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LEGISLATION, REGULATION & STANDARDS

Senators Call For Removal of Dioxane from Cosmetic Products

U.S. Sens. Chuck Schumer (D-N.Y.) and Kirsten Gillibrand (D-N.Y.) have petitioned the Food and Drug Administration to prohibit detectable levels of 1,4-dioxane in bath and cosmetic products. The solvent creates suds in shampoos, shower gels, foaming hand soaps, bubble baths and lotions. Manufacturers are not currently required to list 1,4-dioxane as a product ingredient. The Environmental Protection Agency (EPA) and the Department of Health and Human Services have identified the chemical as a likely carcinogen.

Schumer and Gillibrand submitted their petition after an EPA study found that 1,4-dioxane was present in a majority of the water supply in Long Island, New York, and that 71 percent of the supply tested showed levels of the chemical exceeding the national average. When 1,4-dioxane is used in bath and cosmetic products, the senators claim, it washes off and travels through water systems, contaminating lakes and rivers. Schumer said that the chemical has “no purpose in these products” and called on manufacturers to begin removing it from product ingredients.

FDA Invites Comments on Proposal to Ban Lead Acetate in Hair Coloring

The U.S. Food and Drug Administration (FDA) is accepting comments on a proposal to repeal the color additive regulation

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permitting the use of lead acetate in cosmetics used in hair coloring. The petition contends that lead acetate is "readily absorbed through human skin," is "reasonably anticipated to be a human carcinogen" and that "there is no safe level of exposure to lead." The petitioners have also claimed a categorical exclusion from preparing an environmental impact statement or assessment. Electronic and written comments on the petition will be accepted through June 5, 2017.

False Lashes and Special Effects Misleading in Mascara Ad, ASA Rules

The U.K. Advertising Standards Authority (ASA) has barred Coty U.K. from re-airing a television commercial for Rimmel's Scandaleyes Reloaded mascara, finding the ad misleading because the company exaggerated the product's cosmetic effect. Coty claimed it used individual eyelash inserts in the challenged ad to "fill in gaps and provide a uniform lash line" on model Cara Delevingne and drew in additional lashes "when they were not visible due to the model's dark eyeshadow." ASA found that the lash inserts and post-production effects "conveyed a volumising, lengthening and thickening effect of the product" that consumers would not be able to duplicate and ruled Coty could not show the ad again or exaggerate the effect of the mascara product.

NAD Refers Adderin Supplement Health Claims to FTC

The National Advertising Division (NAD) has referred health claims for the dietary supplement Adderin to the Federal Trade Commission (FTC) for investigation after the supplement's maker did not respond to NAD's request to substantiate its product claims. Adderin's advertising claims that the product could increase energy, improve "cognitive growth," "sky-rocket concentration by 312%," "enhance memory recall," "improve creative thinking" and "increase IQ Scores by 77%." NAD asked Adderin's maker, KNH Online, Inc., about the claims after receiving a complaint from the Council for Responsible Nutrition.

FDA Announces Public Meeting on Cosmetics Regulation

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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.

The U.S. Food and Drug Administration (FDA) will convene a public meeting May 25, 2017, on various topics related to the regulation of cosmetics. FDA may use information from the meeting to prepare for the International Cooperation on Cosmetics Regulation-11 meeting scheduled for July 12-14, 2017, in Brasilia, Brazil.

The public meeting will be held at FDA's Center for Food Safety and Applied Nutrition in College Park, Maryland, but attendees may listen to the meeting by phone. The registration deadline is May 11.

NAD Recommends Neurocet Discontinue Pain Relief Claims

The maker of the dietary supplement Neurocet claims its product provides "pain relief 48 times stronger than morphine" and "lasts 26 times longer than 10 popular pain drugs," but the National Advertising Board (NAD) has concluded such claims can't be substantiated and should be discontinued. After NAD reviewed articles and studies the National Media Group provided in support of its advertising, the board concluded that the materials were "third-party reports summarizing existing research on the ingredients contained in Neurocet" that were "insufficiently reliable to substantiate" the product claims. Neurocet contains calcium fructoborate, CL-phenylalanine and Boswellia serrata gum extract. NAD also has recommended the company discontinue claims that Neurocet improves mobility, can be used to prevent pain and can demonstrate "clinically proven results."

LITIGATION

Consumers Cannot Force HGH Supplement Makers to Prove Ad Claims, Ninth Circuit Holds

The U.S. Court of Appeals for the Ninth Circuit has affirmed the dismissals of two putative class actions, holding that California law does not provide a private cause of action to compel defendants to substantiate advertising claims. *Engel v. Novex Biotech, LLC*, No. 14-3457 (9th Cir., order entered April 20, 2017); *Kwan v. SanMedica Int'l.*, No. 14-3287 (9th Cir., order entered April 20, 2017). Both cases involved claims that the companies' advertising and labeling of human growth hormone (HGH) supplements were false and misleading.

The court found that California's Unfair Competition Law and Consumers Legal Remedies Act expressly limit private causes of action to consumers who have suffered an injury; consumers who can prove an injury may sue to enjoin false advertising and obtain restitution, but they retain the burden of proving the challenged advertising claims are false. The plaintiffs failed to plead an injury, the Ninth Circuit found, and could not shift the burden to the HGH manufacturers for proof of the companies' advertising claims.

NutriMost Weight Loss and FTC Settle Claims of Unfair and Deceptive Acts

The Federal Trade Commission (FTC) has obtained a consent judgment against the sellers of the weight-loss program NutriMost, which includes a potential $32-million payout as well as prohibitions against future deceptive practices and advertising. *FTC v. NutriMost LLC*, No. 17-0509 (W.D. Pa., order entered April 20, 2017). Raymond Wisniewski, NutriMost LLC, and NutriMost Doctors LLC sold the program nationwide, claiming that users could lose 20 to 40 pounds in 40 days without exercising or dieting and that NutriMost could deliver "permanent" weight loss. Users were required to sign a non-disparagement clause specifically targeting speech in online media and complaints to the Better Business Bureau; any violation would subject users to a fee of $35,999 in liquidated damages. After participants paid $1,895 for the program, NutriMost then disclosed that they had to follow a 500-calorie per day diet to obtain results.

The consent order prohibits NutriMost from (i) making weight-loss and health claims unless they are not misleading and are supported by scientific evidence; (ii) claiming buyers do not need to follow a restrictive diet; (iii) making deceptive endorsements; and (iv) including non-disparagement claims in contract provisions. It also requires the company to disclose any requirement of a calorie-restrictive diet and the need for physician monitoring as well as pay $2 million in consumer refunds. After the initial $2 million, the remaining judgment may be suspended based on the defendants' financial condition.

Swiss-American SPF Suit to Continue

A federal court has rejected Swiss-American's preemption arguments in a putative class action alleging the company misrepresented the SPF value of its EltaMD UV Aero sunscreen,

which was labeled as SPF 45 but that consumers argue is only SPF 18. *Dayan v. Swiss-American Products, Inc.*, No. 15-6895 (E.D.N.Y., order entered March 31, 2017). Disagreeing with Swiss-American's arguments, the court found that the plaintiff's claims were "not entirely dependent on the [Food, Drug, and Cosmetic Act (FDCA)] because they would exist as common law tort claims even if the FDCA had never been issued." The court also rejected Swiss-American's argument of implied preemption, finding the state law claims were not based on a failure to comply with FDCA requirements.

Supplement Co. Alleges Competitor's Products Contain Illegal Steroids

Nutrition Distribution LLC has filed a lawsuit against Acolyte Sports Nutrition LLC alleging that some of Acolyte's "prohormone" products contain anabolic-androgenic steroids—federally controlled substances that apparently "expose humans to extreme health risks." Nutrition Distrib. LLC v. Acolyte Sports Nutrition LLC, No. 17-0841 (S.D. Cal., filed April 25, 2017). Marketed to body builders, athletes and fitness enthusiasts, the "prohormone" performance enhancers promise to "add mass and strength that is sure to impress" but can purportedly cause liver damage, acute renal failure and infertility because of their dimethazine and methylstenbolone content. Dimethazine is an altered form of methasterone, a Schedule III controlled anabolic steroid under the Controlled Substances Act, the plaintiff alleges. The complaint also notes that multiple body-building organizations have expressly banned the steroids from competition, and further, consumption "will lead to disqualification from any competition using the World Anti-Doping Agency's standards."

Nutrition Distribution alleges false advertising under the Lanham Act, asserting that it has "suffered both an ascertainable economic loss of money and reputational injury by the diversion of business from Plaintiff to Acolyte and the loss of goodwill in Plaintiff's products. Indeed, Acolyte's conduct is a black eye on the industry as a whole and has the tendency to disparage Plaintiff's products and goodwill." The company seeks an injunction, damages, restitution and attorney's fees.

Plaintiff Alleges Glutamine Supplement Has No Measurable Benefit

A consumer has filed a lawsuit against the maker of a glutamine nutritional supplement alleging the company's claims that the product enhances muscle growth and speeds exercise recovery are false and misleading. *Yeldo v. MusclePharm Corp.*, No. 17-11011 (S.D. Mich., filed March 30, 2017). The suit alleges that MusclePharm's claims "have been found by numerous scientific research papers to be blatantly false," and that the product has no measurable beneficial effect on users. Claiming violations of the Food, Drug and Cosmetic Act and state laws, breach of warranties, misrepresentation and unjust enrichment, the plaintiff seeks class certification, damages and attorney's fees.

Class Action Alleges Weleda Products Are Not "Natural"

A consumer has filed a putative class action against the maker of Weleda bath and body products claiming that the company's "Certified Natural" products contain synthetic ingredients created by chemical processing. *Hughes v. Weleda, Inc.,* No. 17-2494 (S.D.N.Y., filed April 6, 2017). The complaint asserts that 41 Weleda products—including shower gels, soaps, toothpaste, lotions, baby products, shampoos and conditioners—are not "natural" because they contain ingredients such as lactic acid, citric acid, alcohols and glycerin, which are created through chemical processes. The plaintiff argues that the U.S. Department of Agriculture deems a product "natural" only if "it has not undergone a chemical change" and that Congress has defined "synthetic" as "formulated or manufactured by a chemical process."

For violation of the Magnuson-Moss Warranty Act, state consumer-protection laws, deceptive acts and practices, false advertising and breach of warranties, the plaintiff seeks class certification, an injunction, restitution, damages and attorney's fees.

"Natural" Class Action Filed Against Kiss My Face

Kiss My Face LLC faces a putative class action alleging that its products contain synthetic chemicals despite product labeling that markets the products as "natural" and containing "botanical blends." *Gasser v. Kiss My Face, LLC*, No. 17-1675 (N.D. Cal., filed March 27, 2017). The complaint asserts that Kiss My Face makes body lotion and body wash products with labels stating that they

"nourish naturally" and are "naturally effective" but contain the synthetic chemicals phenoxyethanol or ethylhexylglycerin. For alleged violations of California's consumer-protection statutes, breach of express warranty, unjust enrichment and fraud, the plaintiff seeks class certification, legal and equitable relief, restitution, damages and attorney's fees.

Projected Class Action To Proceed Against Osteo Bi-Flex

The U.S. Court of Appeals for the Second Circuit has overturned a dismissal of a putative class action against the maker and marketer of nutritional supplement Osteo Bi-Flex, finding the Supreme Court's holding in *Campbell-Ewald v. Gomez* determines that companies can no longer prevent class action claims by making offers of full relief. *Lary v. Rexall Sundown, Inc.*, No. 15-0601 (2d Cir., order entered April 10, 2017). The plaintiff filed suit under the Telephone Consumer Protection Act (TCPA) after receiving an unsolicited fax offering a free sample of the supplement. In February 2015, a federal court in New York dismissed his claim, finding the defendants had made an offer of the full statutory damages under the TCPA. After the plaintiff filed his appeal, the Supreme Court held in *Campbell-Ewald* that an offer of relief cannot make a case moot. "An unaccepted settlement offer—like any unaccepted contract offer—is a legal nullity, with no operative effect," the court said. "[W]ith no settlement offer still operative, the parties remained adverse; both retained the same stake in the litigation they had at the outset."

Plaintiff Claims Target's Biotin Supplement Claims Misled Consumers

Target Corp. is facing a putative class action in California alleging that the company falsely claimed its biotin supplement would support healthy hair and skin. *Greenberg v. Target Corp.*, No. 17-1862 (N.D. Cal., filed April 4, 2017). Target purportedly sells its house-branded Up & Up Biotin in 1,000 mcg, 5000 mcg and 10,000 mcg dosages. The plaintiff alleges that the adequate intake level for biotin is 30 mcg for healthy adults, and once that "saturation" level is reached, the body cannot use the surplus for "any benefits, let alone [to] support healthy hair and skin." Claiming violations of California's Fraudulent Business Acts and Practices code and Consumers Legal Remedies Act, the plaintiff is seeking class certification, injunctive relief, corrective advertising, restitution, damages and attorney's fees.

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