

LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS
• DIETARY SUPPLEMENTS
• NUTRACEUTICALS



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INSIDE GOVERNMENT

FDA Says Homeopathic Remedies May Contain Undeclared Drugs

The U.S. Food and Drug Administration (FDA) has [issued](#) a recall of more than 50 products manufactured by homeopathic remedy company Terra-Medica after tests revealed that they may contain penicillin or one of its derivatives as a result of the fermentation process used during manufacture.

The Ferndale, Washington-based company, whose Website claims that its Pleo Sanum range of products can “address acute and chronic inflammations and infections without the use of traditional antibiotics,” has recalled 56 lots of Pleo-FORT, Pleo-QUENT, Pleo-NOT, Pleo-STOLO, Pleo-NOTA-QUENT, and Pleo-EX homeopathic products in all forms. Noting that “anyone who is allergic to penicillin, or allergic to beta-lactam antibiotics, even at low levels, could have a serious or life-threatening anaphylactic reaction if they consume the[] products,” FDA has urged consumers to report adverse effects to its [MedWatch](#) adverse event reporting program.

FDA Rejects Cosmetics Industry Safety Proposal

In a recent letter to senior cosmetics-industry officials at the Personal Care Products Council (PCPC) and Independent Cosmetics Manufacturers and Distributors, U.S. Food and Drug Administration (FDA) Deputy Commissioner Michael Taylor [rejected](#) the cosmetic industry's latest proposal for a regulatory overhaul aimed at improving the safety of beauty and personal care products and accused the industry of creating an impasse in the current negotiations to update old legislation.

Expressing “profound disappointment” in industry proposals that he contends “would actually reduce FDA’s current ability to take action against dangerous cosmetics,” Taylor writes that the provisions in the draft industry bill are “[in] consistent with the framework agreement we reached last July” and “abandon the most important of the agreed-upon safety principles.”

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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.

For additional information on SHB's Health, Wellness & Personal Care Products capabilities, please contact

Debra Dunne
215-278-2555
ddunne@shb.com



Laurie Henry
816-559-2421
lhenry@shb.com



Madeleine McDonough
816-559-2342
mmcdonough@shb.com



If you have questions about this issue of the Update, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.

Among other things, Taylor notes that the industry draft would (i) require Congress to “declare a wide range of potentially harmful chemicals ‘safe’ for use in cosmetics without a credible scientific basis, shifting the burden to FDA to prove them unsafe through a lengthy rulemaking”; (ii) require FDA to determine other cosmetic ingredients “safe” “even if we knew that they posed real and substantial risks to consumers”; (iii) “eliminate FDA’s ability to verify that cosmetic companies have substantiated the safety of their products”; (iv) “undercut FDA’s ability to enforce quality control rules for the safe manufacturing of cosmetics”; and (v) eliminate states’ ability to oversee any aspect of the safety of cosmetics. “Because your proposal meets none of the safety goals on which we had all agreed last year, I have difficulty seeing a path forward in this process,” he concludes.

Agreeing with FDA, advocacy organization the Environmental Working Group argued that the industry’s proposal would “deprive” the agency of the power to keep hazardous substances out of personal care products. “We are deeply disappointed that the cosmetics industry has refused to support reasonable reforms which would ensure that ingredients used in cosmetics are safe and to provide FDA with the tools to respond when dangerous ingredients enter the marketplace.”

In response, PCPC President and CEO Lezlee Westine said that FDA misrepresented the industry proposal and the council “strongly disagrees” with the agency’s allegation that the proposed legislation would weaken FDA regulatory oversight of cosmetics. “We urge the Agency to return to the table so we can continue to work together to build consensus that is necessary to these discussions.”

OEHHA to Add Artificial Fingernail Chemical to Prop. 65 List

California EPA’s Office of Environmental Health Hazard Assessment (OEHHA) has issued a notice of intent to list *N,N*,-Dimethyl-*p*-Toluidine as known to the state to cause cancer under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65). Citing the National Toxicology Program as one of several institutions that have identified the substance, used as an accelerator in the curing of methyl methacrylate monomers in artificial fingernail preparations, as a cause of “increased incidences of malignant and combined malignant and benign tumors in male and female rats and male and female mice,” OEHHA requests comments as to whether the chemical meets the criteria set forth in the Prop. 65 regulations for authoritative bodies’ listings. They must be submitted by April 14, 2014. Manufacturers that sell products containing listed chemicals in the state must provide exposure warnings to consumers. *See OEHHA News Release*, March 14, 2014.

Eighth Circuit Rules on Lovely Skin Trademark Dispute

The Eighth Circuit Court of Appeals has determined that while Lovely Skin, Inc.'s two trademarks—LOVELYSKIN and LOVELYSKIN.COM—should not have been canceled for an alleged failure to acquire distinctiveness through substantially exclusive use for the five years preceding their registration, the company did not demonstrate a likelihood of confusion between its trademarks and those of online cosmeceutical competitor [livelyskin.com](#). [Lovely Skin, Inc. v. Ishtar Skin Care Products, LLC, No. 12-3631 \(8th Cir., decided March 13, 2014\)](#). Thus, the court reversed a lower court's ruling canceling the registrations and affirmed its ruling entering judgment in the defendant's favor in this trademark-infringement lawsuit.

According to the court, the defendant did not introduce sufficient evidence to overcome the strong presumption of validity of Lovely Skin's trademark registration and establish a prima facie case of invalidity. The defendant introduced evidence of third-party registrations—LOVE YOUR SKIN, registered to a dermatologist; Lovely Skin, Inc., registered to an aesthetician; and Lovely Nails & Skin Care—to show that Lovely Skin's trademarks had not acquired distinctiveness when they were registered. The court found, however, that the defendant failed to "present any evidence regarding how these third parties had used the marks, if at all, in the five years before Lovely Skin's trademarks were registered. Nor did it offer evidence of how, or even if, the third parties promoted or advertised these marks during those years or whether the public recognized these third party marks."

As to Lovely Skin's claims of trademark infringement, the court agreed with the lower court that its "descriptive" marks "were both conceptually and commercially weak," the defendant's competing marks were not identical, evidence of actual confusion was scarce, and both parties "operate in a niche market selling expensive products." Because Lovely Skin's products sell for an average of \$185 and some are as costly as \$400, the likelihood of confusion is reduced "because consumers will exercise a high degree of care when making their purchases." The court also noted that Lovely Skin's marks had not attained a strong secondary meaning because most of the company's marketing displays the marks of the third-party products it sells, primarily online, rather than its own trademarks. Accordingly, the court determined that the probability of confusion was low.

Arthritis Supplement Maker Settles False Marketing Claims

Schiff Nutrition International, Inc. will pay at least \$5 million to settle a putative class action alleging that the company falsely marketed its glucosamine and chondroitin dietary supplements as an arthritis treatment. *Lerma v. Schiff*

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Nutrition Int'l, Inc., No. 11-1056 (U.S. Dist. Ct., S.D. Cal., motion for preliminary approval filed March 25, 2014). The proposed settlement, if finalized, will resolve similar claims filed in other jurisdictions and centralized before the California court. The core issue in all of the lawsuits is the veracity of the joint-health benefit representations made about the company's products.

Without admitting any liability, the company would remove certain labeling claims—"repair joints," "repair cartilage," "rebuild joints," "rebuild cartilage," "rejuvenate joints," or "rejuvenate cartilage"—from product labels for 24 months. It may resume making the claims if it possesses and relies on "an independent, well-conducted, published clinical trial that substantiates the representations." Three named plaintiffs would receive \$10,000 each, and plaintiffs' counsel would be paid \$3 million in fees and expenses under the proposed agreement. A settlement fund of at least \$2 million would be established for class members with and without proof of purchase; they would be entitled to receive varying amounts under the fund. According to a news source, the company's supplements exceeded \$100 million in sales in 2010. See *Law360*, March 26, 2014.

Tom's Toothpaste Allegedly Not Natural

Seeking to represent a nationwide class of product purchasers, a Florida resident has filed consumer-fraud claims against Tom's of Maine, Inc., alleging that the company's toothpaste is falsely marketed, advertised and labeled as "natural" because it contains "heavily chemically processed" ingredients, "including xylitol and sodium lauryl sulfate." *Gay v. Tom's of Maine, Inc.*, No. 14-60604 (U.S. Dist. Ct., S.D. Fla., filed March 7, 2014).

The plaintiff claims that she relied on the product representations to her economic detriment and that reasonable consumers "do not have the specialized knowledge necessary to identify the ingredients in the Products as being inconsistent with the Natural Claims." She cites National Advertising Division and U.S. Department of Agriculture definitions of "natural" to support her claims; they focus on the extent of processing an ingredient undergoes as a factor in determining whether a substance is synthetic or natural. According to the complaint, the company's Website discusses these specific ingredients and claims that they are derived from natural sources.

Alleging a single count—violation of the Florida Deceptive and Unfair Trade Practices Act—the plaintiff seeks restitution and disgorgement; compensatory and other damages; actual and statutory damages; injunctive relief, including corrective advertising; attorney's fees; costs; and interest.

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Vitamin Shoppe Efficacy Claims Challenged

A Florida resident has filed a putative nationwide class action against the Vitamin Shoppe, Inc., alleging that the company makes efficacy claims for its dietary supplements, "sold in the growing and extremely competitive fitness industry as highly digestible protein products," which purportedly contain insufficient quantities of a digestive enzyme to deliver the promised benefits. *Mermida v. Vitamin Shoppe, Inc.*, No. 14-0172 (U.S. Dist. Ct., M.D. Fla., Fort Myers Div., filed March 27, 2014). The plaintiff also alleges that the company "falsely claims that lactase helps aid in the absorption and digestion of protein."

Claiming that he relied on the allegedly deceptive product representations and sustained economic damages because the products do not provide the claimed benefits, the plaintiff alleges breach of express warranty, fraud by uniform written misrepresentation and omission, violation of the Florida Deceptive and Unfair Trade Practices Act (on behalf of a Florida subclass), unjust enrichment, and injunctive relief. He seeks actual, consequential, compensatory, and exemplary damages; restitution and disgorgement; injunctive relief; attorney's fees; costs; and interest.

Securities Fraud Claims Proliferate Against Nu Skin

The State-Boston Retirement System has become the latest shareholder to file a putative class action alleging that Nu Skin Enterprises and its CEO and CFO violated U.S. securities laws with optimistic statements about opportunities and growing markets in the People's Republic of China (PRC) when its "operations in China are nothing more than a pyramid scheme based on multi-level marketing where such schemes are strictly prohibited in China." *State-Boston Retirement Sys. v. Nu Skin Enters., Inc.*, No. 14-0217 (U.S. Dist. Ct., D. Utah, Cent. Div., filed March 24, 2014).

After the Chinese press reported in January 2014 that the company's practices were unlawful and immoral in violation of that country's laws, the company's stock allegedly declined more than 25 percent, and a number of putative class actions against the company started appearing on the Utah federal district court's docket. According to the complaint, an August 2012 analyst report concluded that the company's China operations were based on multi-level marketing or pyramid selling schemes that "grossly violat[ed] the laws of the PRC." Yet, the company allegedly filed a Form 8-K with the Securities and Exchange Commission that month claiming confidence that its "China operations are in compliance with applicable regulations as interpreted and enforced by the government of China."

Alleging violations of Section 10(b) and Rule 10b-r5, as well as Section 20(a) of the Exchange Act, the plaintiff seeks unspecified damages, attorney's fees, costs, and interest.

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EMERGING TRENDS**Allegedly Dangerous Hair Straighteners Still Sold in USA**

New research from the national nonprofit group Women's Voices for the Earth (WVE) has reportedly revealed that, despite the Cosmetic Ingredient Review Expert Panel's (CIR's) 2011 determination that formaldehyde is unsafe for use in hair-straightening products, 33 such products containing high levels of the allegedly cancer-causing chemical remain on the U.S. market. The advocacy group claims that no formaldehyde-containing hair-straightening products have ever been removed from the U.S. market as a result of CIR's announcement and notes that many other governments prohibit the use of such products.

"Based on sound science, other countries are taking strong measures to protect the health of salon workers and their customers from formaldehyde-containing products," said WVE spokesperson Alex Scranton. "U.S. government regulations continue to fall short, [and] consumers deserve to know what's in their products in order to make safer decisions about their hair care." See *WVE News Release*, March 13, 2014.

Body Shop's Cruelty-Free Claims Questioned

The L'Oréal-owned beauty company, The Body Shop, known for manufacturing cruelty-free products, has reportedly removed all of its products from duty-free stores in Chinese airports after learning that the products were at risk of random testing on animals by the country's authorities. Although airport-sold products are exempt from China's mandatory animal-testing regulations, they are apparently subject to random spot tests by Chinese authorities.

"It's a standard part of the Chinese cosmetic regulation process," said CEO Alan Kirkland of the Australian watchdog group Choice, which led the investigation into the products' sale. "Chinese officials have said [] there is no way that a product sold in airports could be guaranteed to be exempt from that. There is no way they can guarantee those products are not tested on animals."

A Body Shop Australia spokesperson reportedly said that all products have been removed from airport stores while the company works with Chinese authorities to determine the full nature of the post-market testing. "We still maintain that we're very much committed to our cruelty-free values," the spokesperson said. "We're working very closely with Chinese authorities to get to the bottom of what's happening ... [and] we will not waiver on our cruelty-free commitment. If it comes about that there's any reason to be concerned, we will absolutely stay out of the [Chinese] market." See *TheGuardian.com*, March 11, 2014; *The Body Shop News Release*, March 12, 2014.

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Meanwhile, Tarte Cosmetics, a beauty company that has traditionally marketed itself as an environmentally conscious cosmetics company that does not test products on animals, has come under scrutiny following its recent acquisition by Kosè Corp., a Japanese cosmetics company. Like many Asian countries, Japanese regulations require animal testing on cosmetic products, and, according to news sources, although Tarte CEO and Founder Maureen Kelly has stated that Tarte will remain a cruelty-free company and will never test products on animals, many Tarte customers are upset about the acquisition and have stated that they will no longer purchase the company's products. *See LogicalHarmony.net*, March 18, 2014.

INTERNATIONAL DEVELOPMENTS

Amazon China Closes Vendor over Fake Cosmetics Report

The China unit of Amazon.com Inc. has reportedly closed a third-party vendor following state media reports that it was selling counterfeit cosmetics, some of which were purportedly sourced from local grey-market wholesalers. With online shopping reportedly the preferred shopping method among Chinese consumers, increasing concerns about fake cosmetics have prompted policy makers to examine current regulatory and supervisory practices policing the industry.

According to a news source, regulations that specifically address online cosmetics sales channels are "poorly represented" in China's overall cosmetics regulatory framework despite the country's consumer base of nearly 300 million Internet shoppers. Amazon China says that it plans to increase scrutiny on such retailers, particularly beauty and personal care product distributors. *See ChemLinked.com* and *ZDNet.com*, March 21, 2014.

EU Adopts New ABS Biodiversity Rules

The European Parliament has [adopted](#) new rules on access to genetic resources and the fair and equitable sharing of benefits resulting from their use (known as ABS) in the European Union (EU). The Parliament has also granted its consent for the EU to be legally bound by the Nagoya Protocol on ABS, an international agreement under the Convention on Biological Diversity.

Expected to become effective in October 2014, the new regulations will establish due diligence obligations applicable to research and development conducted on genetic resources, and require biodiversity-based research and development companies from sectors, such as cosmetics, food and beverage, biotechnology, and pharmaceuticals to seek, keep and transfer certain information, including date and place of access, source and subsequent users, and compliance with ABS requirements. Further details about genetic

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resource governing appear in Issue [430](#) of Shook, Hardy & Bacon's *Environmental & Chemical Update*. See *EthicalBiotrade.org*, March 12, 2014.

Nu Skin Fined \$540,000 by Chinese Regulators

China's State Administration for Industry and Commerce (SAIC) has fined U.S. direct sale skincare and dietary supplement company Nu Skin Enterprises \$540,000 for allegedly conducting illegal sales and making unsubstantiated product claims. The action follows a months-long investigation into the firm's business practices apparently triggered by a report in the state-run *People's Daily* newspaper, claiming that Nu Skin operated a "suspected illegal pyramid scheme" and "brainwashed" staff. According to a company news release, Nu Skin is "taking steps" to correct the issues raised in the SAIC reviews and "working diligently" to enhance sales representative training and supervision. The company also added that it would "seek direction from the government" before restarting normal business activities in China. Information about a securities-fraud claim recently filed against Nu Skin Enterprises, appear elsewhere in this *Report*. See *Nu Skin News Release* and *Reuters.com*, March 24, 2014.

Illegal Skin-Whitening Products for Sale in Belgium

A recent study conducted by Belgian Institute of Public Health scientists has reportedly revealed that nearly 60 percent of skin-whitening products available in shops and drugstores in Belgium contain one or more illegal ingredients. Using a new analysis method that can apparently better detect components present in suspect cosmetics, scientists examined 163 skin-whitening products and observed that two out of three products contained at least one illegal substance. The most commonly found ingredients were corticosteroids—chemical variants of a natural hormone that inhibits bodily reactions occurring in cases of inflammation or infection, and hydroquinone—a chemical purported to have carcinogenic and mutagenic effects. See *ChemicalWatch.com*, March 14, 2014.

South Africa to Commence Cosmetics Industry Regulation

According to a news source, South African lawmakers intend to start regulating the country's cosmetics industry, which, for the past 20 years, has apparently been self-regulated with assistance from the Cosmetic, Toiletry & Fragrance Association (CTFA) of South Africa. With a goal "to support and develop a sustainable and respected South African Cosmetic Industry by proactively stimulating actions and developing tools that contribute to its growth and the progress of its Members as well as promot[e] consumer safety," CFTA has reportedly served as the industry's main voice, guiding members on the self-regulatory codes of practice and standards. Sinah Mosehla, South African Department of Trade & Industry director of cosmetics is scheduled to present an overview of the country's current and future regulatory landscape at the upcoming Global Cosmetic Compliance summit slated for May 27-29, 2014, in Amsterdam. See *Cosmeticweb.com.za*.

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SCIENTIFIC/TECHNICAL DEVELOPMENTS

Elsevier Launches New Nanotechnology Journal

Dutch publishing company Elsevier B.V., has announced the launch of *Colloid and Interface Science Communications*, an open access journal that the company says will provide “convenient and time-saving” information on novel findings in the “increasingly interdisciplinary area” of colloid and interface science. Intended for professionals in nanotechnology-related industries, topics covered in the journal will include nanomaterials; biotechnologies; nanomedicine; environmental sustainability; food; personal care products; and cosmetic products. The first volume is scheduled for publication in June 2014. See *Elsevier News Release*, March 10, 2014.

Sustainable Cosmetics Summit to Focus on Improving Social Footprint of Personal Care Products

Industry leaders will **convene** May 15-17, 2014, in New York City, to discuss key sustainability issues affecting the personal care products industry at the fifth annual North American edition of the Sustainable Cosmetics Summit. Organized by Organic Monitor, the conference aims to “encourage sustainability in the beauty industry by bringing together key stake-holders [to] debate major issues in a high-level forum.” With a focus on novel green ingredients, marketing developments and consumer behavior, conference sessions will also cover topics such as biomimetics in cosmetics, mobile apps, ingredients authenticity, sustainability standards, marketing regulations, packaging waste, eco-design approach, and sustainability metrics.

OFFICE LOCATIONS

- Geneva, Switzerland**
+41-22-787-2000
- Houston, Texas**
+1-713-227-8008
- Irvine, California**
+1-949-475-1500
- Kansas City, Missouri**
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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. The firm helps 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.

SHB is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most significant national and international product liability and mass tort litigations. The firm’s clients include large multinational companies in the tobacco, pharmaceutical, medical device, automotive, chemical, food and beverage, cosmetics, oil and gas, telecommunications, agricultural, and retail industries.

