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LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

CONTENTS

INSIDE GOVERNMENT

Spate of FDA Warning Letters Focus on Product Labeling and Marketing

A number of dietary supplement and personal care product manufacturers have recently been the recipients of U.S. Food and Drug Administration (FDA) warning letters over product labels and promotions that purportedly establish the products as drugs under the Food, Drug, and Cosmetic Act. Most of the supplements are advertised as products designed to address blood sugar levels. They include (i) Health King Enterprise & Balanceuticals Group's "Sugar Balance" and "Blood Pressure Balance"; (ii) PharmaTerra's "Pro Beta"; (iii) Neuliven Health's "Glucocil"; (iv) Nature's Health Supply's "Diabetes Daily Care"; (v) Naturecast Products' "Eradicator" and "Nature's Gold"; and (vi) Internal Remedies' "Glytain." Two of the companies, Health Care Products and Anastasia Marie Laboratories, sell topical creams for uses targeted specifically to diabetic patients.

According to FDA, these companies made therapeutic claims for their products on their Websites and product labels, had not secured FDA approval for their products as new drugs and failed to provide serving sizes or adequate directions for use. FDA cited some of the companies for including citations to scientific journals to promote their products, noting that they may become evidence of a product's intended use. FDA also took issue with the metatags that some of the companies used to direct consumers to their Websites, including "Diabetes," "Fasting blood sugar," "Hblac," "Natural diabetes treatment," "alternative diabetes treatment," and "lower blood sugar." One of the companies apparently included the statement "FDA Approved" on its product label, which FDA said was false. *See FDA Warning Letters*, July 11 and 15, 2013.

FDA Issues Warning about Anabolic Steroids in Vitamin B Dietary Supplement

According to the U.S. Food and Drug Administration (FDA), vitamin B dietary supplement Healthy Life Chemistry By Purity First B-50 contains two anabolic steroids—methasterone and dimethazine—and should not be purchased

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or used by consumers. Purity First Health Products has apparently declined to voluntarily recall the product or issue consumer warnings despite alleged adverse incident reports, including "fatigue, muscle cramping, and myalgia, as well as abnormal laboratory findings for liver and thyroid function, and cholesterol levels." FDA warns that these steroids can cause acute liver injury, unwanted hair growth in women and infertility in men. The agency further advises health care professionals to ask their patients about dietary supplement use, particularly in patients with certain signs associated with steroid use, and to report any adverse reactions through FDA's MedWatch program. *See FDA News Release*, July 26, 2013.

GNC Agrees to Destroy Dietary Supplements with DMAA

Still apparently contending that supplements containing 1,3-dimtheyl-amylamine (DMAA) are safe and with assurances of reimbursement from manufacturer USPLabs, General Nutrition Centers Inc. (GNC) has apparently agreed to destroy 1,500 cases of OxyElite Pro® in its Leetsdale, Pennsylvania, warehouse. The U.S. attorney's office filed a civil lawsuit against GNC in June 2013 to seize the products. Additional information about the suit appears in Issue 5 of this *Report.* According to U.S. Attorney David Hickton, USPLabs has also destroyed all of the DMAA-containing products—valued at more than $8 million—in its Dallas facility and will stop producing supplements with the ingredient. Hickton also apparently indicated that 10 other supplement makers will stop using DMAA. *See The New York Times*, July 16, 2013; *Triblive.com*, July 23, 2013.

LITIGATION & REGULATORY ENFORCEMENT

NAD Calls for New Nordic US to Cease Certain Hair Volume® Claims

The National Advertising Division (NAD) of the Advertising Self-Regulatory Council (ASRC) has recommended that New Nordic US, Inc. either modify or discontinue certain claims for its Hair Volume® dietary supplement on the ground that they imply an ability to reverse balding, including genetic-pattern baldness, in women. Among the purportedly questionable product claims that NAD reviewed were (i) "Thousands of people have already experienced the benefits of Hair Volume, which has made it the world's leading hair tablet with natural apple hair growth factor"; and (ii) "Strengthens your hair. With hair growth factors and minerals for hair follicles, skin and nails."

The company also apparently promoted its product with a testimonial: "I started taking the new Hair Volume tablets and the transformation was incredible. My hair appeared with more thickness, more life. It feels and

looks more vibrant and healthier . . . Even my nails are stronger. All this with one tablet a day. This is proof that with the right nutrients you don't have to accept your family fate." NAD, part of an industry self-regulatory system administered by the Council of Better Business Bureaus, recommended that the company discontinue the claims at issue, as well as the testimonial. The company agreed to accept the recommendation, although it stated, "we felt we had some substantiation from the clinical studies of our ingredients." *See ASRC News Release*, July 25, 2013.

Federal Court Allows Claims over Muscle-Building Supplement to Proceed

A federal court in California has, for the most part, found the consumer-fraud and breach-of-warranty claims filed on behalf of a putative class of dietary-supplement users sufficiently pleaded to survive the defendants' motion to dismiss. *Yacu v. All Am. Pharm. & Natural Foods, Inc.*, No. 13-0508 (U.S. Dist. Ct., C.D. Cal., in chambers order entered July 24, 2013). The product, Kre-Alkalyn®, is marketed as a muscle builder. At issue were allegations relating to three separate types of product representations: superior bioavailability, lower dosage and diminished side effects in comparison to other similar products.

Rejecting the defendants' argument that superiority claims are non-actionable puffery, the court observed, the "claim that the Product is the only creatine in the world that does not lose potency is a specific and measurable characteristic of creatine products that could be proven false. Accordingly, Plaintiff's claims based on Defendants' bioavailability statements are not based on non-actionable puffery." The court also concluded that the reasonable consumer "could be led to believe that the Product is more bioavailable compared to creatine monohydrate even though it is not."

While the court found that the plaintiff's allegations as to one of the defendants' lower dosage statements failed to state a plausible claim, it found allegations as to two other statements actionable: "And you'd need only a small amount since the full dose could finally reach your muscle cells intact" and "In just 60 days, the Kre-Alkalyn® group experienced an overall strength increase of 28.5% above those in the creatine monohydrate group." The plaintiff alleged that "the statements are misleading because they fail to disclose that the 28.5 percent statistic was based on a 2006 study in which subjects took 7.5 grams of the Product per day," far in excess of the recommended 1.5 grams per day dosage. According to the court, "Defendants' statements touting its relative strength gains are arguably misleading because consumers would need to consume substantially greater quantities each day to achieve such results."

The court further determined that just one of the diminished side-effects allegations—claiming that the product lacked the loading-phase was misleading to consumers because studies show that the comparison product does not produce that side effect—was sufficiently pleaded. Allegations about product promotions claiming that the supplement did not lead to water retention were not sufficiently pleaded, in the court's view, because the plaintiff cited conflicting studies on the issue, suggesting that "the research on this particular downside is inconclusive or unsubstantiated" and because "there is no private remedy for unsubstantiated advertising" in California.

Dismissed with prejudice was the plaintiff's claim for unjust enrichment on the basis of recent federal and state opinions holding that the state "does not recognize a freestanding cause of action for unjust enrichment."

Dietary Supplement Maker Sued in Death of 34-Year-Old Man

The widow of a 34-year-old who allegedly collapsed from a heart attack and died after using OxyElite Pro®, a fat-burning supplement containing 1,3-dimethylamylamine (DMAA), has filed a lawsuit in federal court against USPLabs, the company that produces it, and Bodybuilding.com, the company that sold the product on its Website. *Battuello v. USPLabs, LLC*, 13-4101 (U.S. Dist. Ct., E.D. Pa., filed July 15, 2013).

According to news sources, the decedent died after finishing dinner with his wife in May 2012, and the lawsuit was filed after his family learned that the U.S. Food and Drug Administration (FDA) had recently ordered that the pills be destroyed. FDA has warned consumers that DMAA "can elevate blood pressure and could lead to cardiovascular problems, including heart attack, shortness of breath and tightening of the chest . . . [and] may be particularly dangerous when used with caffeine." Additional information about FDA's action appears elsewhere in this *Report*.

The family's attorney has reportedly said that toxicology tests showed that the decedent, a physical-fitness buff, had DMAA in his system when he died. The lawsuit alleges that despite a warning currently on USPLabs' Website about not mixing DMAA and caffeine, the company failed to warn consumers that the product posed a potentially lethal risk. *See Philly.com* and *Daily Mail*, July 26, 2013

EMERGING TRENDS

NPA Responds to "Vitamin Myth" Article in *The Atlantic*

The Natural Products Association (NPA) has responded to an article by Paul Offit in *The Atlantic* titled the "The Vitamin Myth: Why We Think We Need Supplements" that discusses the argument between nutrition experts

who contend that a routine diet, high in fruits and vegetables, provides the necessary vitamins and nutrients for optimal health and dietary supplement representatives who claim that foods do not contain enough nutrients and thus supplements are needed.

Noting that Offit's objections to dietary supplements and vitamins "erroneously discount the many health benefits that can be derived from taking them," NPA contends that decades of scientific research, supported by recommendations from the U.S. Food and Drug Administration, World Health Organization and American Heart Association, show that "millions of Americans take vitamins and supplements for one simple and powerful reason, because they work."

"We firmly believe that taking dietary supplements and vitamins can improve an individual's health, well-being and longevity," concluded NPA. *See npainfo.org.*

INTERNATIONAL DEVELOPMENTS

Japanese Government Claims Kanebo Delayed Recalling Skin-Whitener with 4HPB

The Japanese government has criticized Kanebo Cosmetics Inc. for its handling of the recall of some 4.36 million skin-whitening products from retailers in Asia and England following complaints that the products cause patchy skin lightening, de-pigmentation and vitiligo-like symptoms. Kanebo approved a recall of the products, which contain the ingredient 4HPB, or Rhododenol—a synthetic version of a compound found in the bark of birch trees—on July 4, 2013, but critics claim that the action came too late. Sources indicate that Kanebo was notified in mid-May that some consumers had experienced de-pigmentation after using the company's skin-whitening products, but the cosmetics maker neither reported those cases to the government until the end of June nor issued the recall until July. Company executives said that they reported the problem as soon as they could properly assess the situation.

A July 23 Kanebo news release stated that as of July 19, more than 6,800 people had contacted the company with complaints about the products and among these, 2,250 people had reported one of the following symptoms: "depigmentation in three or more areas of the body," "depigmentation in an area of at least 5 cm" and "clearly visible depigmentation in parts of the face."

Kanebo reported that it has established a task force to take "full responsibility for the care of all customers who experience vitiligo-like symptoms following the use of the affected products, through to the stage of full recovery," and that company representatives will visit "each and every customer" with reported symptoms in the coming weeks. "This is an extremely large number [of cases]. I apologize deeply to all people who have been affected," said Kanebo Presi-

dent and CEO Masumi Natsusaka. "We will make sure we can ensure the full recovery of all our customers." *See abs-cbnnews.com,* July 23, 2013; *wsj.com,* July 25, 2013.

Philippines FDA Orders Ban and Seizure of 16 Cosmetic Products

The Philippines Food and Drug Administration (FDA) has banned and ordered seized 16 cosmetic products, including sunscreen and skin-whitening creams, mostly from China, after discovering that they had no market authorization from the agency and are suspected of containing levels of metals such as lead, cadmium, mercury, and arsenic beyond allowable limits. Declaring that the products are "unsafe" and pose "imminent danger or injury to consumers because they were not manufactured in compliance with the standards of the Code of current Good Manufacturing Practice or cGMP," FDA ordered that they be banned and seized from public sale and distribution.

"Continuous use of these products may cause adverse or allergic reactions that can result to severe or irreversible skin problem," wrote FDA acting Director General Kenneth Hartigan-Go in FDA **Advisory No. 2013-019**. He also noted that all FDA-authorized cosmetic products labels should contain the following information: the name and address of the local company; a full ingredient listing; a batch code; and the date of manufacture or expiration date.

Safety Warning Issued in UK Following Seizure of 640 Contaminated Cosmetics

The U.K.'s Luton Borough Council's Trading Standards service—a consumer protection group—has issued a cosmetics safety warning after seizing 640 products that purportedly contained banned or "dangerously high" levels of chemicals such as mercury, arsenic, lead, and p-phenylenediamine. The seized items, which evidently breached European Union (EU) labeling requirements, included hair products and skin-whitening creams, some of which reportedly contained up to 17,700 milligrams per kilo of mercury, a banned ingredient in all cosmetic products in the EU.

The Trading Standards service has asked retailers to check their stock and remove any potentially dangerous cosmetics from sale and said that it intends to continue spot checks on retailers. The agency has also urged retailers to buy beauty products only from reliable suppliers and to avoid cosmetics such as eye liners, lipsticks and mascaras unless they are correctly labeled. *See Luton.gov.uk.,* July 15, 2013.

Australian Cosmeceutical Company CEO Implicated in $5.7-Million Theft

Melbourne, Australia-based biotech Phosphagenics, which manufactures anti-aging and body-sculpting products, has accused its former Chief Executive, Esra Ogru, and another former employee of stealing $5.7 million from the company during an eight-year period by misappropriation of funds with false invoices. Ogru was reportedly suspended July 1, 2013, after the company noticed irregularities in its invoicing and accounting records, and she resigned on July 18. According to a Phosphagenics news release, the company alleges that Ogru "is implicated in and has benefited from the misappropriated funds."

Phosphagenics reported that it has taken steps to preserve and secure the assets of those who are allegedly involved and is confident that it will "receive substantial restitution and compensation from the various parties responsible for the misappropriations," said Executive Director Harry Rosen. He also noted that the company's clinical programs, product development and marketing have not been affected by the internal problems. *See Phosphagenics News Release,* July 1 and July 24, 2013; *au.gwn7.yahoo.com,* July 24, 2013.

China Launches Campaign to End Animal Testing

Be Cruelty-Free, an international campaign to end animal testing for cosmetics globally, has reportedly launched in China. Led by advocacy group Humane Society International (HSI), the campaign has asked China, reportedly the world's fourth largest beauty market, to cease its mandatory testing of cosmetics on live animals. *Be Cruelty-Free* has led similar campaigns across South Korea, Oceania, Brazil, Russia, Canada, and India, which became the first South Asian country to prohibit animal testing for cosmetics in July 2013.

According to HSI, hundreds of cosmetics companies worldwide avoid animal testing by using safe, existing ingredients and available non-animal tests. Chinese regulators, however, have reportedly been slow to accept most internationally recognized non-animal tests. "Beauty products made or sold in China come at a huge and totally unnecessary cost to thousands of animals," said Capital Animal Welfare Association Director Qin Xiaona. "While the rest of the world is turning away from animal testing, our regulations are holding us back from leading the way in cruelty-free cosmetics. It's time for our country to take the important step of phasing out animal testing."

India's animal-testing ban for cosmetics is discussed in Issue 6 of this *Update*. *See ChemLinked.com,* July 18, 2013.

SCIENTIFIC/TECHNICAL DEVELOPMENTS

Study Links PFC Levels in Blood to Thyroid Function

A recent study shows that exposure to perfluorinated chemicals (PFCs), a class of chemicals that are commonly used in many consumer products, including cosmetics, can reportedly affect thyroid function. Li-Li Wen, et al., "Association Between Serum Perfluorinated Chemicals and Thyroid Function in U.S. Adults: The National Health and Nutrition Examination Survey 2007-2010," *Journal of Clinical Endocrinology & Metabolism,* July 17, 2013. Analyzing data from more than 1,100 people who took part in the 2007-2008 and 2009-2010 U.S. National Health and Nutrition Examination Survey, researchers looked at levels of four different PFCs as well as participants' thyroid function, concluding that PFCs break down very slowly and take a long time to leave the body. Along with determining that high levels of PFCs in the body can alter thyroid function in both men and women, the researchers also found that PFCs may increase the risk of mild hypothyroidism—when the thyroid gland does not produce enough hormones—in women.

"Our study is the first to link PFC levels in the blood with changes in thyroid function using a nationally representative survey of American adults," said study co-author Chien-Yu Lin. Although manufacturers have phased out use of some PFCs, Lin observed that the chemicals remain a concern because they linger in the body for extended periods. "Too little information is available about the possible long-term effects these chemicals could have on human health," noted Lin. *See health.usnews.com,* July 17, 2013.

Trade Associations Challenge Claims Linking Omega-3 Supplements and Prostate Cancer

The Natural Products Association (NPA), Global Organization for EPA and DHA Omega-3 and Council for Responsible Nutrition (CRN) have challenged a recent study published in the *Journal of the National Cancer Institute* which suggests that taking omega-3 supplements can increase the risk of prostate cancer.

Claiming that the study discusses only a "correlation between cancer and omega-3 supplementation, and correlation does not equal causation," NPA Senior Vice President Cara Welch said, "Simply put, there is nothing in this study that raises any red flags for NPA. We welcome the Journal of the National Cancer Institute to continue publishing research on the health effects of omega-3s because we're confident the benefits outweigh risks." "Omega-3 supplements are used every day by consumers all across the country who wish to reap the crucial health benefits these products provide,"

said NPA Executive Director John Shaw. "From promoting heart health to assisting in prenatal care, the benefits of omega-3s are numerous."

Additional information about omega-3 fatty acids and their purported link to increased prostate cancer risk appears in Issue 6 of this *Update. See NPA News Release,* July 11, 2013; *Natural Products Insider*, July 12, 2013.

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LEGAL TRENDS REPORT

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