Shook, Hardy & Bacon L.L.P.

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LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

CONTENTS

INSIDE GOVERNMENT

Advocates Frustrated by FDA Delay in Approving Sunscreen Ingredients

According to news sources, the U.S. Food and Drug Administration (FDA), which has long delayed approving the use of eight sunscreen ingredients available in many foreign countries, but not in the United States, expects to issue a proposed rule addressing five of the ingredients in September 2013. Citing applications to approve three of the ingredients "sitting at the FDA since 2002," lawmakers, skincare companies and public health organizations said that it "just doesn't make any sense" that products available on the market in other developed countries are not available in the United States.

At issue is a process called time and extent applications (TEA) that FDA established in 2002 to streamline the review of over-the-counter (OTC) products that have been used safely in other countries. Apparently, no product has been approved through the TEA process. According to FDA Deputy Commissioner Sally Howard, the agency has recently prioritized its review of safety and efficacy data for those ingredients "because of the public health importance of OTC sunscreens." Howard reported that reviews are being completed for the eight TEA sunscreen ingredients and the agency expects to take further action in the "near future."

Members of the advocacy group Public Access to Sunscreens Coalition said, "we are hopeful that FDA will engage with stakeholders and Congress in a bipartisan manner to enact policies that clear the 10-year backlog in sunscreen applications and allow for new sunscreen products to receive a transparent review within a predictable timeframe." *See CQ News,* August 16, 2013; *TheHill.com,* August 18, 2013.

Aloe Council Debunks CSPI Warning

Citing "carefully conducted" U.S. government studies, which purportedly found clear-cut evidence that aloe vera extracts caused intestinal cancers in male and female laboratory rats, the Center for Science in the Public Interest (CSPI) has listed the substance as one to "avoid" in its guide to food additives.

SHB 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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CSPI also noted that, when taken orally, aloe vera can cause cramps and diarrhea and has been banned in over-the-counter laxatives by the U.S. Food and Drug Administration since 2002.

Calling food and manufacturers' claims that aloe has "powerful healing properties," "balances stomach acidity" and detoxifies or promotes "overall well-being" unfounded, CSPI Executive Director Michael Jacobson suggested that consumers "save [aloe] for sunburns. Used topically, aloe vera is safe. But the fanciful health claims manufacturers are slapping on various drinks and pills are unfounded, so people simply shouldn't expose themselves to the risks."

Meanwhile, the International Aloe Science Council (IASC) issued a statement which claims that products made to IASC standards, using "decolorized" (purified) aloe are safe. "The powerful laxative effect from ingesting unpurified aloe vera products would make it obvious if that's what people were consuming," said IASC Executive Director Devon Powell. "Decolorized whole leaf aloe vera juice is devoid of the toxic chemicals that have caused so much concern, yet CSPI seems willing to make uninformed and sensational comments that will only serve to confuse and frighten consumers despite the facts." *See CSPI News Release,* August 21, 2013; *IASC News Release,* August 23, 2013.

LITIGATION AND REGULATORY ENFORCEMENT

Neutrogena Agrees to Pay $1.3 Million to Settle Consumer Fraud Claims

A federal court in California has approved a settlement between Neutrogena Corp. and a putative nationwide class of consumers who allegedly purchased the company's "Naturals" product line of personal care products, relying on purportedly false marketing claims that the products contained "[no] harsh chemical sulfates, parabens, petrochemicals, dyes, [or] phthalates." *Stephenson v. Neutrogena Corp.*, No. 12-426 (U.S. Dist. Ct., N.D. Cal., order entered August 22, 2013).

Under the terms of the agreement, Neutrogena will change its labeling and some product packaging, which will include a statement about "the percentage of each product that is naturally derived." The company will also reportedly establish a $1.3-million settlement fund from which class members may receive $1 per purchase of cleansers and $2 per purchase of moisturizers, for a total of $10. Attorney's fees are capped at $500,000, and each named class representative will receive $2,000.

Neutrogena recently settled another consumer fraud suit alleging that its anti-wrinkle cream did not work as advertised. The settlement occurred after a federal court denied class certification in that action. Additional information about the court's ruling appears in the January 31, 2013, issue of Shook, Hardy & Bacon's *Product Liability Litigation Report*. *See Bloomberg BNA Product Safety & Liability Reporter,* August 26, 2013.

Animal Rights Plaintiffs Drop Class Action Against Avon

After Avon Products, Inc. challenged a motion for class certification in a suit alleging that the company misled consumers by failing to inform them about its animal testing policy, the named plaintiffs reportedly agreed to voluntarily dismiss the litigation with prejudice. *Beltran v. Avon Products, Inc.*, No. 12-2502 (U.S. Dist. Ct., C.D. Cal., joint dismissal motion filed August 23, 2013). The case began with putative class claims against three cosmetics companies, seeking more than $100 million in punitive and compensatory damages. Each company has since been sued individually, and the other cases remain pending.

According to Avon, the proposed class was not ascertainable and lacked commonality, and the predominance requirement of Rule 23(b)(3) could not be met. More significantly, however, the company argued that plaintiff Maria Beltran has "rampant credibility problems." Beltran filed the lawsuit after People for the Ethical Treatment of Animals (PETA) removed Avon from its "cruelty-free" cosmetics company list and launched a campaign to inform consumers that the company had changed its animal testing policy and was paying for tests on animals in China. Avon further noted that the two individuals added as plaintiffs following PETA's active search for potential class representatives were also not adequate, because one, as a Michigan resident, could not prosecute claims on behalf of California consumers, and the other "refused to appear for her deposition."

As to Beltran's credibility issues, Avon noted that she was a former Avon independent sales representative, "who started purchasing Avon products without knowing Avon's animal testing policy and, who, to this day, has never read nor even searched for Avon's animal testing policy," which is apparently available on its Website. The company argued that the plaintiffs' counsel published false statements about Beltran in the third amended complaint, in her sworn discovery responses and in her declaration in support of the motion for class certification. Apparently, all of those pleadings asserted that she purchased Avon products on the basis of purported misrepresentations that the products were not tested on animals. Yet, during her deposition, she admitted that her purchasing decisions "were not affected in any way by Avon's animal testing policy."

The company apparently avoids animal testing except when required by law in other countries, and, if that is required, the company "will first attempt to persuade the requesting authority to accept non-animal test data." It claims that the lawsuit was "controlled entirely by the class attorney" and "was conceived well before a plaintiff existed." *See Law360*, August 26, 2013.

Prop. 65 Enforcement Action Focuses on Products with Cocamide DEA

The Center for Environmental Health (CEH), a frequent Proposition 65 (Prop. 65) enforcement plaintiff, has filed a lawsuit against several producers and retailers, as well as up to 700 Doe defendants, selling shampoo, soap and shower gel products containing coconut oil diethanolamine condensate (cocamide DEA), an alleged carcinogen, contending that they have failed to provide appropriate warnings to consumers about the chemical's presence in their products. ***Ctr. for Envtl. Health v. Lake Consumer Prod.*, Inc., No. n/a (Cal. Super. Ct., Alameda Cnty., filed August 27, 2013)**.

According to the complaint, California EPA's Office of Environmental Health Hazard Assessment added cocamide DEA to the Prop. 65 list of chemicals known to the state to cause cancer in June 2012, and the listing required warnings one year later. Allegedly "used in Products as a foam stabilizer, emulsifier and viscosity builder in cosmetic products," the chemical is allegedly absorbed through the skin or ingested. The plaintiff seeks civil penalties of $2,500 per day for each violation of Prop. 65. According to CEH, tests on some 100 items, including brand name products and store brands for both children and adults, revealed the presence of cocamide DEA in dozens of them at levels ranging from 10,000 parts per million (ppm) to more than 200,000 ppm. *See CEH Press Release*, August 27, 2013.

Prop. 65, the Safe Drinking Water and Toxic Enforcement Act of 1986, was enacted as a ballot measure. It requires warnings for products containing chemicals listed as "known to the State" to cause cancer or reproductive harm. Failure to provide these warnings can result in substantial financial penalties. Both government law enforcement authorities and private citizens can bring court proceedings alleging failure to give required warnings. In this case, despite certificates of merit about the alleged violations provided by CEH to the state attorney general and district attorneys in the state's larger counties, none of the public prosecutors chose to enforce Prop. 65 against these defendants.

Preliminary Approval Sought for Settlement of Class Claims Against Organix® Maker

Without admitting wrongdoing, the company that makes a line of hair and skin care products under the Organix® brand and advertises them as organic despite the purported *de minimis* amounts of organic ingredients in them has agreed to pay $6.5 million to settle a putative nationwide consumer-fraud class action. *Golloher v. Todd Christopher Int'l*, No. 12-6002 (U.S. Dist. Ct., N.D. Cal., San Francisco Div., motion for preliminary approval of class settlement agreement filed August 22, 2013). The company has also agreed to cease using the Organix® brand name for hair and skin care products and will not market its products as "organic" unless they contain at least 70 percent organically produced ingredients.

Under the agreement, class members would be able to recover $4 for each product they purchased, but no more than $28. The settlement fund would be used to pay attorney's fees and costs of up to $1.625 million as well as "modest service awards to the class representatives." Any remaining funds would be distributed in equal amounts to the Center for Food Safety and Consumers Union, "two non-profit entities that serve the interest and needs of the Class." Claiming that the settlement is fair and reasonable because it provides substantial benefits to the class, the memorandum in support of the motion includes a footnote indicating that litigation filed before this suit was instituted settled in September 2012 with restrictions on the defendant's use of the Organix® brand name and the word "organic" on labels, advertisements or marketing materials in California. A hearing date of September 26, 2013, has been requested.

Putative Class Claims Estee Lauder ANR Products Do Not Perform as Advertised

A New York resident has filed a putative class action against The Estee Lauder Cos., alleging that its line of Advanced Night Repair (ANR) cosmetic products cannot produce the age-defying results the company promises on the basis of "purported scientific studies." *Tomasino v. The Estee Lauder Cos., Inc.*, No. 13-4692 (U.S. Dist. Ct., E.D.N.Y., filed August 20, 2013). Claiming that she relied on the product representations to make her purchases, the plaintiff alleges that she sustained economic losses by buying expensive products that cannot, as claimed, repair DNA damage or reduce lines and wrinkles by 68 percent.

Among the named plaintiff's claims are that the company (i) refers in its marketing materials to worldwide patents, but has not marked any of its products with information about such patents; (ii) airbrushes or alters images of its models, who, like Gwyneth Paltrow, have not actually achieved younger-looking skin by using the products; (iii) spends more money annually on marketing ($2.65 billion) than on research and development ($96.5 million)—a ratio of 27 to one; and (iv) engages in a continual series of new product cycles in which old products are discontinued and new products are introduced "based upon some new 'research' or purported new formulation, technology, discovery or ingredient . . . to keep driving sales and profits that would otherwise stagnate once consumers used the products and realized that they do not perform as promised."

Seeking to certify a nationwide class and New York subclass of product purchasers, the plaintiff alleges violations of the New York General Business Law—unconscionable commercial practice, deception, fraud, false promise, misrepresentation and/or the knowing concealment, suppression, or omissions in connection with the sale or advertisement of merchandise, and false advertising; breach of express warranty and the implied warranty of merchantability; and unjust enrichment. She requests declaratory and injunc-

tive relief; compensatory, treble and punitive damages; interest; restitution; attorney's fees; and costs.

Indian Supreme Court Assesses Care or Cure Properties of Product in Tariff Dispute

The Indian Supreme Court has affirmed lower tribunal rulings that Moisturex® is a medicament used for its curative properties and, as such, is subject to a 15-percent duty rate, rather than the 70-percent rate applied to cosmetic and personal care products used to enhance a person's appearance or beauty. ***Comm'r of Cent. Excise v. M/s. Ciens Labs.*, No. 6988 of 2003 (India, decided August 14, 2013)**.

Seeking to impose the higher duty rate for cosmetic or toilet preparations, the appellant argued that the product's pharmaceutical constituents are a minor component of the skin-softening cream, it is sold over the counter without a medical prescription, and consumers use it mainly for skin care.

The Court addressed each issue in turn and established the following guiding principles: (i) "when a product contains pharmaceutical ingredients that have therapeutic or prophylactic or curative properties, the proportion of such ingredients is not invariably decisive"; (ii) "though a product is sold without a prescription of a medical practitioner, it does not lead to the immediate conclusion that all products that are sold over/across the counter are cosmetics"; and (iii) "prior to adjudicating upon whether a product is a medicament or not, Courts have to see what people who actually use the product understand the product to be. If a product's primary function is 'care' and not 'cure,' it is not a medicament. . . . A product that is used mainly in curing or treating ailments or disease and contains curative ingredients even in small quantities, is to be branded as a medicament."

According to the Court, Moisturex® contains pharmaceutical substances and, in the product literature, is "indicated for any dryness of skin associated with winter, fissure feet, cracked nipples, in the treatment of pathological dry skin conditions and also for dryness associated with leprosy and clofazimine." It is also "prescribed by the dermatologist for treating dry skin conditions." Thus, the Court found that the product is a medicament and dismissed the appeals filed in two consolidated cases.

EMERGING TRENDS

New Forensic Technique for Analyzing Lipstick Traces at Crime Scenes

A new technique developed by forensic scientists at the University of Kent in the United Kingdom, has reportedly established a way to identify which brand of lipstick is present at a crime scene, such as on a glass, a tissue or

a cigarette, without removing the evidence from its bag, thereby avoiding contamination. The new technique uses Raman spectroscopy to detect laser light and is considered a significant development for forensic science. Current lipstick-trace analysis apparently relies on destructive forensic techniques or human opinion.

"Continuity of evidence is of paramount importance in forensic science and can be maintained if there is no need to remove it from the bag," said Kent forensic scientist Michael Went. "Raman spectroscopy is ideal as it can be performed through transparent layers, such as evidence bags."

According to Went, Raman spectroscopy produces a characteristic "fingerprint," which can be compared to various lipstick types and brands, allowing investigators to identify lipstick traces quickly and without destroying evidence. Research into applying the same method to other types of cosmetic evidence, such as powders, eye-liners and skin creams is reportedly underway. *See ScienceDaily.com* August 8, 2013.

Analysts Call for Response to Beauty Product Packaging Concerns

Cosmetic industry experts have noted that while the safety and efficacy of product formulations should be top concerns for cosmetics manufacturers, product packaging should not be neglected as it can significantly affect consumer experience. According to Virginia Lee, a senior research analyst at market research firm Euromonitor International, poorly designed cosmetics packaging is one of the "biggest consumer gripes" in the industry and can negatively affect how a product is viewed, regardless of how well it may work. Lee noted that beauty enthusiasts say that they "stay away from packaging that gets dirty" and even post tips about how to clean certain products on Web blogs. In response to consumer feedback, some cosmetic companies have re-packaged certain products, such as changing from breakable containers to tubes due to damage issues. Manufacturers need to realize that "today's beauty consumers are on-the-go and want products that work—not just on their faces, but that won't get crushed or spill in their handbags," said Lee. *See Cosmeticsdesign-europe,* August 16, 2013; *GCImagazine.com,* July 26, 2013.

INTERNATIONAL DEVELOPMENTS

EU Seeks Comments on Preservatives Used in Cosmetics

The European Commission's Scientific Committee on Consumer Safety (SCCS) has **announced** a public consultation on whether the substances methylchloroisothiazolinone and methylisothiazolinone—often used as preservatives in cosmetics—should be restricted to rinse-off products only. Although current

legislation permits use of the chemicals in small concentrations, SCCS has expressed concern that they may cause excessive skin sensitization, particularly when used as a mixture. The panel will accept comments until October 8, 2013.

UK Reinstates Fat-Burning Supplement After Ban

Use of the fat burning supplement Dexaprine, which was banned in the Netherlands and the United Kingdom last week over concerns that the product may contain an ingredient purported to cause life-threatening conditions, has been reinstated in the United Kingdom after the California company that makes it reportedly produced a U.K.-specific formulation. Sold mainly online in the two countries, Dexaprine, which contains a proprietary blend plus green tea, acacia and citrus extracts and caffeine, has been linked to side effects such as severe nausea, headaches, heart palpitations, and in one case, cardiac arrest. Following its ban, the U.K. Foods Standards Agency issued a warning about fat-burning products and noted the deaths of two people believed to have taken such products. The agency did not disclose the products in question, but said that they contained DNP (2,4 dinitrophenol), an industry chemical known to have "serious short-term and long-term effects, which can be extremely dangerous to human health."

The U.K. Medicines and Healthcare products Regulatory Agency said that the reformulated version of the product—which does not include any medicinal ingredients—can stay on the market, pending results of further laboratory analyses. *See processingmagazine.com,* August 23, 2013; *Nutraingredients.com,* August 21 and 26, 2013.

SCIENTIFIC/TECHNICAL DEVELOPMENTS

Scientists Receive $8 Million to Study Triclosan

University of Illinois researchers have reportedly decided to use an $8-million grant originally earmarked for studies on whether exposure to bisphenol A (BPA) and phthalates alters child development, to further investigate the health effects of exposure to triclosan—used in antibacterial products—and parabens—used in cosmetics, sunscreen products and shampoo. The substances, which can accumulate in the body, have purportedly been linked to cancer, endocrine disruption, reproductive toxicity, immunotoxicity, neurotoxicity, and skin irritation. Studies have also shown that because the majority of products that contain triclosan are washed down consumers' drains, high levels of the substance have accumulated in water systems, posing a potential risk to fish and other aquatic life. The U.S. Food and Drug Administration has reportedly found no evidence that antibacterial washes containing triclosan are superior to plain soap for protecting consumers from bacteria. *See Cosmeticsdesign.com,* August 20, 2013; *safecosmetics.org.*

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Ginseng Supplements Linked to Reduced Fatigue in Cancer Patients

A new study by scientists at the North Central Cancer Treatment Group and the Mayo Clinic has reportedly revealed that the supplement Wisconsin Ginseng can boost energy levels in cancer patients. Debra Barton, et al., "Wisconsin Ginseng (Panax quinquefolius) to Improve Cancer-Related Fatigue: A Randomized, Double-Blind Trial, N07C2," *Journal of the National Cancer Institute,* July 13, 2013.

"In a phase III clinical trial, researchers studied 364 patients who had completed cancer treatment or were being treated for cancer at one of 40 community medical centers. They divided 364 patients into two groups; one group received a placebo and the other received 2,000 milligrams of Wisconsin Ginseng each day for two months. At the beginning of the study, both groups ranked their fatigue, on average, 40 out of 100. After eight weeks, the group that took Wisconsin Ginseng reported a 20-point increase in energy levels and noted "higher vitality levels and less interference with activity due to fatigue."

Calling the studies "promising," Catherine Alfano, deputy director at the National Cancer Institute in Bethesda, Maryland, reportedly noted that they are not enough to support physician recommendations that patients use the supplement and that more research needs to be done. "It is not yet known how ginseng may interact with drugs or with cancer treatment itself—another reason [why] patients should not go out and use it to medicate themselves just yet," she added. *See Reuters.com,* August 15, 2013.

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