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LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

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INSIDE GOVERNMENT

FDA Advisory Group Recommends More Study of Sunscreen Safety

During a recent meeting at U.S. Food and Drug Administration (FDA) headquarters, the Nonprescription Drugs Advisory Committee recommended that active ingredients in over-the-counter (OTC) sunscreen products be subject to additional safety testing. FDA convened the meeting for expert scientific advice on the scope of safety testing that should be required to support an agency determination that an active sunscreen ingredient is generally recognized as safe and effective (GRASE) for over-the-counter drug use and for advice on "a framework for evaluating the safety of sunscreen ingredients rather than on the safety of specific ingredients or sunscreens in general."

Sixteen active ingredients are currently allowed to be used by sunscreen manufacturers based on a 2011 final monograph, but the monograph process has been challenged by the regulated industry and some members of Congress as too slow for unapproved ingredients. OTC sunscreen products may also be marketed under FDA's new drug application process.

During the meeting, FDA reportedly proposed as new safety test requirements for sunscreen active ingredients (i) human safety testing, consisting of dermal safety studies and bioavailability; and (ii) nonclinical safety testing, consisting of carcinogenicity testing, developmental and reproductive toxicity studies, as well as toxicokinetics. According to a news source, most of the advisory committee members agreed that this type of testing should be a baseline, but called for industry studies focusing on the long-term safety of sunscreen active ingredients. Others contended that the monograph process lacks strong enough safety standards. A pharmacology professor apparently opined, "I am really shocked and surprised these products have been used so widely by so many people for so many years, without much public safety information. I think the framework that FDA proposed is fair, a minimal standard. But I would go further and say that these are drugs." *See Bloomberg BNA Product Safety & Liability Reporter™*, September 5, 2014.

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OEHHA to Consider Adding Personal Care Product Chemicals to Prop. 65 List

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has announced that its Carcinogen Identification Committee will consider on November 19, 2014, whether to add certain N-Nitrosomethyl-*n*-alkylamines (NMAs) to the state's list of chemicals known to cause cancer (Prop. 65). OEHHA seeks comments on the NMA hazard identification document by October 13, 2014. Some NMAs have apparently been detected in personal care products, such as shampoos and conditioners. According to OEHHA, these substances have not been intentionally added to the products, "but may form as a result of the reaction of nitrite with amine compounds." *See OEHHA News Release*, August 29, 2014.

LITIGATION AND REGULATORY ENFORCEMENT

Hi-Tech Pharmaceuticals Executives Arrested for Failed Weight-Loss Products Recall

Two Hi-Tech Pharmaceuticals directors were arrested after a Georgia federal court found that they failed to comply with an order to recall their weight-loss supplements. *FTC v. Nat'l Urological Grp. Inc.*, No. 4-3294 (U.S. Dist. Ct., N.D. Ga., order entered September 2, 2014). The court previously ordered the company to pay $40 million to the U.S. Federal Trade Commission (FTC) and recall several of its products, including Fastin, Lipodrene, Benzedrine, and Stimerex-ES. Additional information about the sanctions appears in Issue 25 of this *Report*.

The court assessed the company's recall efforts following its previous order and found several deficiencies. Hi-Tech delayed the initiation of the recall—it began drafting a recall notice 41 days after the order, and it mailed the recall notices 50 days after the order was entered. The court also noted that the scope of the recall could not be accurate because the company mailed 2,402 notices but had previously identified to the court that it had more than 3,700 retailers and distributors. In addition, Hi-Tech's recall notice was insufficient because it closely resembled a legal brief rather than a recall notice, included several paragraphs of unnecessary information and failed to include important information. According to the court, the recall notice's envelope did not identify its contents as a recall notice but instead featured product advertisements, including one of the recalled products. This could have caused recipients to confuse the notices with an advertisement or general business correspondence, "which may have been by design," as the court noted.

Further, Hi-Tech's Website did not feature a prominent notice; it included a small link labeled "Recall," which notably did not appear on the product purchasing page. The court also took issue with the company's follow-up contact because the sales department did not keep records of whom they

contacted and the sales representatives were not given a script to ensure that accurate and complete information was given to consumers, retailers and distributers. The court also cited the limited participation in the recall as evidence that the recall was deficient, because only eight companies returned products, totaling less than 3,000 bottles. FTC investigators were also apparently able to purchase the products in stores several months after the order was issued. Finally, using expiration dates, the court determined that some of the products in evidence were likely manufactured after the court ordered the recall, so it ordered the defendants to file reports on the date of manufacturing, labeling and packaging of those products.

The defendants will remain in jail until they "1) ensure that the products are not available for purchase from retail stores; 2) send out a proper recall notice for each product; 3) ensure the recall notice has been distributed to all retailers and anyone else associated with the products; and 4) ensure that links to the recall notices are prominently displayed on each page of the company's website."

Jury Convicts Former Virginia Governor and Wife in Star Scientific Scandal

Following a 27-day trial, former Virginia Governor Bob McDonnell and his wife Maureen were found guilty of corruption for allegedly accepting loans and gifts from the former CEO of supplement maker Star Scientific in exchange for using the power of the governor's office to help the company promote its Antabloc product, which was not approved by the U.S. Food and Drug Administration. Details about the original criminal indictment appear in Issue 18 of this *Report*. The trial generated considerable media attention, as witnesses testified about the luxury shopping trips, dinners and plane tickets that CEO Johnnie Williams funded for the McDonnells. The former governor reportedly failed in his trial strategy of blaming his wife for the misconduct, and sentencing for the two will take place on January 6, 2015. According to a news source, they could face lengthy prison sentences and fines exceeding $1 million. *See The Hill* and *Huffington Post*, September 4, 2014.

Putative Class Action Alleging Deceptive Advertising Against Estée Lauder Dismissed

A New York federal court has dismissed a putative class action accusing Estée Lauder of falsely advertising its Advanced Night Repair (ANR) line's anti-aging benefits, finding that the plaintiff lacked standing and failed to state a claim upon which relief could be granted. *Tomasino v. The Estée Lauder Cos. Inc.*, No. 13-4692 (U.S. Dist. Ct., E.D.N.Y., order entered August 26, 2014). The plaintiff was unlikely to purchase Estée Lauder products in the future, the court found, so she failed to sufficiently allege a future injury to establish standing for an injunction.

The court also identified problems with the merits of the plaintiff's allegations. She failed to plead with the plausibility required of a deceptive business practices claim, the court said. In addition, her claims that Estée Lauder's promotional materials deceived her were incomplete; the court found that "the only factual support she provides in support of her assertion is that 'the ANR Products do not and cannot live up to the efficacy claims made by Estee Lauder because none of their ingredients can provide the promised results,'" without alleging what ingredients the products contain or explaining how these ingredients are insufficient to support the company's claims.

The plaintiff further alleged that Estée Lauder cited patent protection in its advertisements but failed to provide the relevant patent numbers; the court found that she had misread a statute which requires a patent holder to include a patent number to recover damages in a patent-infringement action. "The statute has nothing to do with advertising," the court said. It also dismissed the plaintiff's arguments that (i) a product that actually achieved the results Estée Lauder claimed would be regulated as a drug, and, that the product was not regulated as such was proof that it could not achieve the results; and (ii) that the company releases new products "every few years" meant that the products cannot work as they claim, or else it would not need to update them.

Court Allows Clarins Deceptive Advertising Claims to Proceed

A Florida federal court has denied Clarins' motion to dismiss in a case alleging that the company deceptively advertises its products by basing its campaigns on flawed scientific studies; the court also refused to deny class certification, saying that the issue would be better handled when a motion for class certification is filed. *Garcia v. Clarins USA Inc.*, No. 14-21249 (U.S. Dist. Ct., S.D. Fla., order entered September 4, 2014). The court limited the claims, however, to the products the plaintiff purchased—Vital Light Night Revitalizing Anti-Ageing Cream and Body Life Cellulite Control, each for $90—finding that she could not show injury as to products she had not purchased and thus lacked standing.

The plaintiff alleged that the "clinical" and "consumer" tests which Clarins cited in its advertising were manipulated to achieve the desired results, and the court allowed her false and misleading advertising claim to proceed because the plaintiff had argued that she relied on the advertising in purchasing the products. The court further denied the motion to dismiss the plaintiff's claims of unjust enrichment and violation of the Florida Deceptive and Unfair Trade Practices Act, but it dismissed with leave to amend her breach of express warranty claim because she failed to notify the seller of the breach as required by Florida law.

FTC Approves Final Settlement in BrainStrong Adult Deceptive Advertising Case

The U.S. Federal Trade Commission (FTC) has reached a settlement with marketers i-Health, Inc. and Martek Biosciences in a case accusing the companies of falsely advertising their BrainStrong Adult supplement as preventing cognitive decline and improving memory without clinical proof to support their claims. *In re i-Health, Inc.*, No. C-4486 (FTC, order issued August 21, 2014). The order prevents i-Health and Martek from using these representations without competent and reliable scientific evidence; more generally, it also prohibits the marketers from making other health claims about BrainStrong Adult without scientific evidence or misrepresenting the results of any study in their advertising. In addition, the marketers must maintain a collection of all promotional materials for the product and all research related to it for five years, and the order will remain in force for 20 years.

Applied Food Sciences Settles FTC Charges of Faulty Study

The U.S. Federal Trade Commission (FTC) and Applied Food Sciences (AFS) have reached an agreement settling FTC charges that AFS "used the results of a flawed study to make baseless weight-loss claims about its green coffee extract to retailers, who repeated those claims in marketing finished products to consumers," according to a September 8, 2014, FTC press release. *FTC v. Applied Food Scis.*, No. 14-851 (U.S. Dist. Ct., W.D. Tex., order entered September 8, 2014). The FTC complaint accused AFS of citing a study as scientific proof for green coffee extract's weight-loss benefits despite its significant flaws, including the alteration of key subject measurements, adjustment of the trial's length and confusion over which subjects took AFS's Green Coffee Antioxidant (GCA) product and which took a placebo during different trial phases. Under the settlement agreement, AFS will pay $3.5 million, and, in addition, it cannot claim that GCA causes weight or fat loss—or any other health benefits—without competent and reliable scientific evidence.

Prop. 65 Enforcement Group Settles Claims with Multiple Cosmetic Cos.

The Public Interest Alliance, which sued some 100 cosmetic and personal care companies in California alleging that they violated the state's Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65) by failing to warn consumers that their powder makeup and sun-protection products contain titanium dioxide (TiO2), a substance known to the state to cause cancer, has reportedly settled with 19 of them. According to a press release issued by the group's counsel, the defendant companies that most recently settled the claims agreed to remove the chemical from their products, provide the Prop. 65 warnings or remove products containing TiO2 from the California market.

In a statement counsel said, "The Public Interest Alliance is not saying that powder cosmetic products are necessarily unsafe, but it does want to raise awareness that the scientific-based link between the inhalation of titanium dioxide powder and tumor growth requires more study. This suit is intended to increase corporate responsibility and pressure the large cosmetics manufacturers to do sufficient research to be able to say with scientific reliability whether or not their powder makeup products may cause cancer." Counsel further claimed that the companies had "pooled resources to fight in court" rather than evaluate their products to determine "'how much' TiO2 is inhaled over a lifetime." *See lawyersandsettlements.com*, September 4, 2014.

Putative Class Action Claims NBTY "Protein Spikes" Its Products

Six plaintiffs have filed a putative class action in New York federal court against NBTY, Inc. alleging that the supplement manufacturer engages in "protein spiking," a process in which the protein content of a product is artificially inflated by adding amino acids such as taurine, glycine, arginine, and creatine to produce additional nitrogen—used to calculate the amount of protein. *Mencer v. NBTY, Inc.*, No. 14-5030 (U.S. Dist. Ct., E.D.N.Y., filed August 25, 2014). According to the complaint, NBTY's Body Fortress Super Advanced Whey Protein dietary supplement contains approximately 30-percent less whey protein than the packaging indicates. The plaintiffs accuse NBTY of intentionally misleading customers into believing that its product's 30 grams of protein per serving is derived exclusively from its Super Advanced Whey Protein ingredient rather than from free form and non-protein amino acids. They seek nationwide class certification as well as certification for six state subclasses, an injunction, damages, and attorney's fees.

Class Claims Filed Against Weight-Loss Supplement Maker

A Miami resident has sued Hi-Tech Pharmaceuticals, Inc. in a Florida federal court alleging that its weight-loss dietary-supplement Garcinia Cabogia Extract, a product that Mehmet Oz purportedly promoted on his TV program, is not effective as advertised at controlling appetite, boosting metabolism, burning fat, and promoting weight loss. *Hostrup v. Hi-Tech Pharm., Inc.*, No. 14-23309 (U.S. Dist. Ct., S.D. Fla., Miami Div., filed September 8, 2014). Seeking to certify a nationwide class and statewide subclass of product purchasers, the plaintiff alleges that research has shown that the product's high-content hydroxycitric acid (HCA) fails to produce weight loss or fat-mass loss any more effectively than a placebo. Even at large doses, HCA allegedly "did not increase total fat oxidation in vivo in endurance-trained humans." The plaintiff claims that she relied on the defendant's advertising, labeling and marketing and was harmed economically because the product is not worth what she paid for it, or she would not have purchased the product at all. Alleging breach of express warranty, fraud by uniform written misrepresentation and omission,

violation of Florida's consumer-fraud statute (on behalf of the subclass only), unjust enrichment, and injunctive relief, the plaintiff seeks damages in excess of $5 million, restitution, disgorgement, attorney's fees, costs, and an order directing the defendant to cease its deceptive and misleading marketing campaign.

Thermolife CEO Sues Blogger for Defamation

Thermolife International CEO Ron Kramer has filed a defamation action against a bodybuilding blogger, whom Kramer says called him a "rat" who helped bring down a distributor of illegal steroids to athletes, including baseball player Barry Bonds. *Kramer v. Romano*, No. 14-6790 (U.S. Dist. Ct., C.D. Cal., filed August 29, 2014). In March 2014, a New Jersey federal court ordered another blogger for the same site to cease claiming that Kramer had helped an investigation into the Bay Area Laboratory Co-Operative, which authorities accused of supplying "The Clear," an illegal steroid, to Barry Bonds, runner Tim Montgomery and track-and-field Olympian Marion Jones. Kramer claims that another blogger for the site continues to accuse him of aiding the investigation, and he says the blogger has also implied that (i) he has erectile dysfunction, (ii) he and Thermolife are patent trolls and (iii) he is a "danger to children." He seeks $4 million in damages. *See Courthouse News Service*, September 3, 2014.

INTERNATIONAL DEVELOPMENTS

Ecetoc Proposes "Multiple Perspective" Approach to Nanomaterial Grouping

The European Centre for Ecotoxicology and Toxicology (Ecetoc) Task Force on Nanomaterials has analyzed existing methods of grouping nanomaterials for human-health risk assessment and concluded that a "multiple perspective" framework would be the most efficient approach for regulatory purposes. Josje H.E. Arts, et al., "A critical appraisal of existing concepts for the grouping of nanomaterials," *Regulatory Toxicology and Pharmacology* (2014). The task force will next put forward a specific proposal for this approach.

Among other matters, the nanomaterial grouping would encompass, as relevant to the specific use contemplated, "all aspects of the substance's entire life cycle," including material properties, biophysical interactions, external exposures, uptake and internal exposures, as well as "biokinetics and possibly early biological and apical effects." The task force explained, "Overall, a comprehensive, 'multiple perspective' NM [nanomaterial] grouping framework, linked to concern-driven IATAs [integrated approaches for testing and assessment], serves to streamline testing to the collection of data that is relevant for NM safety assessment. Since the 'multiple perspective' framework

is founded on scientifically justifiable categories, safe uses of NMs can be identified and unsafe uses excluded. Finally, the 'multiple perspective' NM grouping framework allows assessing NMs economically and in a timesaving manner and contributes to replacing, reducing, and refining the need for animal testing."

ASA Upholds Challenge to Bootea Website Health Claims

The U.K.'s Advertising Standards Authority (ASA) has upheld 10 issues relating to Internet advertising for Eighty Twenty Ventures Ltd's Bootea health-supplement products, promoted as an effective way to increase metabolism, burn fat and calories, regulate blood sugar levels, aid in digestion, suppress appetite, improve skin health and sleep quality, cleanse and detoxify, and help with weight-loss goals. According to ASA, all of the claims highlighted by the complainant "were health claims." Noting that while Bootea had removed the specific claims from corresponding pages of its Website, "the same, or similar claims, still appeared elsewhere on the site. Therefore, we considered that Bootea needed to provide evidence to show that the EU Register included authorised claims supporting all the challenged health claims, for at least one of the nutrients or substances within the product." Bootea was unable to do so, thus ASA concluded that the claims violated the U.K. Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing. *See ASA Rulings*, September 3, 2014.

Australia Considers *Gamma* Butyrolactone Risks in Cosmetics

Australia's Department of Health has **closed** the comment period on a proposal to amend the entry of *gamma* butyrolactone in the Standard for the Uniform Scheduling of Medicines and Poisons. Until September 11, 2014, the agency sought comments on "whether a separate entry for gamma butyrolactone is required in either Appendix C or Schedule 9 to restrict its use in cosmetics or other types of products." According to a news source, the standard classifies substances in nine different schedules depending on the degree of purported risk, and each schedule recommends the level of control over a substance's public availability. Prohibited substances are listed on Schedule 9, while Appendix C contains other substances considered a danger to health and prohibited from sale, supply or use. Department committees will consider the comments and provide their recommendations. An interim decision is expected on February 5, 2015. *See ChemicalWatch*, August 18, 2014.

China May Require Celebrities to Use the Products They Endorse

An updated draft of a "truth in advertising" law submitted to Chinese lawmakers reportedly says that celebrity endorsements should be "based on facts," or that paid spokespersons should actually try the products they endorse. The revision follows a 2013 update to the Law on Protection of the Rights and Interests of Consumers that assigns legal liability to celebrities appearing in misleading commercials and media outlets that broadcast the advertisements. The move is apparently in response to a rash of false endorsements across Asia.

In 2006, a Hong Kong actress was sued after endorsing a product from luxury skincare brand SK-II after the product was later revealed to contain the purportedly toxic metals chromium and neodymium. More recently, actor Jackie Chan was criticized for endorsing Bawang International's anti-hair-loss herbal shampoos, which a Hong Kong magazine accused of containing carcinogens. Some Chinese consumers have pointed out potential enforcement issues with the proposed law, such as the difficulties in ensuring that celebrities test the products they endorse and determining a minimum amount of the product that the spokespersons must try. *See The Wall Street Journal*, August 26, 2014.

EMERGING TRENDS

Students Develop Nail Polish to Detect Date-Rape Drugs

Four North Carolina State University students have reportedly developed a line of nail polishes that can change color on contact with date-rape drugs such as Rohypnol and GHB. The product is still in testing, but the students plan to sell the nail polish as Undercover Colors, "The First Fashion Company Empowering Women to Prevent Sexual Assault." The students won a university entrepreneurship competition with their product in spring 2014 and are raising money to fund its wide release. "Through this nail polish and similar technologies, we hope to make potential perpetrators afraid to spike a woman's drink because there's now a risk that they can get caught," the students said. *See CBS News*, August 25, 2014.

Taurine Toothpaste Called "A Trend to Watch"

Consumer market research company Canadean has identified energized toothpaste—or toothpaste formulated with taurine, which the mouth can absorb while brushing—as a trend to watch. The company surveyed U.K.-based adults and found that nearly 40 percent identified themselves as sufferers of sleep deprivation, and 29 percent of respondents indicated

that they would consider using an energized toothpaste at least once a day. Meanwhile, Russian oral care company ROCS has reportedly released a taurine toothpaste, and Canadian analysts predict that the product could find a market in other countries as well. In an August 26, 2014, press release, one analyst warned that regulatory considerations may be necessary. "Due to a chance of ingestion manufacturers need to set age limitations and daily intake occasions," she said.

SCIENTIFIC/TECHNICAL DEVELOPMENTS

Researchers Find Substantial Occupational Exposure to Triclosan

Studying a small number of physicians and nurses at two hospitals, one that used triclosan-based soap and one that used plain soap and water, researchers funded in part by the Natural Resources Defense Council have found that the use of "triclosan-containing antibacterial soaps in health care settings represents a substantial and potentially biologically relevant source of occupational triclosan exposure." Julia McIsaac, et al., "Health Care Worker Exposures to the Antibacterial Agent Triclosan," *Journal of Occupational and Environmental Medicine* (2014).

Measuring urine triclosan levels in the study participants, the researchers found a geometric mean total concentration of 92.92 ng/mL for the exposed and 36.65 ng/mL for the unexposed hospital subjects. This compares with a 15.5 ng/mL geometric mean total urine triclosan level in 2009-2010 NHANES adult participants. Acknowledging the study's shortcomings, including that the use of triclosan-containing toothpaste by participants in the triclosan-free soap hospital "obscured the differences between the two hospitals," the authors suggest that further biomonitoring studies take place with a larger sample size of randomly selected individuals to confirm their results. Still, because they assert that some laboratory research has associated triclosan exposure with adverse health effects, and the chemical may contribute to antibiotic resistance and is biopersistent in the environment, the authors suggest that precautionary measures be taken.

Sunscreen Ingredients Could Damage Marine Environments

Spanish researchers have reportedly determined that the titanium dioxide in sunscreens that are rinsed off human skin in coastal waters could cause damage to the marine environment because the substance interacts with solar radiation to produce "significant amounts of hydrogen peroxide, a strong oxidizing agent that generates high levels of stress on marine phytoplankton." David Sánchez-Quiles and Antonio Tovar-Sánchez, "Sunscreens as a Source

of Hydrogen Peroxide Production in Coastal Waters," *Environmental Science & Technology* (2014). The researchers studied Palmira beach on the Spanish island of Majorca, visited by some 10,000 beachgoers who wash 4 kilograms of titanium dioxide into the water each day, producing an additional 270 nM of hydrogen peroxide daily, significantly above the natural levels of 100 nM. This was apparently a conservative estimate, based on each adult using just half of the recommended amount of sunscreen. *See conservationmagazine.org,* August 27, 2014; *cosmeticobs.com*, September 5, 2014.

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LEGAL TRENDS REPORT

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