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LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

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INSIDE GOVERNMENT

FDA Updates Guidance on NDIs in Dietary Supplements

The U.S. Food and Drug Administration (FDA) has published guidance titled "Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues" that aims to clarify when premarket safety notifications for dietary supplements containing new dietary ingredients (NDI) are necessary and how to prepare premarket safety notifications (NDI notifications). Arranged in a question-and-answer format, the guidance covers the following topics: (i) what qualifies as an NDI; (ii) when an NDI notification is necessary; (iii) the procedures for submitting an NDI notification; (iv) the types of data and information that FDA recommends manufacturers and distributors consider when evaluating the safety of a dietary supplement containing an NDI; and (v) what should be included in an NDI notification. It also clarifies the definition of a dietary supplement, which affects whether a particular substance may be marketed as a dietary ingredient in a supplement.

Industry Groups Issue Guide for Organic Labeling

The American Herbal Products Association (AHPA) has released a guide to help supplement manufacturers better understand how to comply with organic labeling requirements.

Produced with Quality Assurance International (QAI), an organic and gluten-free certifying agency, "*Guidance on Formulation and Marketing of Organic Dietary Supplements Under the National Organic Program (NOP),* provides an overview of organic labeling categories and discusses manufacturing rules. It also discusses the organic certification process, common organic certification issues, production methods for allowed ingredients, and technical additives and processing aids.

Depending on the percentage of organic content in a product and the manufacturing methods used, products may bear one of four label designations: "100 percent organic"; "organic"; "made with organic (specific organic

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ingredients)"; or "some organic ingredients." The guidance details the requirements for each labeling option and provides examples of correct labeling for each category. *See AHPA News Release,* September 4, 2013.

PCPC Seeks Comments on Microbiology Guideline

The Personal Care Products Council (PCPC) has announced a public consultation on the revised microbiology guideline "Determination of Preservation Efficacy in Water-Miscible Personal Care Products," intended to help manufacturers, contract packagers and raw material suppliers establish and maintain microbiological quality programs within their companies. According to PCPC, each guideline undergoes extensive review by the council's technical committees and scientific staff, as well as a public review by member and non-member companies, federal government agencies, and scientific professional societies. Comments will be accepted until October 3, 2013. *See PCPC News Release,* September 5, 2013.

LITIGATION AND REGULATORY ENFORCEMENT

Federal Court Agrees to Limited Stay in Hair Product Litigation

A federal court in California has agreed to stay further action involving a certified class of New York purchasers of L'Oréal's allegedly flammable Garnier Fructis Sleek & Shine Anti-Frizz Serum®, but will allow the named representatives of a California class of purchasers to renew their motion for certification while L'Oréal's appeal of the New York certification order is pending. *Altamura v. L'Oréal, USA, Inc., Guido v. L'Oréal, USA, Inc.*, Nos. 11-5465, -1067 (U.S. Dist. Ct., C.D. Cal., order entered August 26, 2013). Additional information about the court's class certification rulings in these consolidated matters appears in Issue 6 of this *Report*.

The court determined that one of the issues raised by L'Oréal's interlocutory appeal of the order certifying the New York class—whether the court erred in applying *Comcast v. Behrend*, 133 S. Ct. 1426 (2013), to a statutory damages provision, which was an unsettled area of law—had a sufficient likelihood of success to justify a stay. The court also found that L'Oréal would be unnecessarily harmed if it were required to issue class-wide notification to members of the New York class, thus damaging its reputation, if the New York class were later decertified on appeal. The company had also argued that "the current two-track format of this action will force it to simultaneously litigate certification for the California class and merits discovery for the New York class." The court agreed that staying the New York proceedings would obviate this concern.

Because the plaintiffs had agreed to stay merits discovery and class notification, the court found that a stay would not harm them and also determined that staying the New York proceedings pending the appeal would be in the public interest because the court would thereby "avoid[] costly and potentially unnecessary litigation if the New York class is eventually decertified." The plaintiffs must file their renewed motion to certify a California class by November 1, 2013, and the court has scheduled a hearing on the motion for February 24, 2014.

Cal/EPA Air Board Settles VOC Emissions Violations with PCP Companies

California EPA's Air Resources Board has reported that since January 2013 it has settled more than two-dozen cases involving companies that manufacture or sell consumer products that exceeded the state's standards for smog-contributing gases, known as volatile organic compounds (VOCs). Among the companies agreeing to pay fines ranging from $3,000 to $15,500 were a number that sell personal care products (PCPs), such as hair styling mousse and spray, temporary hair colors and hair-curling spray products. For example, Continental Fragrances, Ltd. agreed to pay $9,000 to settle claims that its "'Salon Grafix 450 F Maximum Heat Protect Spray' . . . contained concentrations of VOCs exceeding the 6 percent by weight VOC limit. There were approximately 0.68 tons of excess emissions." The board claimed that fines to date have totaled $377,950. *See Cal/EPA Air Resources Board News Release*, September 9, 2013.

EMERGING TRENDS

Brazilian Cosmetics Co. Purchases Carbon Offsets in CSR Initiative

A Brazilian rainforest tribe has reportedly partnered with cosmetics giant Natura Cosméticos in a carbon offset deal that will help the company advance its corporate social responsibility (CSR) goals and the tribe's plan to create a sustainable economy. Natura purchased 120,000 tons of carbon offsets from the Suruí of the Amazon, and the company's director of sustainability said that it is now offsetting 100 percent of its emissions. The money will be used to preserve the rainforest and the indigenous culture. According to a news source, the Suruí project aims to prevent the emission of approximately 5 million tons of carbon that would otherwise be released under current deforestation trends. The credits have been certified under the Verified Carbon Standard, and Climate, Community, and Biodiversity Alliance.

The initiative is apparently the first-ever REDD+ (reduced emissions from deforestation and degradation, plus sustainable forest management) project conceived and developed by indigenous people. Chief Almir Narayamoga Suruí was quoted as saying, "REDD+ is a bridge between the indigenous

world and the non-indigenous world, so it's an appropriate way to begin this process. It creates a vehicle through which the capitalist system can recognize the value of standing forests, and indigenous people can be rewarded for preserving them." The Suruí lost much of their territory to logging, and the Suruí chief approached a U.S. environmental organization for help in reforestation. The tribe's four clans and 25 villages have since imposed and enforced a logging moratorium and will use proceeds from the carbon offset project to blend traditional land-use practices, ecotourism and non-timber forest product harvesting with modern scientific methods and procedures. *See Business Wire* and *mongabay.com*, September 10, 2013.

NPA Challenges *Consumer Reports* Article

The Natural Products Association (NPA) has claimed that *Consumer Reports* made "false, sweeping declarations," in an October 2013 article titled "4 ways to avoid supplement dangers." Calling "negligent" the article's claim that vitamin E "can lead to an increased risk of prostate cancer," and noting that many vitamin E studies show significant health benefits, NPA CEO John Shaw said that it is "irresponsible to pick one study and mislead your readers to believe that vitamin E is harmful."

Consumer Reports apparently warns consumers to be skeptical of claims because "…federal law does not require that dietary supplements be proved safe to the FDA's satisfaction or that supplement companies show that most label claims are accurate. "To say that dietary supplements do not have to be safe or accurately labeled under federal law is entirely untrue," Shaw said. "In actuality, the Federal Food, Drug, and Cosmetic Act does require supplements to be safe and label claims to be accurate, otherwise the product is considered adulterated."

NPA has asked *Consumer Reports* to correct the article immediately. "It's highly unfortunate that a publication dedicated to serving consumers' best interests would run a story that gets the facts wrong on dietary supplements. This article [] is peppered with factual inaccuracies and misleading blanket statements that could scare consumers out of taking products that can benefit their health," Shaw said. *See NPA News Release,* September 6, 2013.

INTERNATIONAL DEVELOPMENTS

Shanghai Quality Bureau Threatens Fines for Cosmetics Packaging

The Shanghai Quality and Technical Supervision Bureau has reportedly found that cosmetics produced by firms such as Olay, L'Oréal and Nivea have too much packaging, due either to the use of too many layers of packaging papers or because the ratio of empty space inside the boxes is too high.

The watchdog group has apparently instructed supermarkets that sell the products to cease doing so or face fines as high as 50,000 yuan (US$8,064). According to a news source, the bureau assessed 105 batches of cosmetics products and determined that 22 of them failed the packaging criteria. *See Shanghai Daily*, September 6, 2013.

Finland Calls for Ban on Fat-Burning Food Supplements

Stating that synephrine is known to cause heart damage and that caffeine "enhances" the effects of synephrine—an ephedrine-like substance found naturally in the peels of citrus fruit—the Finnish Food Safety Authority (EVIRA) has asked for all fat-burning food supplements containing the ingredients to be withdrawn from the market. "Doubts have been voiced about the safety of food supplements containing synephrine and caffeine," said EVIRA. "Based on the risk assessments they have carried out, Denmark and Sweden have declared food supplements containing synephrine and caffeine in a combination to be unsafe to health and they may therefore not be marketed."

British Agency Warns Against Melanotan Tanning Injections

The U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA) has issued a warning about the dangers of unlicensed tanning injections and nasal sprays that contain Melanotan. The agency has reportedly received 18 reports detailing 74 separate reactions, including stomach and heart problems and blood and eye disorders, suspected to be side effects linked to use of the compound. The products—Melanotan I, Melanotan II and Ubertan—are sold in gyms, beauty and tanning salons and through the Internet, and purportedly work by increasing the levels of melanin, the body's natural protection from the sun.

Stating that people "need to be wary," MHRA Senior Policy Advisor Lynda Scammell said, "these tanning products have not been approved for use in the UK and there are no guarantees that they are safe, of an acceptable quality or effective in use. They have the potential to cause serious side-effects." The agency also warned that because the products can be self-injected, they carry the risk of cross-contamination and infection.

Within the last three months, MHRA has shut down 72 Websites that supply Melanotan and reports that it will continue to monitor the situation. A British Association of Dermatologists spokesperson noted that "The very fact that it is illegal for sale in the UK should serve as the strongest warning against injecting a substance into your body for which we don't yet have the full safety data." *See MHRA News Release,* August 29, 2013.

EC Extends Comment Period for Nano Opinions

The European Commission's (EC) Scientific Committee on Consumer Safety (SCCS) has extended until September 18, 2013, the comment period for recently released opinions on nano-forms of the substances titanium dioxide, zinc oxide and MBBT ((2,2'-Methylene-bis-(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol)) to allow applicants and other interested parties "to provide limited additional perspective and/or clarification on the evaluation, interpretation, and incorporation of the submitted specific data package in the SCCS opinion." According to a news source, the comments are expected to be technical and, according to SCCS policy, will not be subject to a revision for at least three years. *See nanotechnia.org,* September 4, 2013.

Indian Parliament Considers Bill to Regulate Drugs and Cosmetics

Officials in India have introduced a bill that would establish a Central Drugs Authority (CDA)— headed by the secretary of health and family welfare—to regulate drugs and cosmetics. The Drugs and Cosmetics (Amendment) Bill, 2013, intended to replace the 1940 Drugs and Cosmetics Act, would also establish a separate chapter on the clinical trials sector that would introduce penal provisions for the payment of compensation, registration and the creation of ethics committees. Under the proposed legislation, CDA would be able to review, suspend or cancel permission or license for drugs and cosmetics manufacturing. *See The Times of India,* August 30, 2013.

SCIENTIFIC/TECHNICAL DEVELOPMENTS

Argan Powder Linked to Occupational Asthma

A small study, presented September 9, 2013, at the European Respiratory Society Annual Congress in Barcelona, has reportedly revealed that argan powder, used to manufacture foundation products, could be linked to occupational asthma. According to news sources, researchers examined nine French cosmetic factory workers who had been exposed to the ingredient in three different forms—crude granules, powder and liquid. The participants completed a medical history questionnaire, and researchers performed lung function and allergy tests as well as an inhalation challenge test, which examines the airway's specific reaction to a substance.

Four workers reportedly displayed asthma or rhinitis symptoms and a blocked nose when handling argan powder. The inhalation challenge test revealed that three out of the four participants with asthma or rhinitis symptoms had occupational asthma triggered by the powder. Half of the participants with asthma-like symptoms tested positive for a skin allergy to argan powder. Noting that the study is "preliminary," lead author Emmanuelle Penven said

that it suggests an association between argan powder and occupational asthma and that initial findings "warrant further research to understand any health risks associated with the compound." *See MedicalDaily.com,* September 9, 2013.

Scientists Develop Stable Silver Nanoparticles

Chemists at the University of Toledo in Ohio and Xiamen University in China have reportedly developed similar methods for creating silver nanoparticles that may be even more stable than their gold counterparts. The findings have been published in the scientific research journals, Nature and Nature Communications, respectively.

Both teams were apparently looking for a way to create silver nanoparticles to use in place of the more expensive gold ones, which are widely used in the cosmetic industry because of their ability to reflect light, act as preservatives and deliver active ingredients deep into the skin. Silver, while more abundant and less expensive than gold, is sensitive to oxidation, which evidently makes it unstable and thus unsuitable for many applications.

To manufacture the nanoparticles, the scientists created a mixture that combined silver atoms with organic molecules that formed an outer protective layer and sulphur atoms that bridged the two. The result was a silver nanoparticle that appears to be as impervious to oxidation as gold nanoparticles, produced at a significantly reduced cost. The scientists reported that key details still need to be addressed, such as whether or not the nanoparticles will be stable in the human body. *nature.com,* September 4, 2013; *BBC News,* September 6, 2013.

Study Implies That Recycled Sewage Water Is Safe for Crop Irrigation

A recent University of California-Riverside study has reportedly revealed that crops grown with recycled sewage are safe to eat. The study, which examined the potential harm caused by pharmaceuticals and personal care products (PPCPs) left in recycled sewage, showed that even in foods eaten raw, such as carrots, tomatoes, spinach, and bell peppers, the levels of PPCPs were "quite low" and most likely "do not pose any health concern." The chemicals tested included the anti-bacterial triclosan, caffeine, an anticonvulsant, and a tranquilizer. Recent drought and water shortages, which have led to increased use of recycled sewage water to irrigate food crops, have apparently raised concerns about the health and environmental effects of residual PPCPs.

Acknowledging that more studies are needed to gain a full understanding of potential health risks, the scientists called the findings a "first step" toward assessing the potential human health effects of PPCPs in sewage water. They also noted that (i) other substances from PPCPs may occur in recycled water

but were not included in the study; and (ii) young children, older individuals and people with chronic diseases may be more susceptible to low levels of PPCPs. *See American Chemical Society News Release,* September 9, 2013.

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LEGAL TRENDS REPORT

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