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LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

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INSIDE GOVERNMENT

FDA Says It Is Ready for Nanotechnology

The Food and Drug Administration (FDA) has reported that after conducting various exercises to evaluate its nanomaterial standards, the agency is "fully capable" of regulating cosmetics, medical tools, food and other products that take advantage of nanotechnology. In a recent *FDAVoice* blog, Celia Cruz, senior reviewer of chemistry, manufacturing and controls at FDA's Center for Drug Evaluation and Research, wrote about the agency's approach to managing nanotechnology's risks and the agency's plans to ensure the industry is onboard. "Our risk management exercise determined that our current regulatory review processes indeed can adequately protect the public from potential risks associated with the use of nanotechnology in drug products," she said.

Cruz also identified areas that "could benefit from improvement," such as increasing nanotechnology regulatory science research and providing up-to-date staff training. She noted as well that the administration "does not make a categorical judgment that nanotechnology is intrinsically safe or harmful. Rather, for nanotechnology-derived and conventionally manufactured products alike, FDA considers the characteristics of the finished product and, as applicable, its safety, effectiveness or other product attributes."

A workshop to bring together FDA officials, industry leaders and researchers to brainstorm best practices for the future is scheduled for January 14-15, 2014. *See TheHill.com,* October 24, 2013.

LITIGATION AND REGULATORY ENFORCEMENT

TV Pitchman Freed from Jail, Could Face Perjury Charges

TV pitchman Kevin Trudeau, who has twice been sued by the Federal Trade Commission (FTC) for making unsubstantiated claims about his weight loss book and other products, including a purported cancer cure, has reportedly

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gained his freedom from jail, for a second time, by swearing that he has provided a receiver with information about all of his assets. A federal court found Trudeau in contempt for failing to disclose assets and not cooperating with the receiver, appointed to collect a $37.6-million judgment against him for violating an FTC injunction by continuing to make false claims in infomercials for his book. The government contends that Trudeau has assets hidden in offshore accounts and sham companies, while he claims that he has nothing more to disclose. *FTC v. Trudeau*, No. 03-3904 (U.S. Dist. Ct., N.D. Ill.).

Still, Trudeau has recently written to a number of individuals urging them to provide information to the receiver or, in correspondence with his estranged wife, urging her to sell assets such as cufflinks, gold bars and gold coins. He also requested that she seek the return of $300,000 sent to her mother to pay the mortgage on a Kiev apartment. FTC asked the court to ignore these efforts to purge the contempt, claiming they are irrelevant to whether Trudeau himself knows about his assets. The agency also argued that responses from his associates and banks, claiming that no assets or accounts exist, conflict with evidence to the contrary. The court reportedly warned Trudeau that he could face perjury charges if "there are any other assets that are discovered or turned up . . . or that I find you control."

The court was apparently reluctant to keep Trudeau in jail because his trial on criminal contempt charges related to the allegedly fraudulent infomercials begins the first week of November and he will need time to prepare with his attorneys. *See abclocal.go.com*, October 21, 2013; *Law360*, October 22, 2013; *Chicago Tribune*, October 28, 2013.

Estée Lauder Subsidiary Wins Trademark-Infringement Lawsuit

BeautyBank, Inc., an Estée Lauder subsidiary, has reportedly prevailed in litigation alleging that defendants selling EAU FLIRT perfume, which they claimed was clinically proven to make "men flirt with women," infringed its FLIRT-branded cosmetics trademark and constituted false advertising and unfair competition under New York and federal law. *BeautyBank Inc. v. Ramani*, No. 10-0955 (U.S. Dist. Ct., S.D.N.Y., jury verdict rendered October 24, 2013). A jury awarded the plaintiff more than $3.6 million including punitive damages of $1.1 million from each defendant, after finding willful and bad faith trademark infringement and false advertising. Post-trial motions must be filed by November 14, 2013, and any oppositions are due January 8, 2014. *See Law360*, October 24, 2013.

Nutraceutical Company Wins $3.3 Million from Protein Powder Supplier

A federal jury in Florida has reportedly awarded California-based nutraceutical company Natrol, Inc. nearly $3.3 million for breach of contract and warranty, finding that Nature's Products Inc. (NPI) of Sunrise, Florida, supplied

Natrol with protein powder products, labeled and advertised as gluten- and wheat-free, leading to a Food and Drug Administration recall order because the products contained gluten and wheat, potential allergens for some consumers. *Nature's Prods. Inc. v. Natrol, Inc.*, No. 11-62409 (U.S. Dist. Ct., S.D. Fla., jury verdict rendered October 24, 2013). While Natrol will have to pay the supplier some $750,000 in unpaid invoices, its counsel stated that the nutraceutical company would seek attorney's fees and the costs of litigation under the contract.

The recalled products, a dozen varieties of protein powder supplements, were manufactured by NPI and sold to Natrol from June 2010 through September 2011. According to Natrol's counsel, "The jury got it right. NPI refused to honor its pre-manufacturing indemnification agreement with Natrol and then sued Natrol for invoices, requiring Natrol's counterclaim for the full amount of the damages NPI caused Natrol to incur." *See Sacher, Zelman Press Release*, October 25, 2013; *South Florida Business Journal*, October 26, 2013.

FDA Seeks Injunction Against Dietary Supplement Maker

The U.S. Food and Drug Administration (FDA) has brought an action for a permanent injunction against a Hood River, Oregon-based dietary supplement maker, "following the company's repeated distribution of unapproved drugs and adulterated dietary supplements in violation of the Federal Food, Drug, and Cosmetic Act." Filed by the Department of Justice, the complaint names manufacturer James G. Cole, Inc., President James Cole and General Manager Julie Graves as defendants.

According to an FDA spokesperson, "This company has ignored the multiple warnings they have been issued by the FDA by continuing to make unsubstantiated drug claims about products it sells and by failing to conform to the cGMP [current good manufacturing practice] requirements for dietary supplements. We are taking this action to protect the public health." The alleged cGMP violations, stemming from 2012 and 2013 inspections, involve failures to (i) establish a master manufacturing record or component specifications, (ii) conduct ingredient identity tests, (iii) identify personnel responsible for quality-control operations, (iv) prepare batch production records, and (v) collect and hold reserve samples of each dietary supplement lot.

The products at issue are marketed online, "with some sites linking to the company's Facebook page," according to FDA. The company allegedly claims that its dietary supplements treat cancer, heart disease, rheumatoid arthritis, autism, Alzheimer's, fibromyalgia, and high cholesterol. Products offered for these uses are considered under federal law to be drugs, and the defendants' products, including PCA, PCA-Rx, C-60, ACAI Resveratrol, Cytomune, Anavone, Liver Rescue, Probiotics, and others marketed under the brand names Maxam Labs, Advanced Sports Nutrition and Maxam Nutraceutics, have not been

approved by FDA for these uses. *See FDA Warning Letter,* September 28, 2012; *FDA News Release*, October 21, 2013.

FTC Charges Diet Supplement Maker with False Advertising

The Federal Trade Commission (FTC) has filed an action for injunctive relief, restitution and disgorgement against companies and individuals involved in the production, sale and marketing of "homeopathic human chorionic gonadatropin ('hCG') and other purported weight-loss products, including, but not limited to, multiple formulations under the brand name 'HCG Platinum.'" *FTC v. Wright*, No. 13-2215 (U.S. Dist. Ct., D. Ariz., filed October 30, 2013). According to the complaint, the "HCG Platinum weight-loss program consists of ingesting HCG Platinum drops sublingually before meals and following a very low calorie diet, between 500 and 800 calories per day. Corporate defendants' advertisements claim their program is safe."

FTC alleges that a joint FTC/Food and Drug Administration November 2011 warning letter advised the defendants that these products were not considered homeopathic drug products under the Food, Drug, and Cosmetic Act, were unapproved new drugs and were misbranded. The letter also indicated that the claims were unlawful under the FTC Act "unless Defendants possessed competent and reliable evidence, including, where appropriate, well-controlled human clinical studies, substantiating that the claims were true at the time they were made." HCG is apparently not an established homeopathic active ingredient. As to product advertising, FTC specifically alleges that ads "appeared in magazines, in retail stores, training manuals, and on the Internet" at a number of sites, including YouTube and Facebook. "Other advertisements were disseminated through the use of Internet pop-ups, as well as on product packaging and in 'success guides' that accompanied Defendants' products."

According to the complaint, the products sold for between $60 and $149 for a month's supply, and sales have exceeded $13 million since 2010. Product labels included in the complaint show that the defendants claimed that the products, either homeopathic drug formulas or dietary supplements, contain ingredients "known to promote: Fat Burning, Muscle Growth, Blood Flow, Appetite Control, [and] Higher Energy." Alleging false or unsubstantiated claims, FTC seeks permanent injunctive relief to prevent future violations of the FTC Act, as well as rescission or reformation of contracts, restitution, the refund of monies paid, disgorgement, and costs.

EMERGING TRENDS

Garnier Wins Sustainable Beauty Award

Garnier USA has received the first-ever Sustainability Pioneer Award presented by Organic Monitor, a research and consulting firm that focuses on global organic and related product industries. Presented at the 5th Edition of the Sustainable Cosmetics Summit in Paris on October 21, 2013, the award was created to "recognize exceptional brands making international sustainability strides in five categories, including green formulations, sustainable packaging, sustainable ingredients, sustainability pioneer, and sustainability leadership." Garnier won for its leadership in the areas of packaging, waste management, energy management, and corporate social responsibility and philanthropy, which it accomplishes through a partnership with TerraCycle®, a company that specializes in post-consumer waste recycling.

Through what is called the Personal Care and Beauty Brigade®, individuals and groups are encouraged to recycle hair care, skin care and cosmetic packaging waste by sending it to TerraCycle® for free. For every piece of waste received, Garnier contributes 2 cents to the school or charity of the sender's choice. In addition to diverting packaging from landfills, the Personal Care and Beauty Brigade® program recycles some of the beauty waste into plastic lumber that is used to build raised garden beds, picnic tables and trash receptacles.

"This is a long term commitment to sustainability for the L'Oréal Group and Garnier," said President of Maybelline New York-Garnier-essie David Greenberg. "We have currently collected over 2.7+ million pieces of beauty waste with more than 12,000 Beauty Brigades established domestically and internationally." *See PRNewswire,* October 25, 2013.

One Million People Call for Global Ban on Animal Testing for Cosmetics

Animal rights group Cruelty Free International and The Body Shop International cosmetics company have presented a petition with more than one million signatures, resulting from a two-year global campaign to the Association of South East Asian Nations (ASEAN) in support of the groups' efforts to end global animal testing for cosmetics.

ASEAN, which consists of 10 Southeast Asian nations including Malaysia, Indonesia and Thailand, is responsible for regulating animal testing in cosmetics in countries in the region. As in many countries, including the United States, ASEAN countries lack regulations or laws that prohibit animal testing of cosmetic products and ingredients. The European Union banned animal-tested cosmetics in March 2013, and India removed animal testing from its cosmetic standard in July. Cruelty Free International hopes that such actions

will make an economic case for companies around the world to change their business models and switch to modern non-animal testing methods. The group said that it will continue to campaign for a global ban as more than 80 percent of the world still allows animal testing. *See Cruelty Free International News Release,* October 25, 2013; *beautypackaging.com,* October 28, 2013.

Purportedly Toxic Chemicals Found in Revlon Cosmetics

A recent survey by the Breast Cancer Fund and the Campaign for Safe Cosmetics has reportedly revealed that many of the beauty products sold by cosmetics giant Revlon contain cancer-causing and hormone-disrupting chemicals. The two groups have teamed with the online women's group Ultra-Violet to demand that the company stop using these and other substances in its products.

According to the survey, Revlon products from hair dyes and mascara to lip gloss and eyeliners contain toxic chemicals, including butylated compounds (BHA or BHT), an antioxidant and preservative that is banned in cosmetics in the European Union. Other chemicals found in the tested products include (i) Quaternium-15 and other formaldehyde-releasing chemicals—found in mascaras, pressed powders and eyeliner—purportedly linked to cancer; (ii) parabens—found in eyeliners and hair dyes—a putative endocrine disruptor linked to cancer; (iii) Octinoxate—found in foundation makeup—a putative endocrine disruptor linked to thyroid disorders; (iv) Resorcinol—found in hair dye—an alleged endocrine disruptor and allergen; (v) p-Phenylenediamine—found in hair dye—a purported respiratory toxicant; and (vi) Carbon black—found in eyeliners—allegedly linked to cancer.

The advocacy groups plan to launch a full campaign against Revlon and have demanded that the company (i) develop a comprehensive "safe cosmetics policy" to protect women from chemicals linked to cancer and other adverse health effects; (ii) support federal cosmetics safety legislation; and (iii) share the Revlon product safety policy publicly on the company's Website. *See Campaign for Safe Cosmetics News Release,* October 24, 2013; *Natural News.com,* October 30, 2013.

INTERNATIONAL DEVELOPMENTS

French Food Safety Agency Seeks Comments About Red Yeast Rice

The French food safety agency ANSES has issued a notice inviting comments about the safety of red yeast rice, an ingredient commonly used in food supplements to help maintain normal cholesterol levels. Citing 25 reports of adverse reactions (mostly muscle and liver damage) "likely to be linked

to consumption of this [] food supplement," ANSES warned that use of food supplements containing the ingredient may expose consumers—particularly those who are vulnerable due to genetic predispositions, pathologies and ongoing treatments—to health risks. The agency also emphasized that products containing red yeast "must not be used by patients taking statin-based medications, nor by those who had to stop taking statin-based medications due to adverse reactions ('statin-intolerant' patients)." Vulnerable individuals (pregnant or breastfeeding women, children and adolescents, people older than age 70, or people who consume large amounts of grapefruit), should also avoid taking these supplements, ANSES warned. Comments will be accepted until December 15, 2013.

Skin-Whitening Creams in Philippines Test Positive for Mercury

The environmental group EcoWaste Coalition has issued a warning that some skin-whitening creams purchased in Chinese drug stores in the Philippines contain high levels of mercury. According to product tests recently conducted by the group, 12 skin-whitening creams contained mercury up to 45,100 parts per million (ppm)—far above the 1 ppm regulatory limit for mercury under the Association of South East Asian Nations (ASEAN) Cosmetics Directive.

Calling the mercury-laden products "truly scary," EcoWaste Coalition's National Coordinator Aileen Lucero said that instead of the promised lighter and flawless skin, the products may discolor and scar skin, cause rashes and weaken dermal resistance to bacterial and fungal infections. "Mercury can also harm the kidneys and the nervous system and obstruct healthy brain development in fetuses and children," she added. EcoWaste recommends that consumers read product labels carefully and seek registered mercury-free products. The group also suggests that purchasers ask for official product receipts in case they want to file a complaint. *See EcoWaste Coalition News Release,* October 29, 2013.

China Streamlines Cosmetics Production Licensing

The China Food and Drug Administration (CFDA) has issued a **notice** outlining new licensing measures to regulate cosmetics production in light of a recent institutional restructuring that has placed nationwide surveillance, registration and production of cosmetics within the agency's ambit. The move is reportedly considered a major step in consolidating cosmetic regulatory power solely into CFDA's hands. Under the previous regulatory regime, cosmetic production was controlled by both CFDA and the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), which required Chinese cosmetic manufacturers to obtain a cosmetics production license from AQSIQ as well as a hygiene license from provincial FDAs. These overlapping regulatory requirements placed a burden on cosmetic manufacturers and hampered regulatory efficiency and industry innovation.

AQSIQ will apparently no longer be involved in supervising cosmetics manufacturing and will focus instead on cosmetics import and export. In addition, toothpaste will now be considered a cosmetic, and manufacturers of the product will need to acquire a license. Licenses obtained under the old regime will evidently remain valid until a deadline yet to be set by CFDA. *See ChemLinked.com,* October 16, 2013.

State Body Opposes India Drugs and Cosmetics Bill, 2013

According to news sources, the All India Drug Control Officers' Confederation (AIDCOC) has raised objections to proposed amendments to India's Drug and Cosmetics (Amendment) Bill, 2013, which seeks to create a Central Drug Agency (CDA) to regulate the import, export, manufacture, and distribution of drugs and cosmetics in that country. Evidently at issue is concern from state drug control associations, drug manufacturers and consumers that the amended legislation will limit the power of state authorities by moving the licensing of 17 product categories to central government.

Noting that such a move would create "absolute power in one hand," AIDCOC Secretary General Ravi Uday Bhaskar reportedly stated that "if manufacturing activity is controlled by one agency and the sale and distribution is regulated by another, it [will] create[] problems of jurisdiction, investigation, enforcement and co-ordination between State and Central governments." The amended bill was presented to the Indian parliament in August 2013, and the process of examining new amendments began during the second week of October. A full report will reportedly be available in November. *See Cosmeticsdesign-Asia,* October 29, 2013; *Metro India,* October 30, 2013.

Increasing Concern Surrounding Connection Between Weight-Loss Supplements and Liver Failure

Following the recent U.S. Food and Drug Administration (FDA) investigation into the dietary supplement OxyELITE Pro, allegedly linked to 41 cases of liver injury in the United States, Food Standards Australia New Zealand (FSANZ) has issued an alert to consumers not to use the products and has asked health authorities to be on the lookout for acute cases of non-viral hepatitis in both countries. More information about the FDA investigation into OxyELITE Pro may be found in Issue 6 of this *Report*.

OxyELITE Pro supplements are manufactured by USPLabs LLC of Dallas, Texas, and generally sold in Australia and New Zealand through the Internet and sports supplement stores. The products contain aegeline—a new ingredient purported to be in violation of U.S. federal law, which requires companies to report new dietary ingredients and evidence of their safety to FDA. While neither government has issued a product recall, FSANZ Chief Executive Officer

Steve McCutcheon warned consumers to exercise caution when using the dietary supplements and to do so under medical supervision. "People also need to be particularly careful about purchasing products online. Online products can have unsafe ingredients and consumers can't be certain they are getting legitimate products," he said.

Meanwhile, U.S. Sen. Dick Durbin (D-Ill.) has called on USPLabs to provide proof that it has complied with federal law. In a letter to USPLabs CEO Jacob Geissler, Durbin stated his concerns about the "mounting evidence that products manufactured by USPLabs endanger consumer health and contain adulterated ingredients." He also noted that the recent cases of adverse events—including liver injury and death—surrounding USPLabs products raise serious questions about the company's practices and commitment to consumer safety. USPLabs has reportedly voluntarily ceased domestic distribution of OxyElite Pro while FDA investigates, but maintains that the product is safe. *See ONE News,* October 23, 2013; *Sen. Dick Durbin News Release,* October 29, 2013.

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