supplements as scientifically proven to reduce blood-sugar levels and cause weight loss. *FTC v. Wellness Support Network, Inc.*, No. 10-4879 (U.S. Dist. Ct., N.D. Cal., decided February 19, 2014). The court ordered the defendants to pay restitution of nearly \$2.2 million and granted FTC's request to require regular disclosures to the agency of certain types of information for 20 years.

To order restitution against both owners—a father and daughter—in their individual capacity, the court decided that the daughter of the company's owner was reckless in her product efficacy representations. In this regard, the court stated, "Robyn Held's conduct in relying on Robert Held's judgment as to the scientific validity of the claims made by [Wellness Support] about the Products reflects reckless indifference to the truth or falsity of those statements." The court rejected the company's claims that its supplements are medical foods not within FTC's bailiwick and that FTC's action violated its First Amendment rights. As to the latter, the court stated that manufacturers or sellers of dietary supplements do not have "a First Amendment right to make claims that are false or deceptive."

Jury Rules Former Veep Did Not Steal Fragrance Co. Trade Secrets

A federal jury in New Jersey has returned a verdict in favor of former Givaudan Fragrances Corp. perfumery department vice president James Krivda, finding that he did not breach his employee confidentiality agreement or misappropriate the company's trade secrets when he left in April 2008 and took a job with Givaudan competitor Mane USA. *Givaudan Fragrances Corp. v. Krivda*, No. 08-4409 (U.S. Dist. Ct., D.N.J., verdict entered February 6, 2014). Givaudan alleged that Krivda accessed the company's "secret, protected, formula database" on the eve of his resignation and took more than 650 proprietary fragrance formulas. The company also alleged that some 38 of its formulas were used in similarly or identically named Mane fragrances. Givaudan sought \$80 million in damages.

Law Firm Says It Can Use Product Trademark to Find Plaintiffs

Seeger Weiss LLP has asked a federal court in New York to dismiss claims that it infringed the trademarks of Vitamin Shoppe Industries, Inc. by using them on a Website—*vitaminshoppeprotein.com*—established to solicit information from plaintiffs for a potential class action involving the company's BodyTech® protein supplements. *Vitamin Shoppe Indus., Inc. v. Seeger Weiss LLP*, No. 13-8333 (U.S. Dist. Ct., S.D.N.Y., motion filed February 10, 2014). According to the law firm, the Website could neither confuse consumers that the site was

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affiliated with the supplement maker nor dilute the company's trademark. "No reasonable person could believe that Vitamin Shoppe was soliciting disgruntled customers to sue itself." Seeger Weiss has apparently taken down the Website since the lawsuit was filed and offered to transfer the domain name to the company, thus rendering the lawsuit moot as well, the firm argues.

Skin Care Co. Sues Hatchery for Breach of Exclusivity Agreement

New York City-based Restorsea, L.L.C. has reportedly sued the supplier of salmon hatching fluid used in the skin-care company's beauty products, claiming that Norway's largest salmon hatchery, Aqua Bio Technology, has breached an exclusivity agreement by selling its own skin care products, which allegedly contain sufficient levels of the hatching fluid to bring it within the agreement. *Restorsea, L.L.C. v. Aqua Bio Technology ASA*, No. 14-0811 (U.S. Dist. Ct., S.D.N.Y., filed February 7, 2014). According to a news source, Restorsea CEO Patricia Pao discovered the skin-softening qualities of salmon hatching fluid when touring Aqua Bio's hatchery in 2010 and noticing how much more youthful workers' hands were than their faces, despite submerging their hands in hatchery waters all day. The companies entered a supply and license agreement and an exclusivity agreement in 2012, a year after Aqua Bounty had launched its own product line. Restorsea seeks \$6 million in compensatory damages and an order compelling Aqua Bounty to honor the exclusivity agreement. Aqua Bounty has reportedly indicated that the complaint is without merit and that it will "vigorously defend" against the allegations. See *Courthouse News Service*, February 13, 2014.

FCPA Violations Could Cost Avon \$132 Million

In a recent filing with the Securities and Exchange Commission (SEC), Avon Products, Inc. has reported that its 2013 financial results and share price were "significantly" affected by an "additional accrual" related to the potential settlement of U.S. Department of Justice (DOJ) and SEC investigations into its alleged violations of the Foreign Corrupt Practices Act (FCPA). According to the company, the settlements could reach \$132 million.

Avon reportedly instituted an internal investigation in June 2008, concerned that employees had violated the FCPA, and informed DOJ and SEC of the internal probe a few months later. The company has apparently terminated a number of employees, specifically those heading corporate affairs and finance for its China operations and its former head of global internal audit and security. Avon offered to settle the FCPA investigation for \$12 million, but the government rejected the proposed settlement and made a counterproposal "that included monetary penalties of a magnitude significantly greater than [the company's] earlier offer." *The Wall Street Journal* reported on February 14, 2014, that Avon has already spent \$340 million in legal and other costs associated with its internal probe and the government investigation. Avon's CFO

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has reportedly indicated that company has sufficient funds to cover financial penalties. See *Law360*, February 13, 2014.

Online Retailer's Diversion of Customer Searches Deemed IP Infringement

The High Court of England and Wales has determined that Amazon.co.uk Ltd. infringed the Lush trademark by diverting customers who searched for the personal-care product company's products to equivalent goods made by others. [*Cosmetic Warriors Ltd. v. Amazon.co.uk Ltd., No. HC 12C00385 \(EWHC \(Ch\), decided February 10, 2014\)*](#). Amazon apparently bid on the Google AdWord "Lush Bath Products" but did not sell any Lush products.

The court found that Lush established infringement as to (i) advertisements showing the Lush mark, but the relevant link takes consumers to an Amazon site with no Lush products, and Amazon provides no message that Lush Soap is unavailable for purchase from Amazon; and (ii) the online retailer's Website operation that opened a drop-down menu when a consumer simply types in the letters "lu" and offered "lush bath bombs"—other companies' products similar to those available from Lush—again without referring to the Lush products' lack of availability through Amazon.

According to a news source, Amazon is expected to appeal the ruling, and Lush has registered the name of Amazon's UK chief as a trademark for toilet products. See *brandchannel.com*, February 12, 2014.

EMERGING TRENDS

NSF International Launches Program to Address Cosmetics Safety and Quality Concerns

In response to growing concern from consumers and retailers regarding adulteration, mislabeling and counterfeiting issues, global public health organization NSF International has launched a Cosmetics and Personal Care Program to help manufacturers confirm the safety and quality of their products by offering auditing, training, product testing, claim substantiation, and certification services.

According to NSF International, the program addresses the needs raised by new legislation, retailer-prohibited chemical lists and manufacturing-related quality issues that have driven rapid changes to the global cosmetics and toiletries market. Noting that consumer safety concerns also fueled the initiative, the agency cites research indicating that 48 percent of consumers are concerned about the quality and safety of personal care products. See *NSF International News Release*, February 11, 2014.

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INTERNATIONAL DEVELOPMENTS

EFSA Announces Public Consultation on Niacin

At the request of the European Commission, the European Food Safety Authority (EFSA) has [launched](#) a public consultation on draft guidance issued by the agency's panel on Dietetic Products, Nutrition and Allergies (NDA) for niacin, the generic term for the soluble organic compounds nicotinic acid and nicotinamide that belong to the group of B vitamins. Concluding that no new scientific data have become available to change the Population Reference Intake (PRI) for niacin set in 1993, the panel endorses a PRI of 1.6 mg per day for adults and children. The agency will accept comments on the guidance until March 28, 2014.

EC Requests Information on Silica in Nano Form

The Scientific Committee on Consumer Safety (SCCS) has received a [request](#) from the European Commission (EC) for a scientific opinion on the safety of silica in its nano-structured form.

Used as an anti-foaming, anti-caking and skin-conditioning agent in many cosmetic products, concern is reportedly on the rise about the use of silica in nano form because of "the potential high exposure in many types of products and ... the potential for nanoparticles of silica to break out of the agglomerates and enter cells." Last year, SCCS reportedly received 172 notifications for cosmetic products containing silica, hydrated silica, silica sylilate, and silica dimethyl.

Among other things, SCCS seeks information about (i) the types of cosmetic products containing nanosilica; (ii) differences in solubility; (iii) adverse health effects; (iv) toxicological studies; and (v) other relevant scientific data/publications. Information will be accepted until May 31, 2014. *See Nanotechnology Industries Association*, February 12, 2014.

SCIENTIFIC/TECHNICAL DEVELOPMENTS

Study Questions Whether Antioxidants Can Accelerate Lung Cancer

A new study conducted by researchers at the University of Gothenburg has reportedly found that antioxidants may actually increase the risk of some forms of cancer. Volkan Sayin, et al., "Antioxidants Accelerate Lung Cancer Progression in Mice," *Science Translational Medicine*, January 29, 2014.

Researchers analyzed tumor progression in two groups of mice with lung cancer. One group received additional antioxidants in their diet in the form of vitamin E and acetylcysteine, two common antioxidants. These were given

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at levels equivalent to what a human would get from ordinary multivitamins. The second group received no additional antioxidants in their diet. The researchers found that the mice that received extra antioxidants had three times as many tumors and died twice as fast as the mice that did not receive additional antioxidants. The mice that received additional antioxidants also developed bigger tumors than the control mice. The investigators then confirmed their findings using human lung cancer cells.

Noting that acetylcysteine is commonly used by patients who have chronic obstructive pulmonary disease (COPD) because it can dissolve mucus, lead researcher Martin Bergo said that the findings may have important implications for this patient group. "It is too early to give recommendations regarding the use of acetylcysteine in COPD patients, but our study clearly points to a need for new research on this topic," he said.

Study co-author Per Lindahl warned that people should not stop taking antioxidants based on the team's findings and stressed that the study does not analyze the risk of developing cancer, but instead examines how antioxidants may speed up progression of cancer that is already present. The team reportedly plans to conduct further research to determine how antioxidants affect other types of cancer and to see whether antioxidants contribute to the development of cancer in healthy mice. See *HealthDay.com*, January 29, 2014; *MedicalNewsToday*, January 31, 2014.

New Study Asserts That Vitamin D Supplements Offer Few Benefits

Based on evidence from 40 randomized, controlled studies, a recent study by University of Auckland scientists has reportedly concluded that vitamin D supplements provide little to no health benefit and do not prevent heart attack, stroke, cancer, or bone fractures in the general population by more than 15 percent. Mark Bolland, et al., "The effect of vitamin D supplementation on skeletal, vascular, or cancer outcomes: a trial sequential meta-analysis," *The Lancet Diabetes & Endocrinology*, January 24, 2014.

Noting that previous observational studies showed that vitamin D deficiency was strongly associated with poor health and early death, researchers have concluded that this association is not causal and that supplementation is not likely to have any benefit. "The take-away message is that there is little justification currently for prescribing vitamin D to prevent heart attack, stroke, cancer, or fractures in otherwise-healthy people living in the community," lead author Mark Bolland reportedly said. "The only benefit from vitamin D was in

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reducing hip-fracture risk in elderly women living in residential care; in those 2 studies, the vitamin D supplements were given with calcium, at a dose of 800 IU/day ... In terms of harm, there was uncertainty as to whether vitamin D without calcium might increase the risk of hip fracture," he added. See *Medscape.com*, January 24, 2014.

OFFICE LOCATIONS

Geneva, Switzerland
+41-22-787-2000
Houston, Texas
+1-713-227-8008
Irvine, California
+1-949-475-1500
Kansas City, Missouri
+1-816-474-6550
London, England
+44-207-332-4500
Miami, Florida
+1-305-358-5171
Philadelphia, Pennsylvania
+1-215-278-2555
San Francisco, California
+1-415-544-1900
Seattle, Washington
+1-425-765-0650
Tampa, Florida
+1-813-202-7100
Washington, D.C.
+1-202-783-8400

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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. The firm helps 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.

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