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LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

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INSIDE GOVERNMENT

FSMA Is "Instrumental" in OxyElite Pro Recall

Texas-based USPlabs, LLC., has agreed to recall and destroy its OxyElite Pro dietary supplements that have purportedly been linked to dozens of cases of acute liver failure and hepatitis, including one death. In addition to recalling the products, USPlabs has reportedly assured the U.S. Food and Drug Administration (FDA) that it will destroy warehouse stocks of the supplement, worth about $22 million.

According to FDA, USPlabs took the action after receiving a letter from FDA stating that if the company did not initiate a voluntary recall, the agency could by law order it to immediately stop distributing the dietary supplements and immediately notify other parties to stop distributing them. FDA's action reportedly marks the second time the agency has exercised its recall authority under the Food Safety Modernization Act (FSMA), which allows it to act quickly in the face of a potential danger to public health. Noting that the agency's aim is to prevent the occurrence of such events, Director of FDA's Division of Dietary Supplement Programs Daniel Fabricant said that FSMA has been "instrumental" in the agency's enforcement actions regarding the OxyElite Pro dietary supplements.

Calling the national recall "appropriate as a precautionary measure," USPlabs said that "epidemiological evidence shows that use of these products has been associated with serious adverse health consequences, namely serious liver damage or acute liver failure, concentrated in Hawaii." More information on FDA's investigation into OxyElite Pro may be found in Issue 13 of this *Report*. *See FDA News Release,* November 10, 2013.

FDA Seeks Comments on Dietary Supplement Information Collection

The U.S. Food and Drug Administration (FDA) has requested comments on the utility and burdens of preparing a petition seeking an exemption from 100-percent identity testing of dietary ingredients under its current good manufacturing practice requirements for dietary supplements. According

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to the agency, manufacturers may be able to demonstrate, "through various methods and processes in use over time for its particular operation, that a system of less than 100 percent identity testing would result in no material diminution of assurance of the identity of the dietary ingredient as compared to the assurance provided by 100 percent identity testing." While the agency has not received any new petitions during the last three years, it estimates that one or fewer will be submitted annually with some eight hours required to "prepare the factual and legal information necessary to support a petition for exemption." *See Federal Register*, November 14, 2013.

NIOSH Issues Workplace Nanotech Exposure Guidance

The National Institute for Occupational Safety and Health (NIOSH) has issued a guidance **document** titled "Current Strategies for Engineering Controls in Nanomaterial Production and Downstream Handling Processes." According to NIOSH Director John Howard, "These recommendations represent the kind of science-based guidance that our partners have requested, as a vital component for supporting the safe growth of nanotechnology and U.S. leadership in the global market." The guidance favors the use of engineering controls over administrative controls and personal protective equipment, "because they are designed to remove the hazard at the source, before it comes into contact with the worker." *See NIOSH News Release*, November 8, 2013.

LITIGATION AND REGULATORY ENFORCEMENT

Jury Rules Oregon Man Defrauded Dietary Supplement Customers

Following a six-day trial, a federal jury has determined that James Cole "operated schemes to defraud his customers in the operation of two separate but related businesses." One of the businesses, Maxam Neutraceutics, apparently sold dietary supplements in the form of spray bottles, marketed as effective treatments for "incurable medical conditions, including autism." The bottles were sold for $125, and Cole allegedly claimed they had been created and were marketed by a Harvard chemist. According to the U.S. Food and Drug Administration (FDA), the products were actually "made by a twice-convicted federal felon and self-taught chemist in the Boston area operating in unknown labs under unknown conditions." Cole also allegedly failed to disclose that the products contained rare bacteria and that he had never conducted clinical trials to support his product claims, despite advertising them as "clinically proven" to improve a host of diseases.

The government also showed that the customer service representatives working for Cole's company had no medical training, but "were instructed to provide medical-sounding advice to customers who called the office." Cole's other business involved the sale of machines, falsely claimed to be

FDA-approved, that "were capable of treating over 100 medical conditions if the machine's dials were turned to particular settings, including cancer and HIV." Because the matter was filed as a civil asset forfeiture case, the government is apparently entitled to retain more than $700,000 in assets seized from Cole's home and businesses. Information about FDA enforcement action taken against another Cole company appears in Issue 13 of this *Report*. Tax fraud-related counts are also apparently pending against Cole. *See FDA News Release*, November 20, 2013.

Court Establishes Pre-Trial Timetable in Prada Trademark-Infringement Suit

A federal court in New York has ordered the parties in trademark-infringement litigation involving the "Prada Candy" fragrance to submit a joint case-management plan and scheduling order by December 27, 2013, and will conduct an initial conference on January 3, 2014. *Prada, S.A. v. Preferred Fragrance, Inc.*, No. 13-7371 (U.S. Dist. Ct., S.D.N.Y., order entered October 28, 2013).

According to the complaint, the defendants adopted "the nearly identical PARTY CANDY mark and trade dress for a competing knock-off perfume" that is likely to cause consumer confusion about the source of the defendants' product. Prada claims that its distinctive trade dress includes (i) "a bold pink rectangular carton with black flaps"; (ii) "a cartoon silhouette of a fashionable young woman with long, light-colored hair, who is wearing high heels and a dark above-the-knee dress and kicking up one leg"; and (iii) "a rectangular gold-rimmed banner to showcase the famous PRADA CANDY trademark." The company contends that the Party Candy mark "is nearly identical to and is a colorable imitation of Plaintiff's federal registered PRADA CANDY Mark."

Alleging violations of federal and state law, Prada requests injunctive relief, an accounting and compensatory, exemplary and punitive damages, as well as attorney's fees, costs and interest.

Putative Class Claims Nutrients in "Shapewear" Cannot Deliver Anti-Cellulite Promise

New York residents have filed a putative nationwide class action against two New Jersey-based companies that purportedly make and sell women's undergarments with fabric containing embedded minerals and nutrients, falsely promising that they can permanently change women's body shape and skin tone. *Caramore v. Maidenform Brands, Inc.*, No. 13-6122 (U.S. Dist. Ct., E.D.N.Y., filed November 5, 2013). Produced by a Spanish company, the fabric is allegedly advertised as containing caffeine "to promote fat destruction; vitamin E to prevent the effects of aging; ceramides to restore and maintain the skin's smoothness; and retinol and aloe vera to moisturize and increase the firmness

of the skin." According to the complaint, the Federal Trade Commission calls such representations "about as credible as a note from the Tooth Fairy."

Claiming that they relied on the defendants' anti-cellulite misrepresentations in making their purchases of the "shapewear" and failed to receive the benefit of their bargain, the plaintiffs allege violation of the New Jersey Consumer Fraud Act, breach of express warranties and unjust enrichment. They seek actual, statutory, punitive, or treble damages; interest; injunctive relief; attorney's fees; and costs.

UK MPs Support Agency Position in High Court Glucosamine Lawsuit

A cross-party delegation of seven Members of Parliament (MPs), led by Austin Mitchell (Labor—Great Grimsby), has entered an "early day" motion to support the position taken by the Medicines and Healthcare Products Regulatory Agency (MHRA) in litigation filed by the European arm of a China-based pharmaceutical company seeking to stop the recognition of glucosamine as both a food and a medicine. According to the motion, the MPs support "the Agency's defense of its position against a challenge by one company that seeks to have all glucosamine products designated as medicines so driving up prices, reducing consumer choice and limiting the way in which the benefits of such products may be promoted." The November 7, 2013, motion also "encourages Consumers for Health Choice to keep up its campaign to defend consumer choice in natural health products."

Filed by BlueBio (Yantai) Pharmaceuticals before the United Kingdom's (UK's) High Court, the litigation is reportedly raising concerns throughout the European Union (EU), given the potential obstacle to the free movement of goods across borders posed by differing product classifications. The company apparently holds a prescription-only medicines registration throughout the EU's 28 member states for Dolenio®, a glucosamine sulphate product. MHRA reportedly makes its determinations on a case-by-case basis and supports the supplement's dual status. The agency has the support of the UK Health Food Manufacturers' Association, which, as an "interested party," has made a submission to the court detailing why glucosamine should be deemed a food supplement as well as a medicine. According to a news source, the case will likely be heard in the first half of 2014. *See Nutraingredients.com*, November 13, 2013.

Hawaii Resident Sues OxyElite Pro Maker for Personal Injury

Hawaii resident Everine Van Houten has filed a personal injury lawsuit against USPlabs, LLC, the company that makes OxyElite Pro® protein supplements, and GNC Holdings, Inc., the product seller, alleging that she developed acute non-viral hepatitis after using the supplement, which has since been recalled. *Van Houten v. USPlabs, LLC*, No. 13-635 (U.S. Dist. Ct., D. Haw., filed November

19, 2013). Van Houten alleges that she consumed the muscle-building, weight-loss supplement in February and March 2013, and experienced symptoms diagnosed as hepatitis in August. The product was recalled in November.

According to the complaint, "the recalled products contain[] Aegeline, a synthesized version of a natural extract from the Bael tree. Aegeline is not approved by the FDA [Food and Drug Administration] as a dietary supplement. The Defendant USP's recall was initiated after it was notified by the FDA that its OxyElite products had been linked to cases of liver injury in Hawaii and that there was a reasonable probability that the products were adulterated."

Alleging strict liability, negligence and breach of warranties, the plaintiff seeks damages for "wage loss; medical and medical-related expenses; travel and travel-related expenses; emotional distress; physical pain; physical injury; and all other ordinary, incidental and consequential damages." She claims that she was unable to work through most of 2013 and "continues to undergo testing and medical monitoring of her liver and continues to experience symptoms related to her liver injuries."

DMAA Supplement Maker Sues FDA

A Georgia-based company that produces dietary supplements containing the ingredient 1,3 Dimethylamylamine (DMAA) has filed an action for declaratory and injunctive relief against the U.S. Food and Drug Administration (FDA) alleging that the agency "has engaged in a campaign of intimidation against dietary supplement companies" that include the ingredient in their products and has done so without notice or engaging in proper rulemaking procedures to formally ban DMAA. *Hi-Tech Pharms., Inc. v. Hamburg*, No. 13-1747 (U.S. Dist. Ct., D.D.C., filed November 5, 2013).

The complaint notes that FDA had issued an administrative detention order against the company's goods, and, according to FDA, a week later U.S. marshals seized 1,500 cases of finished goods and more than 1,200 pounds of in-process/raw material goods containing DMAA with an estimated value of $2 million from the company's Norcross facility.

While FDA contends that DMAA is "an unapproved food additive that is deemed unsafe under the law," the company alleges that the ingredient "has existed in the food supply for many years" and that it "has sold over a million bottles of dietary supplement products containing this ingredient without any adverse effects." Seeking to enjoin "FDA's campaign of intimidation," the company calls for the agency to disclose "scientific evidence which brings the safety of DMAA into question . . . and engage in the formal rule making process to ban the ingredient." Hi-Tech Pharmaceuticals alleges that FDA has the burden of proving that a dietary supplement is adulterated and has failed to do so. Rather, "[i]n issuing warning letters, detention orders and seizure orders against DMAA, the Defendants have ignored the express intent

of Congress and simply relied upon an unfounded presumption that a safe level could not be determined." Accordingly, the company contends that the agency has violated the Administrative Procedure Act, Dietary Supplement Health and Education Act and the company's Fifth Amendment due process rights. *See FDA News Release*, November 18, 2013.

EMERGING TRENDS

Human Lung Model Developed as Alternative to Animal Testing

Scientists from the Lung and Particle Research Group at Cardiff University in Wales, have reportedly developed a new human tissue lung model that can be used to detect the toxicity of cosmetic aerosol products to humans without testing on animals. Similar models have previously been used in the cosmetics industry, but the new model, which involves cultivating different cells into "micro-lungs," can evidently mimic metabolic processes and allow researchers to detect whether a substance will be harmful after it is broken down in the body.

Kelly BéRubé, Director of the Lung and Particle Research Group, said that using cultures derived from human tissue can produce "robust results" and help researchers avoid using animals for cosmetic research. "We're now able to predict with very high accuracy what will happen in a human lung," she added. BéRubé also noted that the new lung model allows scientists to "order or pre-screen" subjects and test by gender or pre-existing medical condition, for example. The research team was recently awarded a LUSH Science Prize for innovation in cruelty-free cosmetics. *See Cardiff University News Release,* November 13, 2013; *CosmeticsDesign-Europe.com,* November 15, 2013.

INTERNATIONAL DEVELOPMENTS

China to Phase Out Mandatory Cosmetics Animal Testing

The China Food and Drug Administration (CFDA) has **announced** that beginning June 2014, the country will remove its mandatory animal-testing requirements for domestically manufactured cosmetic products. Under the new rule, manufacturers of "non-special use cosmetics" such as shampoo or perfume, will no longer be required to provide samples of new products to the government for animal testing. Instead, they will be allowed to conduct their own product risk assessments using ingredient safety data and the results of non-animal test methods, provided the test methods are deemed scientifically valid by the European Union (EU).

Calling China's decision the beginning of what it hopes to be a "paradigm shift towards 21st-century science without animals," the Humane Society Inter-

national (HSI), which has long campaigned to end cosmetics animal testing in China, said that the action "marks a major milestone in our campaign and could constitute a significant watershed moment in our global effort to end cosmetics animal testing worldwide." HSI estimates that as many as 300,000 rabbits, mice and other animals are subject to cosmetics chemical testing in China each year.

Initially the new rules will apply only to cosmetics manufactured in China. CFDA has reportedly stated however, that the new system may be expanded to include imported products and certain "special use" cosmetics. HSI plans to continue to work with Chinese officials toward a complete ban on cosmetics animal testing and in the meantime, will collaborate with its cruelty-free corporate partners to assess the new system when it is implemented next year. *See Humane Society International News Release,* November 7, 2013; *Reuters.com,* November 13, 2013.

UK Agency Issues Deadline for Herbal Medicine Registration

The U.K.'s Medicines and Healthcare Products Regulatory Agency (MHRA) has announced that beginning April 30, 2014, all manufactured herbal medicines must be registered under the Traditional Herbal Registration (THR) scheme before they may be legally supplied or sold in the United Kingdom. The requirements for the THR scheme are listed in the Traditional Herbal Medicinal Products Directive, which was introduced in 2004 and took effect April, 30, 2011. At that time, MHRA instituted a transition period to (i) allow retailers to "sell through" their stock, anticipating that the products would be sold within an 18- to 24- month period—the average shelf-life of these products; and (ii) permit manufacturers to bring production up to the required standards to meet the directive.

Noting that unlicensed herbal medicines were still being sold, the agency launched a July 2013 consultation seeking input about ending the sell-through period. "It is now nearly ten years since the implementation of the European Directive on herbal medicines," said an MHRA spokesperson. "Companies have had this time to bring products up to appropriate standards and apply for a THR registration."

Products registered under the THR scheme must meet safety and quality standards and include patient information about the product and how it should be used. Registered products will also feature a THR logo and number on the label. *See MHRA News Release,* November 21, 2013.

Antibiotic-Tainted Enzymes Found Worldwide

Digestive enzyme products contaminated with chloramphenicol—a potent antibiotic withdrawn from the market in oral forms for human consumption by the U.S. Food and Drug Administration (FDA) in 2012—have reportedly been found in Japan, Europe, Canada, and the United States. Manufactured in India and distributed by California-based Specialty Enzymes & Biotechnologies, the enzymes are sold in various formulations to companies that manufacture dietary supplements, conventional foods and animal feed.

According to a news source, Specialty Enzymes sold a portion of tainted lots of products to a Japanese distributor which then sold and shipped the products to companies in Europe. These affected products were evidently re-formulated and shipped back to the United States and Canada; the Canadian government has issued a warning that some natural health product manufacturers may unknowingly be using contaminated raw materials.

Calling the probability of a serious adverse health consequence "remote" and noting that any other potential consequences would be "temporary or medically reversible," Specialty Enzymes issued a voluntary recall of the specific lot numbers affected by the purported contamination and is apparently working closely with FDA to resolve the matter. *See NutraIngredients-USA.com,* November 4, 2013; *Specialty Enzymes & Biotechnologies News Release,* November 5, 2013.

SCIENTIFIC/TECHNICAL DEVELOPMENTS

Study Says Vitamin and Mineral Supplements Do Not Protect Against Cancer, Heart Disease

An analysis conducted by scientists at the Kaiser Permanente Center for Health Research in Portland, Oregon, has reportedly concluded that "there is little evidence that vitamin and mineral supplements protect people from cancer and heart disease." Stephen Fortmann, et al., "Vitamin and Mineral Supplements in the Primary Prevention of Cardiovascular Disease and Cancer: An Updated Systematic Evidence Review for the U.S. Preventive Services Task Force," *Annals of Internal Medicine,* November 12, 2013. Based on these findings, the U.S. Preventive Services Task Force (USPSTF) has reportedly issued draft recommendations that echo its previous conclusion that it cannot recommend for or against taking vitamins and minerals to prevent such conditions. "At this point in time the science is not sufficient for us to estimate how much benefit or harm there is from taking vitamin or multivitamin supplements to prevent cancer or heart disease," said USPSTF Co-Vice Chair Stephen Fortmann.

According to news sources, nearly one-half of the U.S. population takes vitamin and/or mineral supplements, with the expectation that the prod-

ucts will prevent chronic diseases. The rationale is that heart disease and cancers, reportedly the two leading causes of death, share the risk factors of inflammation, variant methionine metabolism and oxidative stress, and that micronutrients counter these problems.

Although tests of individual nutrients in animals and in vitro evidently support the protection hypothesis, results of larger studies do not, and in 2003, USPSTF concluded that evidence was insufficient to recommend for or against antioxidant combinations—vitamins A, C and E and multivitamins with folic acid. The current analysis, which consulted 26 studies, meta-analyses, bibliographies, and government Websites and evaluated vitamins A (including β-carotene), B1, B2, B6, B12, C, D, and E, as well as calcium, zinc, iron, niacin, magnesium, selenium, and folic acid, purportedly updates and supports the 2003 recommendations.

In response to the review, Vice President of Scientific and Regulatory Affairs at the Council for Responsible Nutrition (CRN) Duffy MacKay stated that "even some, albeit limited, evidence that a simple multivitamin could prevent cancer demonstrates promise and should give consumers added incentive to keep taking their multivitamins." MacKay also noted that although there may be "limited evidence for multivitamins in preventing cancer or cardiovascular disease," CRN believes that the paucity of clinical trial evidence should not be misinterpreted as a lack of benefit for the multivitamin. "We know for sure that multivitamins can fill nutrient gaps, and as so many people are not even reaching the recommended dietary allowances for many nutrients, that's reason enough to add an affordable and convenient multivitamin to their diets." *See NutraceuticalsWorld.com,* November 11, 2013*; Medscape.com,* November 13, 2013.

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