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LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

CONTENTS

Inside Government

FDA Issues Updated Draft Guidance for Cosmetics 1

FDA Offers Guidelines for Cosmetic Export Certificates 1

FDA Seeks Comments on Laser Products Performance Standards 2

NIH Launches Dietary Supplement Database 2

Litigation & Regulatory Enforcement

Estée Lauder Rejects Settlement Offer in Counterfeit Cosmetics Suit 2

Revlon Agrees to $850,000 Penalty for Erecting Informational Barriers in Takeover Deal 3

Reality TV Star Sued for Falsely Promoting Dietary Supplement.....4

Ad Industry Self-Regulatory System Targets Unsupported Claims.....4

Federal Prosecutors Take Action on Dietary Supplements with DMAA.....5

Medical Food Maker Sues FDA to Force Label Approval 6

Emerging Trends

CHPA Adopts Guidelines for Caffeine-Containing Supplements 7

International Developments

Illegal Mercury-Laden Cosmetics for Sale in Philippines 7

New Labeling Standard Identifies Eco-Friendly Cosmetics in Australia 8

CTPA Responds to Sunscreen Allergy Claims 9

IFRA Updates Fragrance Standards.....9

ECHA to Review New Substances Under REACH..... 10

INSIDE GOVERNMENT

FDA Issues Updated Draft Guidance for Cosmetics

The U.S. Food and Drug Administration (FDA) has issued new draft guidance titled "Guidance for Industry: Cosmetic Good Manufacturing Practices" (GMPs) aimed at helping industry and other stakeholders identify standards and issues that affect the quality of cosmetic products. Noting that the previous guidance was based on documents and information from the early 1990s and is now "outdated," FDA indicated that the updated guidance provides clarification on certain topics based on new information. FDA also indicated that as part of an "international harmonization effort" with the International Cooperation on Cosmetic Regulations (ICCR), it considered the current International Organization for Standardization (ISO) standard for cosmetic GMPs (ISO 22716:2007) when revising the guidance. "We reviewed ISO 22716 and decided to incorporate, modify, or exclude specific aspects of it into this guidance based on our experience," said FDA.

ISO is a non-governmental organization that develops and publishes international consensus standards. In September 2007, ICCR and regulators from the United States, Canada, the European Union, and Japan identified a need for standardized GMPs for the cosmetic industry and agreed to follow ISO standards for cosmetic GMPs when developing or updating guidelines. *See FDA News Release,* June 2013.

FDA Offers Guidelines for Cosmetic Export Certificates

The U.S. Food and Drug Administration (FDA) has prepared a Q&A-based tool that explains how U.S. export firms can obtain cosmetic export certificates for their products. Although many foreign governments and customers evidently require a certificate as part of the process to import a product into their country, FDA noted that (i) it does not require companies to obtain export certificates; (ii) it is not required by law to issue certificates for cosmetics (although it will continue to do so as resources permit); and (iii) it will not issue certificates for cosmetics manufactured outside the United States. The

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agency also stated that cosmetics exporters must follow all applicable U.S. laws and regulations and must know the cosmetics requirements of the countries to which they export. *See FDA News Release,* June 2013.

FDA Seeks Comments on Laser Products Performance Standards

The U.S. Food and Drug Administration (FDA) has issued a proposed **rule** that would amend the performance standard for laser products. According to the agency, the current performance standard for laser products—last updated in 1985—is based on an "outdated understanding of photobiological science and no longer reflects the current state of a technologically-evolving industry." The proposed rule aims to align with the International Electrotechnical Commission standards for laser products and medical laser products "to reduce the economic burden on affected manufacturers, to improve the effectiveness of FDA's regulation of laser products, and to better protect and promote the public health." FDA will accept comments on the proposed rule until September 23, 2013. *See Federal Register,* June 24, 2013.

NIH Launches Dietary Supplement Database

The U.S. National Institutes of Health (NIH) has **launched** a Dietary Supplement Label Database that provides information about the ingredients listed on the labels of nearly 17,000 dietary supplements. The searchable, customizable database is targeted toward both consumers and professionals and, according to NIH Office of Dietary Supplements Director Paul Coates, "will be of great value to many diverse groups of people, including nutrition researchers, healthcare providers, consumers, and others."

NIH said that consumers can access the database to research what their dietary supplements contain and then use the agency's online app to track their supplement usage. The database also provides dosage information, health-related claims and related warnings. *See NIH News Release,* June 17, 2013.

LITIGATION & REGULATORY ENFORCEMENT

Estée Lauder Rejects Settlement Offer in Counterfeit Cosmetics Suit

According to a news source, Estée Lauder has refused an offer from the Australia-based Wesfarmers Target retail chain to settle a lawsuit alleging that Target stocked its shelves with heavily discounted and fake Make-Up Art Cosmetics (MAC), a line manufactured by an Estée Lauder subsidiary. Target has reportedly removed the products from its shelves and offered to sever its ties with any products sold under the MAC trademarks, pay MAC its profits from a promotional sale in 2012, plus interest, and reimburse MAC for its legal

fees. Estée Lauder, however, apparently wants the retailer to further admit that it sold counterfeit products and issue an apology.

Target reportedly purchased the products through the "grey market," importing them cheaply from a wholesaler in the United States. While this practice is apparently legal, it left Australian department stores that have an exclusive sales agreement with the high-end cosmetics company no option for redress. But that was only until the products sold in Target stores were alleged to have been made with a different formula than genuine MAC products, and litigation was filed. Target traced the purportedly counterfeit products upstream through its importer to an Arizona supplier, run out of a suburban home by a sole director who has abruptly closed the business, and then to a Texas company, Mudd Puppy Cosmetics.

Target has sued that company in the United States to find where its sole owner obtained her MAC cosmetics. It, too, has apparently curtailed its Internet presence. Target is evidently hoping to rescue its reputation and regain consumer trust by proving the cosmetics were genuine. *See Brisbane Times*, April 22, 2013; *The Age*, May 6, 2013; *UPI.com*, *MENAFN.com* and *BRW*, June 18, 2013.

Revlon Agrees to $850,000 Penalty for Erecting Informational Barriers in Takeover Deal

Without admitting or denying wrongdoing, Revlon has agreed to **settle** Securities and Exchange Commission (SEC) claims that it deceived shareholders and its independent directors in 2009 when majority shareholder, the investment firm MacAndrews & Forbes owned by billionaire Ronald Perelman, attempted to buy out Revlon's minority shareholders and take the company private as part of a deal to recover a loan to the troubled cosmetics maker. The company's alleged conduct, described by an employee as "ring fencing," involved efforts to keep critical investment information, i.e., that a third-party financial adviser found that the benefit—or consideration—offered in the transaction was inadequate for 401(k) shareholders, mostly company employees and retirees.

Among other matters, Revlon (i) amended the agreement with its trustee to ensure that the trustee would not share the adviser's opinion with Revlon shareholders, (ii) "ensured that it was not a party to any engagement letter concerning the adequate consideration determination" by the adviser, (iii) "directed the trustee to inform Revlon of its decision whether to allow 401(k) members to tender their shares without any reference to the [adviser's opinion]," and (iv) in a notice sent to the 401(k) members and filed as an exhibit to the exchange offer documents, "removed the explicit term 'adequate consideration' and replaced it with citations to ERISA statutes." SEC assessed an $850,000 civil penalty against the company. *See SEC Press Release* and *The New York Times*, June 13, 2013.

Reality TV Star Sued for Falsely Promoting Dietary Supplement

A putative class action filed in a federal court in New York alleges that a reality TV personality who was once one of Hugh Hefner's girlfriends promotes a General Nutrition Corp. dietary supplement that does not, as advertised, cause weight loss. *Karhu v. Corr-Jensen Inc.*, No. 13-3583 (U.S. Dist. Ct., E.D.N.Y., filed June 25 2013). According to a news source, plaintiff Adam Karhu claims that the defendants' "Abdominal Cuts" supplements are marketed with claims that they target fats in the midsection and thighs, will reduce body fat percentage by 3.1 percent, enhance lean tissue, and amplify metabolism. The complaint asserts against the manufacturer, retailer and "Girls Next Door" star Kendra Wilkinson that "[e]ach of these representations is false and misleading." He apparently alleges violations of the Magnuson Moss Warranty Act, breach of express and implied warranties, unjust enrichment, and consumer law violations. The plaintiff previously filed an action under the Magnuson Moss Act against a company that makes sports supplements in a Florida federal court. *See Courthouse News Service*, June 27, 2013.

Ad Industry Self-Regulatory System Targets Unsupported Claims

The advertising industry's self-regulation system, administered by the Council of Better Business Bureaus, has found fault with marketing claims for a number of products, including tinted moisturizer, a homeopathic skin tag removal drug and a dietary supplement used as a sleep remedy. According to recent Advertising Self-Regulation Council (ASRC) news releases, the National Advertising Division (NAD) recommended that Gurwitch Products LLC modify the disclosure on its "Laura Mercier Tinted Moisturizer" product, asserting that it is "The #1 selling Tinted Moisturizer," to clarify that the claim is based on sales data from "better" department stores and online retailers. While Gurwitch indicated disappointment with NAD's findings, believing that its reference to the "prestige retail" category provided a sufficient disclosure, the company said it would take NAD's recommendations into consideration.

Meanwhile, NAD called for Meda Consumer Healthcare, Inc. to discontinue certain claims for its sleep-aid dietary supplement—"MidNite PM"—finding them insufficiently substantiated, but concluding that other claims could remain. NAD recommended that the company discontinue: (i) "[t]he only one you can take before bed or in the middle of the night. . .," (ii) "The Only One You Can Take Any Time of Night To Relieve Occasional Pain, Help You Sleep & Wake Alert," and (iii) "The only one you can take when pain keeps you up or wakes you in the night." The company will apparently appeal NAD's recommendation to the National Advertising Review Board.

The Electronic Retailing Self-Regulation Program (ESRP), another part of the self-regulatory system, reportedly recommended that Plymouth Direct quit using certain of its performance and establishment claims for its Tag Away products, "a homeopathic skin tag removal drug." While ESRP concluded that the company could support its "all natural" and safety claims, it took issue with broadcast and

online ads that said the product was "clinically proven to remove skin tags" and that it would "work in 3-8 weeks." According to ESRP, Plymouth Direct should modify its advertising "to clearly communicate to consumers that the evidentiary basis for its product performance claims are a historical and traditional use of the active ingredient, Thuja occidentalis." The company disagreed with ESRP, but said it would make "minor modifications to its advertising language." *See ASRC News Releases*, June 18 and 19, 2013.

Federal Prosecutors Take Action on Dietary Supplements with DMAA

Federal prosecutors in Pennsylvania and North Carolina have reportedly filed complaints in federal court seeking the forfeiture of more than 3,000 cases of dietary supplements containing 1,3 dimethylamylamine (DMAA) from warehouses owned by GNC Holdings. Following inspections in early June 2013, the Food and Drug Administration (FDA) apparently notified GNC that workout products Jack3d and OxyElitePro, which USPLabs has evidently agreed to stop making, are adulterated and have been declared unsafe. Until the matter is resolved, GNC must retain these products in its warehouses. *See The New York Times*, June 21, 2013.

According to a GNC spokesperson, the company "believes that DMAA is a safe, legal dietary ingredient." In a statement, the company also said, "The products are widely available over the Internet and through various retailers across the country. We are unaware if FDA has detained these same products in other retailers' distribution facilities." Vowing that it will continue to sell inventory on store shelves, the company has characterized FDA's action as retaliation for its stance on DMAA's safety. *See Pittsburgh Post-Gazette*, June 20 and 22, 2013.

FDA issued a notice in April, warning that the stimulant DMAA "most commonly used in supplements promising weight loss, muscle building and performance enhancement . . . can elevate blood pressure and could lead to cardiovascular problems, including heart attack, shortness of breath and tightening of the chest." FDA claimed that it had received 86 reports of illnesses and deaths associated with the use of supplements containing DMAA and indicated that it would use all available tools at its disposal to ensure that the DMAA supplements "are no longer distributed and available for sale to consumers in the marketplace." Additional details about the warning appear in Issue 1 of this *Report*.

In a related development, Beta Labs, LTD has issued a recall of its dietary supplements containing DMAA. In a June 20 notice, the company contends that while its Oxyphen XR, Phentalen, Phen FX, and Red Vipers products, sold in all 50 states, are not the subject of adverse event reports, it issued the recall after reviewing recent FDA communications on DMAA. *See Beta Labs, LTD Firm Press Release*, June 20, 2013.

Meanwhile, U.S. Army and NSF International researchers have tested DMAA concentrations in plant species to determine whether manufacturer claims about its natural origin can be authenticated. Krista Austin, et al., "Analysis of 1,3

dimethylamylamine concentrations in *Geraniaceae*, geranium oil and dietary supplements," *Drug Testing and Analysis*, May 2013. They concluded that the DMAA in dietary supplements "is of synthetic origin and is not present in the plant species *Geranium* and *Pelargonium*; thus the 'natural' origin and use of DMAA as an ingredient in [dietary supplements] is not substantiated."

To defend its products, USPLabs had asserted in correspondence with FDA that DMAA was a permitted dietary ingredient under federal law because it was "a constituent of a botanical, namely the geranium *Pelargonium graveolens*" and relied on a number of studies to support its assertion. In its most recent communication with the company, FDA disputed the studies' reliability, finding them confounded "by the lack of adequate information regarding sample origins and handling. . . . Without evidence of authenticated botanicals and a documented chain of custody to ensure the samples analyzed weren't misidentified or contaminated, it is virtually impossible to confirm the presence of any constituent of *P. graveolens*." FDA also indicated that, to the best of its knowledge, "DMAA is not commonly used as a food or drink by humans" and, since it does not qualify as a dietary ingredient, "your OxyElitePro and Jack 3D products are adulterated under [the Food, Drug, and Cosmetic Act] because the products contain an unsafe food additive." The agency's position has been bolstered by the latest research. *See FDA Response Letter to USPLabs, LLC*, April 18, 2013.

Medical Food Maker Sues FDA to Force Label Approval

A company that makes a "medical food" for women with lupus has filed a complaint against the Food and Drug Administration (FDA) in a New Jersey federal court seeking a declaratory judgment that its label complies with federal law. *Health Sci. Funding, LLC v. FDA*, No. 13-3663 (U.S. Dist. Ct., N.J., filed June 13, 2013). The product at issue, Prastera® brand DHEA, apparently restores DHEA to normal levels in female lupus patients and purportedly minimizes certain risks of the disease.

The company claims that it sought FDA approval of its product label, and the agency responded that it had "serious questions and concerns" about the labeling. While FDA allegedly acknowledged that DHEA helps lupus patients, it said "efficacy alone does not qualify a product to be marketed as a medical food" and noted that products freely available to consumers—such as DHEA dietary supplements—are not "automatically" medical foods under the statute. According to the complaint, "While this statement may be correct, . . . it is not relevant. The question at hand is not whether all dietary supplements in the abstract 'automatically' meet the statutory definition of Medical Food, but whether Plaintiff's particular labeling in fact does so."

The complaint also asserts that "FDA advised that it is 'not aware of any distinctive nutritional requirements' for lupus. FDA's ignorance of lupus patients' requirement for DHEA, however, is not relevant as a matter of law. This is because the statute requires that the 'distinctive nutritional requirement' be established not

by FDA, but by 'medical evaluation'—*i.e.*, by the patient's physician." According to the plaintiff, "FDA ignorance of those medical evaluations . . . is not legally relevant under the statute."

The plaintiff claims that on further discussions with FDA representatives, the agency "threatened enforcement action" while continuing to press its legally irrelevant concerns. The company also claims that the agency "demanded 'immediate remedial action,' but failed to say what remedial action would possibly be needed." In light of these alleged threats and FDA's purported pattern of enforcement against other medical food manufacturers, the plaintiff requests a declaratory judgment "confirming that Plaintiff's product label conforms to the statutory definition of Medical Food articulated in 21 U.S.C. § 360ee(b)(3)." It also seeks an injunction to stop FDA from taking enforcement action.

EMERGING TRENDS

CHPA Adopts Guidelines for Caffeine-Containing Supplements

Following recent U.S. Food and Drug Administration calls for food and dietary supplement manufacturers to include more information about caffeine on product labels, the Consumer Healthcare Products Association (CHPA)—a member-based association representing manufacturers and distributors of over-the-counter medicines and dietary supplements—has approved new voluntary labeling **guidelines** for dietary supplements that contain caffeine. According to CHPA Vice President of Regulatory & Scientific Affairs Barbara Kochanowski, the new guidelines will help "ensure transparency" in labeling and provide information consumers need to "safely choose and use a dietary supplement."

The new guidelines address the labeling, packaging and promotion of caffeine-containing supplements and specifically require CHPA members to (i) disclose total caffeine content per serving, (ii) include a statement on supplements that contain more than 100 mg of caffeine per serving indicating that the product is not intended for children or caffeine-sensitive individuals and that pregnant or nursing women should consult a health care professional before using the product, and (iii) stipulate that caffeine-containing supplements not be marketed, advertised or promoted in combination with alcohol. *See CHPA News Release,* June 21, 2013.

INTERNATIONAL DEVELOPMENTS

Illegal Mercury-Laden Cosmetics for Sale in Philippines

EcoWaste Coalition, a Philippines-based environmental and health watchdog organization, has reportedly discovered that despite a government ban prohibiting their sale, skin-whitening cosmetics containing high levels of mercury—a potent neurotoxin—are available in shops and drug stores in greater Manila.

A series of test buys of imported skin-whitening creams conducted by EcoWaste revealed that seven of 10 products purchased were among those banned by the Food and Drugs Administration in 2010-2013 for purportedly exceeding the allowable limit of 1 part per million for mercury in cosmetics. The group's week-long market surveillance in Makati, Manila and Quezon cities reportedly netted 30 units of mercury-loaded, skin-whitening products representing 22 brands, according to EcoWaste.

"By all accounts, the illicit trade of mercury-laced cosmetics has gone rampant and dangerously out of control despite government efforts," said EcoWaste Acting National Coordinator Aileen Lucero. "National and local authorities undeniably need to flex their muscles, hold illegal importers, distributors and vendors criminally liable, and uphold the consumer right to product safety." Citing World Health Organization information, Lucero warned that exposure to mercury in skin-whitening products can damage the kidneys and cause skin rashes, skin discoloration and scarring, as well as reduce skin's resistance to bacterial and fungal infections.

According to a recent EcoWaste statement, the discovery of the toxic skin-whitening products has prompted one Manila government official to file an ordinance banning the sale of mercury-laced cosmetics and imposing harsh penalties on those caught selling them.

"This unlawful trade of dangerous cosmetics loaded with mercury has been embarrassingly going on for years and has to be stopped once and for all. I'm sure Mayor Erap, Vice-Mayor Isko and my fellow councilors will throw their unequivocal support behind such urgent action to curb mercury exposure from cosmetics and protect public health," said Councilor Numero Lim in a statement.

"The violation of the people's right to health under the guise of fairer complexion and flawless beauty, affecting mostly poor to middle-class women consumers, is intolerable," said Lucero as she appealed to the government to "remove the mercury-tainted skin care products at once." *See EcoWaste Coalition News Releases,* June 16, 18 and 22, 2013.

New Labeling Standard Identifies Eco-Friendly Cosmetics in Australia

Choice Australia (GECA), an independent, not-for-profit organization that focuses on developing sustainable goods and services, has added a new environmental standard to its eco-labeling program to cover personal care products such as soaps, shampoos, oral hygiene products, skin care, cosmetics, and deodorants. Created in response to increasing consumer concerns about the use of palm oil, toxic chemicals and greenwashing in personal care products, GECA reported that the new standard was developed following "extensive consultation" and a public comment period.

Among other things, the new standard includes measures to (i) advance the use of sustainable palm oil; (ii) limit the use of volatile organic compounds; (iii) prohibit purportedly hazardous substances such as "carcinogens, nanoparticles

and sensitisers"; (iv) ensure that environmental claims are verified to discourage greenwashing; and (v) minimize production waste and promote environmentally friendly packaging. See *Good Environmental Choice Australia News Release,* June 19, 2013.

CTPA Responds to Sunscreen Allergy Claims

The UK's Cosmetic, Toiletry and Perfumery Association (CTPA) has issued a statement in response to an episode of British Broadcasting Corporation's (BBC's) Watchdog program that described the allegedly severe reaction a woman experienced two years ago after using a popular brand of sunscreen. According to Watchdog, after conducting multiple tests on numerous patients, doctors and researchers at St. John's Institute of Dermatology in London determined that the patients had suffered from allergic contact dermatitis caused by the chemical C30-38 olefin/isopropyl maleate/MA contained in the sunscreen. Since then, the doctors have urged lawmakers to re-assess the use of the chemical, but despite being identified as a potential allergen, the formulation of the product evidently remains the same, and the label contains no warnings about potential adverse effects.

Watchdog also reported that the original team of doctors has now identified a second ingredient, the preservative Methylisothiazolinone, in the same sunscreen product that may also cause a severe allergy.

According to CTPA, the ingredients highlighted in the program are " legally allowed" and "safely used" in cosmetic products. CTPA Director Chris Flower said, "How our bodies react to substances all around us can vary greatly. 'Allergy' is a term that is often misused to describe all kinds of adverse reactions. In fact there's a big difference between being irritated by a substance and being allergic to it. All cosmetic products must be safe according to strict and robust European law and this includes each product being assessed by a qualified safety assessor that will take account of all the ingredients used, the way the product is manufactured, who will use it and how and any directions for use. " *See CTPA News Release,* June 19, 2013; *www.bbc.co.uk*.

IFRA Updates Fragrance Standards

As part of its ongoing safety program, the International Fragrance Association (IFRA) has announced the 47th amendment to its Code of Practice. According to an IFRA news release, changes include "six new standards based on the Quantitative Risk Assessment methodology; four revised standards; one new standard restricting the use of Furfural; a new group standard prohibiting the use of 2,4-Dienals; 11 revised standards which take into account the contributions of Schiff Bases; and one corrected maximum use level standard." One of the six new standards evidently followed the release of data supporting the safe use of Dihyrocoumarin, a previously banned ingredient.

IFRA's safety program aims to assess fragrance materials and either establish 'Safe Use Levels,' or prohibit their use, based on studying their potential effects on people and the environment. *See IFRA News Release,* June 19, 2013.

ECHA to Review New Substances Under REACH

The European Chemicals Agency (ECHA) has added six new substances of very high concern (SVHC) to the candidate list of chemicals subject to authorization under the European Union's Registration, Evaluation, Authorization and Restriction of Chemical (REACH) substances regulation. They are: cadmium; cadmium oxide; ammonium pentadecafluorooctanoate; pentadecafluorooctanoic acid; dipentyl phthalate; and 4-nonylphenol, branched and linear, ethoxylated. The action followed ECHA's review of comments received during public consultation and documentation substantiating the substances' hazards in accordance with Article 57 of REACH. In some cases, ECHA noted, the substances were identified based on more than one SVHC property.

The Candidate List currently contains 144 substances and, as outlined by REACH, "a specific procedure will be followed to decide when [they] should be included in the list of substances subject to Authorization (Annex XIV of the REACH Regulation). *See ECHA News Release,* June 20, 2013.

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