COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

DIETARY SUPPLEMENT & COSMETICS LEGAL BULLETIN

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SHOOK HARDY & BACON

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FIRM NEWS

Shook Attorneys Contemplate Class Actions Post-Scalia

Shook Partner Frank Cruz-Alvarez and Associate Rachel Canfield recently analyzed the future of class actions in light of U.S. Supreme Court Justice Antonin Scalia's passing in an article for the Washington Legal Foundation's *Legal Pulse*. Justice Scalia "repeatedly thwarted the plaintiffs' bar's efforts to encourage liberal interpretation of Rule of Civil Procedure 23 and broadly applied the preemptive effect of the Federal Arbitration Act (FAA)," they write. The article provides an overview of Scalia-authored opinions in class action appeals and discusses immediate effects of his death on the litigation environment.

LITIGATION

California Plaintiffs Settle Class Action Against Hain Celestial Group

A California court has approved the class action settlement agreement in a lawsuit alleging that Hain falsely advertised, marketed, sold, and labeled Avalon Organics® and Jason® products as organic in violation of California's Organic Products Act and state consumer-protection statutes. *Brown v. Hain Celestial Grp., Inc.*, No. 11-3082 (N.D. Cal., order entered February 17, 2016). The court found the "proposed settlement is sufficiently fair, adequate, and reasonable that preliminary approval of the settlement is warranted."

Under the amended order, Hain agreed to pay $7.5 million in cash and $1.85 million in coupons for Avalon Organics® and Jason® products. The balance of the $7.5 million that remains in the fund after all claims, service awards, fees and costs are paid will be "donated *cy pres* in equal shares" to the California Consumer Protection Foundation and the Jesse Smith Noyes Foundation. As part of the compromise, class members who participate in the settlement agreed to release any claims under relevant state or federal laws in connection with Avalon Organics® and Jason® brand cosmetic products sold or manufactured during the class period.

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Honest Company Targeted in Personal Care Products Class Action

Consumers have filed a putative class action lawsuit against The Honest Co. purporting to represent the "hundreds of thousands of consumers throughout the United States" who have purchased Honest products and assert that at least 41 of the company's products are labeled "natural" despite containing synthetic ingredients and chemicals. *Buonasera v. Honest Co.*, No. 16-1125 (S.D.N.Y., filed February 12, 2016). The plaintiffs further allege that certain ingredients in the products are toxic and pose health and environmental risks. In particular, plaintiffs allege that The Honest Co. admits to using phenoxyethanol in some of its products, which plaintiffs contend is a synthetic neurotoxin.

The plaintiffs' complaint alleges violations of New York business law, breach of express warranty and unjust enrichment. The Honest Co.—known for its famous founder, actress Jessica Alba, and the company's stated mission to make safe, natural products available to average consumers—responded to requests for comment by denying plaintiffs' claims and stating that it stands behind its products.

Dr. Oz-Backed Green Coffee Supplement Faces Class Action Lawsuit

A recent putative class action targets the makers of popular weight-loss supplements, including Green Coffee Bean Extract Fat Loss Optimizer, Raspberry Ketones Metabolic Enhancer and Garcinia Cambogia Dual Action Fat Buster. *Woodard v. Labrada*, No. 16-0717 (C.D. Cal., filed February 2, 2016). Additionally, plaintiffs are targeting Mehmet Oz, M.D., along with companies associated with his TV show alleging that the program's endorsements made the supplements more popular despite their lack of effectiveness.

The complaint alleges multiple violations of the California business code for unfair competition, consumer protection and false advertising, as well as other common law claims such as unjust enrichment and breach of warranty. The named plaintiff alleges that marketing and labeling statements referring to the products' weight loss, fat-burning and metabolism-enhancing properties are "false, misleading, deceptive, and unlawful." Plaintiff further alleges that defendants were aware of the false and misleading nature of the statements when made and disseminated.

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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LEGISLATION, REGULATIONS AND STANDARDS

Microbead Legislation Remains a Hot Topic for the PCP Sector

While the U.S. Congress reached an agreement on federal microbead legislation—the Microbead-Free Waters Act of 2015 (Microbead Act)—which was signed into law by President Barack Obama (D) on December 28, 2015, the personal care products (PCP) sector continues to wrestle with the microbead issue.

In response to the negative press surrounding the microbead issue, the Personal Care Products Council (PCPC) penned a letter to the editor of *U.S. News & World Report* (USNWR). In its letter, the PCPC stated that prior coverage by the USNWR was not balanced and failed to include "input from environmental scientists." PCPC further stated that "scientific studies from around the world reveal that cosmetic microbeads are tiny contributors to plastic marine debris – as little as half of one percent." Finally, the PCPC noted that "no current scientific studies showing that microbeads end up in the food chain or that they demonstrate a harmful effect on either humans or wildlife at real-world levels."

FDA Updates Several Key Cosmetics Guides and Discussions

The U.S. Food and Drug Administration (FDA) has issued several cosmetics-related updates:

- In January 2016, FDA published a release noting that "Warning Letters Highlight the Differences Between Cosmetics and Medical Devices." In this statement, the agency notes that several recent warning letters – in addition to past warning letters – explain the differences in the definitions of cosmetics and medical devices. The statement notes that recent warning letters have been directed at certain devices, which have been marketed for "regrowing hair, weight reduction, spider vein removal, and dermabrasion, as well as injectable fillers and decorative lenses."
- In February, FDA updated its guide, "Cosmetics Compliance Program: Import and Domestic," which sets forth guidelines for data reporting "to ensure that imported and domestic cosmetics meet regulatory requirements through inspection, sample collection and analysis." The program emphasizes four primary areas of concern: compliance with mandatory labeling requirements; prohibited or

restricted ingredients; non-certified and non-permitted color additives; and cosmetics that contain bovine-derived tissues imported from countries affected or at risk of bovine spongiform encephalopathy (BSE) outbreaks.

- In March, FDA updated "Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)" and "Color Additives and Cosmetics" to be available in French, Korean, Spanish, Simplified Chinese, and Traditional Chinese. The color additives guide summarizes approval, certification, identity and specifications, use and restrictions requirements. Failure to adhere to the requirements will render a cosmetic "adulterated" under the Federal Food, Drug, & Cosmetic Act.
- On March 16, FDA updated its website to include a release regarding reactions reported by consumers who used EOS Lip Balm®. According to FDA, 58 reports were submitted between August 6, 2014, and January 28, 2016, for several EOS Lip Balm® flavors. The agency is working with EOS and its manufacturing subcontractor to address the issue.

FDA Cracks Down on Dietary Drug Distributor

The U.S. Food and Drug Administration (FDA) issued a warning letter to Texas-based dietary supplement distributor Lucy's Weight Loss System, d/b/a Waisted with Lucy, on February 17, 2016. According to the letter, FDA investigated the company's label distribution facility, website and social media pages and conducted laboratory tests before concluding that four of the company's products contained undeclared pharmaceutical ingredients.

Specifically, FDA found sibutramine—the active ingredient in Meridia®, which was approved by FDA in 1997 for the prescription treatment of obesity but withdrawn in 2010 after clinical data revealed the ingredient increased the risk of heart attack and stroke—in the company's Pink Bikini and Shorts on the Beach supplements. The agency also uncovered diclofenac—a nonsteroidal anti-inflammatory drug (NSAID), which, although currently available by prescription, may dangerously interact with other drugs and cause serious harm—in another version of the company's Pink Bikini product. FDA also confirmed that a variation of the company's Shorts on the Beach product contained sibutramine and phenolphthalein, which have allegedly been linked to cancer. According

to the warning letter, the manufacturer had already initiated product recalls based on FDA's investigation. For example, it stated that in the company's "483 response dated February 2, 2016, [the company] would cease package[ing] and/or label[ing] of any and all products that are considered a dietary supplement."

Mellman Group Survey Tracks Knowledge and Sentiment of PCP Consumers

A survey of 800 "likely 2016 general election voters nationwide" conducted by The Mellman Group in association with the Environmental Working Group (EWG), purports to assess the knowledge and sentiments of consumers of personal care products (PCPs). The survey notes among its key findings that "everybody uses Personal Care Products," but that "few have any idea how minimal current regulations on chemicals are."

Other survey highlights include:

- 37 percent of those surveyed believe the "government has cleared most of the chemicals used in personal care products";
- 67 percent believe "at least some products have been cleared by the government";
- 68 percent believe "The government should make certain that chemicals that end up in my body from the user of personal care products, like makeup, toothpaste, and lotions, are safe";
- 87 percent "think the government should have the power to order a recall of personal care products containing toxic chemicals";
- 94 percent want to require "companies that make personal care products, like makeup, toothpaste, and lotions, to notify the government if their products have injured customers;" and
- 74 percent would be less likely to buy a company's products if the company was fighting regulation of the chemicals in personal care products.

The survey noted that the results varied based on specific subcategories, particularly political-affiliations. Voters identifying as Democrats frequently accounted for supermajority votes for giving the government authority to "make certain personal care products are safe," or to "order

a recall of personal care products containing toxic chemicals." Slightly smaller majorities of the other political preferences also expressed approval of greater government involvement in cosmetics regulation. *See EWG Enviroblog*, March 1, 2016.

GLOBAL TRENDS

Switzerland May End Animal Testing in Cosmetics

Green Party Parliamentarian Maya Graf introduced a motion that, if passed, would end the sale of cosmetics containing ingredients tested on animals. The legislation was drafted in conjunction with the Humane Society. In 2012, Humane Society International announced its global #BeCrueltyFree campaign to end animal testing for cosmetics. #BeCrueltyFree is the largest global undertaking to end cosmetics testing on animals.

In 2015, several countries took steps to phase out the testing of cosmetics ingredients and products on animals, including New Zealand, South Korea, Turkey, Russia, and Taiwan.

If enacted, Switzerland would become the 35th country to enact legislation aimed at curtailing the trade of animal-tested consumer products.

Turkish Ban on Popular Anti-Aging Ingredient Aligns with EU Legislation

Following the European Union's lead, the Turkish Drug and Medical Device Institution has prohibited the use of 3-benzylidene camphor in cosmetic products. Turkey's ban took effect on February 18, 2016, and will affect a number of personal care products, such as sunscreens, hand and body creams, and anti-aging products. The European ban was put into place on July 28, 2015, when the European Commission amended Cosmetics Regulation No. 1223/2009. The substance is a UV filter, thought by some to pose risks to human health.