COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

DIETARY SUPPLEMENT & COSMETICS LEGAL BULLETIN

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SHOOK HARDY & BACON

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FIRM NEWS

Shook Public Policy Partner Phil Goldberg will join a panel discussing "The Culture of Alarmism – Understanding the Real Story Behind Fear Campaigns" during the Personal Care Products Council's upcoming Legal & Regulatory Conference slated for May 4-6, 2016, in Nashville, Tennessee. Shook is a co-sponsor of the event.

Shook Associates Stephanie McGraw and Nazish Shabbir recently presented on drug manufacturing regulations during the Food and Drug Law Institute's (FDLI's) Introduction to Drug Law and Regulation training course in Washington, D.C. Among other things, they discussed U.S. Food and Drug Administration (FDA) requirements for establishment registration and drug listing, misbranding and adulteration; FDA inspections; current good manufacturing practices; and 483 letters and responses.

Cosmetics and Personal Care Products Co-Chair Debra Dunne has been appointed to FDLI's Drugs and Biologics Committee, while Senior Associate Tim Moore has joined the editorial board of *Update*, FDLI's bi-monthly magazine.

SPOTLIGHT

Plaintiffs Target Cosmetic Company's Website Terms and Conditions

A putative class action complaint attacks Lush Cosmetics' website, alleging it "contains a consumer contract that purports to impose illegal, exculpatory and other such provisions upon all users of that website and purports to nullify certain legal duties and responsibilities Defendant owes its customers." *Hite v. Lush Cosmetics, LLC*, No. 16-1533 (D.N.J., filed March 18, 2016). Specifically, it asserts that the website's "Terms & Conditions" violate New Jersey's Truth-in-Consumer Contract, Warrant, and Notice Act.

The complaint highlights the website's limitation of liability and indemnification provisions of the terms and conditions as problematic,

claiming that these provisions would "absolve [Lush] of its legal responsibility to exercise reasonable care and avoid creating an unreasonable risk of harm to consumers" by "bar[ring] Plaintiffs from redress for a breach of Defendant's standard of care." It further claims that these provisions will allow the company to disregard its "responsibility to manufacture and sell safe products" and to protect its users from injuries arising directly from use of the website—for example, illegal actions by hackers or other third parties.

LITIGATION

Ninth Circuit Upholds Dismissal of Fresh, Inc., Sugar Lip Treatment Deceptive Advertising Action

The U.S. Court of Appeals for the Ninth Circuit affirmed a lower court's dismissal of a putative deceptive advertising class action against Fresh, Inc., finding that the plaintiff failed to allege—and could not allege—facts sufficient to state a claim that the labeling of the company's Sugar Lip Treatment was false, deceptive or misleading. *Ebner v. Fresh, Inc.*, No. 13-56644 (9th Cir., order entered March 17, 2016).

In the complaint, the plaintiff alleged the Sugar Lip Treatment tubes portrayed deceptive, inaccurate or misleading information about the amount of product available in each tube, which she claimed caused her to have an incorrect understanding of the "value of her purchases." Her amended complaint asserted four causes of action, including violations of California's business and professions, consumer protection and unfair competition law codes, as well as a claim of unjust enrichment. The circuit court concluded that the plaintiff's claims were barred by California's safe harbor doctrine, which "precludes plaintiffs from bringing claims based on 'actions the Legislature permits,'" were preempted under the Federal Food, Drug, and Cosmetic Act, or had failed to show that a "reasonable consumer" would be deceived as to the amount of product available.

Unilever Hair Product Class Action Settlement Upheld

The U.S. Court of Appeals for the Seventh Circuit rejected a class member's challenge to the $10.2-million settlement agreement reached in a consolidated class action alleging that Unilever U.S., Inc. misrepresented its Suave Professionals® Keratin Infusion 30-Day Smoothing Kit.

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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Reid v. Unilever U.S., Inc., No. 14-3009 (7th Cir., order entered March 25, 2016). Following a stay of the underlying class actions and extensive mediation efforts, the parties reached a settlement in February 2014; two class members objected, then one objector was dismissed from the case.

Applying an abuse-of-discretion standard to review the district court's approval, the Seventh Circuit considered "(1) the strength of the class's case, (2) the complexity and expense of further litigation, (3) the amount of opposition, (4) the reaction of class members to the settlement, (5) the opinion of competent counsel, and (6) the stage of the proceedings and the amount of discovery that was completed." The court rejected the challenger's numerous arguments as conflicting, noting that, the challenger claimed the settlement funds would be insufficient to compensate all prospective claimants but also argued excess funds were a significant possibility. On the whole, the panel found the challenger's arguments insufficient to demonstrate an abuse of discretion by the lower court.

Appellate Review Sought in False Advertising Suit Against Diet Pill Manufacturer and Reality Show Star

Nicole "Snooki" Polizzi and her co-defendants have asked the Second Circuit Court of Appeals to overturn a March 2016 ruling denying their motion to dismiss the plaintiffs' claims that Basic Research LLC misrepresented the efficacy of its diet pill, Zantrex. *Brady v. Basic Research LLC*, No. 13-7169 (E.D.N.Y., motion filed April 7, 2016). The defendants dispute the lower court's interpretation of the U.S. Supreme Court's January 2016 ruling in *Campbell-Ewald v. Gomez*, contending that the interpretation in the context of an unaccepted Rule 68 offer of judgment where the party deposits a subsequent payment would be a controlling point of law, subject to substantial grounds for difference of opinion. They further argue that an immediate appeal would "materially advance the termination of the litigation," because the issue involves subject matter jurisdiction. They take the position that a different application of *Gomez* favorable to the defendants—which the brief asserts is reasonably likely due to the newness of the *Gomez* opinion—would end the litigation.

Old Spice Faces Class Action over Deodorants

A consumer has filed a class action alleging that Proctor & Gamble's (P&G's) Old Spice deodorants caused hundreds—if not thousands—of consumers to suffer rashes, irritation, burning and other injuries. *Colley*

v. Proctor & Gamble Co., No. 16-0225 (S.D. Ohio, filed March 11, 2016). The plaintiffs seek more than $5 million in damages allegedly sustained from use of 13 Old Spice deodorants. According to the plaintiffs, "P&G falsely reported that the [] deodorants have 'no known effect' with regard to skin irritation" while "the internet is replete with examples of consumers who have complained." They accuse P&G of concealing complaints posted on blogs and documented in YouTube videos "to continue selling the product and reaping windfall profits." In addition to photographs of purported injuries, the eight-count complaint includes claims for defective manufacture and design, failure to warn, breach of implied warranty, unjust enrichment and violation of various Ohio consumer-protection statutes.

LEGISLATION, REGULATIONS AND STANDARDS

FDA Invites Stakeholder Input in Preparation for ICCR-10 Meeting

The U.S. Food and Drug Administration (FDA) has announced a public meeting slated for June 15, 2016, in Bethesda, Maryland, to collect public input about various topics in preparation for the International Cooperation on Cosmetics Regulation-10 (ICCR-10) meeting on July 12-15. Those who wish to make oral presentations should contact FDA's Office of Cosmetics and Colors by June 1. *See Federal Register*, April 20, 2016.

FDA Issues Warning Letter Regarding Lead in "Bentonite Me Baby" Topical Clay

The U.S. Food and Drug Administration (FDA) issued a warning letter on March 16, 2016, to Alikay Naturals over its "Bentonite Me Baby" product line, identifying several violations of the Federal Food, Drug, and Cosmetics Act. First, FDA determined that "Bentonite Me Baby" is a drug "because it is an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or an article (other than food) intended to affect the structure or function of the body." Second, FDA characterized the product as a "new drug" requiring an approved application on file "because it is not generally recognized as safe and effective for use under the conditions prescribed, recommended, or suggested in its labeling." Third, "Bentonite Me Baby" was deemed misbranded "because its labeling does not bear adequate directions

for its intended uses" by failing to include directions for internal use. The agency also concluded the product was misbranded "because it is dangerous to health when used in the dosage or manner recommended in its labeling." FDA laboratory tests apparently confirmed that "Bentonite Me Baby" skin and hair care products contain lead at levels of 37.5 parts per million or 37.5 micrograms per gram. According to FDA, "lead exposure is especially dangerous in children and pregnant women" and "Bentonite Me Baby," which is indicated for both topical and internal use, threatens to "excacerbate[]" those risks due to the absence of instructions for internal use regarding dosage, frequency of administration, duration of administration, or preparation for use. There are no confirmed cases of lead poisoning associated with "Bentonite Me Baby" to date. FDA informed Alikay Naturals about its lead concerns in January 2016.

In a press release issued after the initial investigation but before the March warning letter, Alikay Naturals said FDA investigated "Bentonite Me Baby" as a food or drug rather than a product to be used topically to detox hair and skin as it is advertised. The company stated that it has never recommended the product to be ingested internally or used on small children. "Bentonite Me Baby" is marketed as medicinal clay and most consumers use the product as a mask for the hair and face.

FTC Press Release Touts Victory in Forcing Changes to "All Natural" PCP Advertising

The Federal Trade Commission (FTC) recently announced that four personal care products manufacturers entered into consent orders barring the companies from "misrepresenting . . . when advertising, promoting, or selling a product: 1) whether the product is all natural or 100 percent natural; 2) the extent to which the product contains any natural or synthetic components; 3) the ingredients or composition of a product; and 4) the environmental or health benefits of a product." The orders also required the companies to "rely on competent and reliable evidence to support any product claims."

The consent orders will be subject to public comment for 30 days, ending May 12, 2016, and "consent agreement packages" will be published in the *Federal Register*. *See FTC Press Release*, April 12, 2016.

FDA Issues Revised Dietary Supplement Labeling Guidance

The U.S. Food and Drug Administration (FDA) has issued revisions to the Identity Statement portion of its 2005 Dietary Supplement Labeling Guide. The modifications correct the response to the question "Can the term 'dietary supplement' by itself be considered the statement of identity?" The guide now explains "that the term 'dietary supplement' may be used as the entire statement of identity for a dietary supplement and to explain the basis for that conclusion." The revisions also provide "clarity and consistency with 21 CFR 101.3(g) and FDA's guidance on statements of identity for conventional foods in 'A Food Labeling Guide: Guidance for Industry.'" The corrected guidance was issued without opportunity for public comment, for immediate implementation, but will remains subject to comment. *See Federal Register*, March 7, 2016.

FDA Rule Targets Potential BSE Risk by Prohibiting Use of Certain Cattle Materials

The U.S. Food and Drug Administration (FDA) recently issued a final rule to address the risk of bovine spongiform encephalopathy (BSE) by prohibiting the use of certain cattle material in human food, dietary supplements and cosmetics. BSE is a terminal, neurological disease transmitted "when cattle ingest protein meal containing the BSE infectious agent." Prohibited cattle materials include "Specified Risk Materials (SRMs), the small intestine from all cattle (unless the distal ileum has been removed), material from non-ambulatory disabled cattle not inspected and passed, or mechanically separated (MS) (Beef)." SRMs include "the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae, and the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), DRG of cattle 30 months of age and older, and the tonsils and distal ileum of the small intestine from all cattle."

According to FDA, the final rule "completes a rulemaking process that began with an interim final rule (IFR) in 2004 and was followed by IFRs in 2005 and 2008. It also confirms that "milk and milk products, hides and hide-derived products, tallow that contains no more than 0.15 percent insoluble impurities, and tallow derivatives are not prohibited cattle materials." It also amends "the final rule to provide a definition of gelatin and to clarify that gelatin is not considered prohibited cattle material under 21 CFR 189.5(a)(1) and 700.27 (a)(1) as long

as it is manufactured using the customary industry processes specified." Further, per the 2008 amendments, FDA proposed a process for designating a country as "not subject to certain BSE-related restrictions applicable to FDA regulated human food and cosmetics," which is addressed in this final rule. *See Federal Register*, March 18, 2016.

GLOBAL TRENDS

MGC Pharmaceuticals to Expand Cannabis-Based Cosmetics into Australia

On the heels of Australian legislation to allow cannabis cultivation for medical or scientific purposes, MGC Pharmaceuticals is reportedly preparing to enter the Australian market to grow cannabis, extend its clinical trial program and expand outlets for its line of cannabis-based cosmetics. MGC recently released a five-point plan for the local market and is in the process of applying for a growing license from various state authorities. According to MGC, cannabidiol, a non-psychoactive component of cannabis which accounts for more than 50 percent of known therapeutic applications, can be used to treat skin and health conditions such as acne, psoriasis, eczema and dry skin. The company is targeting emerging opportunities in the medicinal and cosmetic cannabis markets worldwide. *See Business Insider Australia*, April 4, 2016.

EC Launches Public Consultation to Strengthen Restrictions on Popular Preservative

Citing an increased incidence of skin allergies, the European Commission (EC) has proposed restricting the maximum amount of methylisothiazolinone (MI) in rinse-off cosmetic products from 100 ppm (parts per million) to 15 ppm. The proposal would also mandate "contains methylisothiazolinone" labeling. MI is a common preservative found in products that include soaps, deodorants, moist wipes and shower gels. The EC is seeking stakeholder feedback about various impacts of the restriction and will accept comments until July 1, 2016. *See EC Press Release*, April 1, 2016.