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LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

CONTENTS

INSIDE GOVERNMENT

USGS, Fish & Wildlife Studying Cosmetics in U.S. Waters

The U.S. Geological Survey (USGS) in Lansing, Michigan, will reportedly update a 2010 study which showed that the amount of cosmetic and pharmaceutical chemicals doubled downstream from an Adrian wastewater treatment plant when compared to an upstream sample. Musk fragrances from beauty products such as lotion and perfume were apparently measured at 200 to 500 nanograms per liter. USGS scientists are now measuring the total load of chemicals from several rivers as they discharge into the Great Lakes, and the new testing site is Monroe. According to a news source, the U.S. Fish and Wildlife Service plans to issue a study later this summer analyzing fish and bird eggs found along the Detroit River to determine whether similar contaminants are present. A Service toxicologist said research is ongoing elsewhere in the United States to study the potential effect of certain chemicals on fish populations. *See Monroe News*, June 24, 2014.

LITIGATION AND REGULATORY ENFORCEMENT

Federal Court Dismisses MDL Consumer-Fraud Claims over GNC Dietary Supplements

A federal multidistrict litigation (MDL) court in Maryland has dismissed without prejudice the consolidated amended complaint filed by eight named plaintiffs after their separate, putative class actions alleging consumer fraud in the advertising and labeling of GNC dietary supplements containing glucosamine hydrochloride and chondroitin sulfate were transferred to the court. *In re GNC Corp. Triflex Prods. Mktg. & Sales Practices Litig.*, MDL No. 14-2491 (U.S. Dist. Ct., D. Md., order entered June 20, 2014). According to the court, the plaintiffs have not sufficiently stated a claim to relief plausible on its face under the standards established in *Ashcroft v. Iqbal*, 556 U.S. 662 (2009) and *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), for the court to reasonably infer that the defendant is liable for the alleged misconduct.

SHB offers expert, efficient and innovative representation to clients targeted by plaintiffs' lawyers and regulators. We know that the successful resolution of health, wellness and personal care product-related matters requires a comprehensive strategy developed in partnership with our clients.

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The plaintiffs alleged that 12 studies have concluded that glucosamine and chondroitin are no better than a placebo in treating symptoms of osteoarthritis of the knee, hip or lower back. They also claimed that "'experts in the field' consider these studies to be an effective proxy for measuring the ability of glucosamine and chondroitin to improve the health and performance of joints in non-arthritic consumers." Because the plaintiffs have not alleged that "experts in the field" would testify that any reasonable expert would reach this conclusion and because they have not alleged that the clinical trial on which the defendants rely does not exist, or does not support GNC's product representations, or exists and supports the label claims but was not conducted "in an appropriately scientific manner," the court characterized the matter as a mere "battle of the experts" that is insufficient "to establish that defendants' advertisements violate the state consumer protection statutes in this case."

In this regard the court stated, "Disagreements between experts, even under the 'reasonable degree of scientific certainty' standard, are to be expected. In my judgment, however, the fact that one set of experts may disagree with the opinions expressed by other qualified experts does not *ipso facto* establish any violation of the applicable consumer protection laws." The court allowed the plaintiffs to file an amended consolidated complaint "if they can do so in accordance with Fed. R. Civ. P. 11," a rule that imposes sanctions on attorneys who sign and file frivolous pleadings.

So ruling, the court declined to address the defendants' challenge to the plaintiffs' standing to assert claims as to products whose labels they did not read or claims under the laws of states other than those in which they made their purchases.

Court Denies Stay in Class Actions Challenging Fat-Destroying Undergarment Claims

A federal court in Massachusetts has denied the motion to stay filed by the defendants in litigation alleging that the companies mislead consumers by claiming that the undergarments they make use a caffeine- and nutrient-infused fabric that destroys fat. *Bellot v. Maidenform Brands, LLC*, No. 14-11834 (U.S. Dist. Ct., D. Mass., order entered June 23, 2014). Additional details about the complaint appear in Issue 24 of this *Report*. The order was without prejudice, however, given the court's allowance of defendants' requests to extend the time to file an answer until August 29, 2014. The defendants had cited a "proliferation of copycat complaints" in their stay requests and indicated that the Judicial Panel on Multidistrict Litigation was scheduled to consider their motion to consolidate the cases on July 31. *See The National Law Journal*, June 11, 2014.

FTC and L'Oréal Settle Gene-Targeting False Advertising Allegations

L'Oréal USA Inc. and the U.S. Federal Trade Commission (FTC) have agreed to settle allegations that L'Oréal advertised its anti-aging Lancôme Génefique and L'Oréal Paris Youth Code lines as capable of targeting genes to reduce the effects of aging without reliable scientific evidence to back up its claims. FTC alleged that L'Oréal claimed its products introduced a "new era of skincare: gene science" and that they were "clinically proven" to "boost genes' activity and stimulate the production of youth proteins" to show "visibly younger skin" in seven days.

"It would be nice if cosmetics could alter our genes and turn back time," said FTC Bureau of Consumer Protection Director Jessica Rich, but ultimately "L'Oréal couldn't support these claims." Under the agreement, L'Oréal is prohibited from claiming that any of its brands' skin-care product lines targets or boosts genes or responds five times faster to aggressors like stress and fatigue unless the representation is true, non-misleading and supported by competent and reliable scientific evidence. A L'Oréal representative reportedly said that the agency did not impose any monetary penalties on the company. *See Law360*, June 30, 2014.

"Diet Queen to the Stars" Fined for Selling Supplements Containing Prescription Drug

A Manhattan magistrate judge has reportedly fined Nikki Haskell and Balanced Health Products Inc. (BHP) $60,000 for distributing StarCaps, a dietary supplement advertised as an "all natural" mix of ingredients such as papaya extract and garlic that also contained undeclared amounts of bumetanide, a prescription drug used to treat heart and renal failure. Haskell, a New York socialite and self-described "Diet Queen to the Stars," sold StarCaps as CEO of now-defunct BHP from 2006 to 2008, when the company voluntary recalled the product.

In the same year, the National Football League (NFL) cited the supplement when suspending six players who tested positive for banned substances such as bumetanide, which can mask steroid use, and later two NFL players sued Haskell and BHP alleging that StarCaps caused their positive test results. In March 2014, Haskell and BHP each pleaded guilty to the misdemeanor of misbranding, which carries a maximum sentence of a $100,000 fine, one year in prison and one year of supervised release for Haskell and a $200,000 fine or twice the gross pecuniary gain for BHP. *See Reuters*, June 20, 2014.

FDA Warns Dietary Supplement Maker About Manufacturing Practice Violations

The U.S. Food and Drug Administration (FDA) has issued a warning letter to a Kansas-based dietary supplement maker, claiming that an investigation has revealed "significant deviations from current good manufacturing practice (CGMP) regulations for dietary supplements."

According to FDA, "[t]hese violations cause dietary supplements manufactured at your facility to be adulterated." Among the alleged violations are failing to (i) prepare and follow a written manufacturing record for each unique dietary supplement formulation the company makes; (ii) include complete information on the production and control of each batch in its batch production record, (iii) "collect and hold reserve samples of each lot of packaged and labeled dietary supplements" that it distributes; (iv) establish certain specifications, make and keep adequate documentation, "fulfill the requirements for reviewing and investigating product complaints," "follow written procedures for handling returned dietary supplements"; and (iv) use hygienic practices to protect against product contamination. A response is required within 15 days of the June 23, 2014, letter date.

INTERNATIONAL DEVELOPMENTS

China FDA Issues Cosmetics Ingredients Inventory

The China Food and Drug Administration (China FDA) has published a final version of its Inventory of Existing Cosmetic Ingredients in China (IECIC 2014 Second Draft Version), which consists of some 8,700 ingredients. The country's Chemical Inspection & Regulation Service recommends that cosmetics companies examine the list, which includes those ingredients allowed to be used because their safety has been assessed as well as approved new cosmetic ingredients, to determine whether their products can be sold in China. According to the IECIC 2014 Second Draft Version, if an ingredient name is a plant abstract—the Latin name—"it means materials come from the whole plant or part of the plant."

Fake Cosmetics-Manufacturing Facilities Sealed in Bangladesh; Truckloads of Goods Destroyed

According to news sources, a mobile court that is part of a Rapid Action Battalion in Bangladesh recently conducted a raid that resulted in the destruction of 10 truckloads of fake toiletries and cosmetic products, the sealing of 17 fake cosmetics-manufacturing facilities in Dakha and a two-year prison sentence for Mohammad Howlader and Sanowar Howlader, the owners of two of the factories. Magistrate Anwar Pasha led the action; he said, "We

conducted a sudden drive at Moina Haji's premises near Matitola Mosque and Chitra Cinema. We found that fake cosmetic goods worth hundreds of thousands of taka were being manufactured there."

One of individuals detained reportedly said that employees would buy empty deodorant bottles from the streets and fill them with fake product before selling them. Another employee apparently told news sources that his job was to paste labels on the deodorant bottles; he also indicated that shampoos were made by mixing coloring and aromatic agents with the liquid soap used in garment factories for washing clothes. The magistrate advised consumers to destroy empty containers after use, saying that the fakes, which had been supplied throughout the country for a long time, could harm the skin and cause hair loss. *See bdnews24.com* and *The Daily Star*, July 8, 2014.

Most Ad Complaints Involving Personal/Health Care Products Upheld in India

The most recent data released by the Advertising Standard Council of India (ASCI) **show** that the largest percentage of complaints upheld (95%--46 advertisements subject to complaint; 44 upheld) were in the personal- and health-care products category. ASCI's Consumer Complaints Council reported that for April 2014 those complaints upheld included advertisements that were "either misleading or false or not adequately/scientifically substantiated" in violation of ASCI's Code. Several ads also violated provisions of the Drug & Magic Remedies Act. The products at issue ranged from those promoted for (i) skin lightening qualities, (ii) the ability to reduce weight and eliminate fat, reduce high blood pressure, improve libido, and cure various diseases, and (iii) provide relief from stress or a cure for stammering.

EU Scientific Committee Seeks Comments on Cosmetic Ingredient Opinions

The European Commission's Scientific Committee for Consumer Safety (SCCS) has issued opinions on four cosmetic ingredients and will accept comments until August 18, 2014. SCCS has concluded that **hydrolysed wheat proteins** (HWPs) are safe in most cosmetic products, with the exception of soaps, due to a higher risk of sensitization. HWPs function as a "surfactant, film-former, foaming agent, hydrating agent, antistatic, and softener in cosmetics." They can also apparently be present in food.

As to 2-(4-(2-(4-Diethylamino-2-hydroxy-benzoyl)-benzoyl)-piperazine-1-carbonyl)-phenyl)- (4-diethylamino-2-hydroxyphenyl)-methanone (**HAA299**), which is used as a UV filter in sunscreen products, SCCS has concluded that it is safe "at a concentration up to 10%" and up to this level "does not pose any risk of systemic toxicity in humans." Mutagenicity risk in consumers "is considered negligible."

The SCCS opinion on acid orange 7 found the substance safe for use in hair dyes up to "a final on-head concentration of 0.8% under oxidative conditions and 0.5% under non-oxidative conditions." Lacking information about the ingredient's concentration, SCCS did not, however, finalize its assessment of the colorant in other cosmetic products, such as eye make-up and eye make-up remover.

Regarding the safety of poly(hexamethylene) biguanide hydrochloride (PHMB), SCCS reached no conclusions. Used as a preservative in cosmetic products at a maximum permitted concentration in the European Union of 0.3 percent, PHMB is apparently useful against "a wide range of Gram positive and Gram negative bacteria, fungi and yeasts and is particularly effective against difficult to control microorganisms such as *Pseudomonas species*." SCCS lacked sufficient data on its genotoxic potential and dermal absorption. Unless SCCS can find PHMB safe for use in cosmetic products, it will be prohibited as of January 1, 2015, because it is classified as carcinogenic, mutagenic and reprotoxic.

EC Conducts Public Consultation on Transparency Measures for Nanomaterials

The European Commission (EC) has launched a public consultation seeking stakeholder views as to whether available information about the presence of nanomaterials and products containing them currently on the market is sufficient "for an adequate response to health and environmental risks and for informed consumer choice." A related workshop took place in Brussels at the end of June, and stakeholder comments are requested by August 5, 2014.

A workshop presentation explaining the current nanomaterial legislative framework and an introduction to the EC's impact assessment on transparency measures estimated that direct employment in nanotechnology represents 300,000 to 400,000 jobs with an economic impact of some €20 billion. Under a 2009 regulation, the EC must be notified of cosmetic products containing nanomaterials six months before marketing, including safety data and a toxicological profile. The regulation also provides that a catalog of all such products placed on the market be made available.

EMERGING TRENDS

China Removes Animal-Testing Requirements for Some Cosmetics

According to news sources, the China Food and Drug Administration stopped requiring animal tests on ordinary cosmetics, such as shampoos and certain skin-care products, as of July 1, 2014. To demonstrate product safety, manufacturers may instead use alternative methods relying on existing ingredient toxicology or tissue culture data when they conduct their risk assessments.

While the rule does not apparently apply to imported products or special-use products such as hair dyes and sunscreens, animal welfare advocates still welcomed the change.

Some cosmetics companies, including Lush and Urban Decay, do not sell their products in mainland China, refusing to compromise their standards. Other companies do export to this market; China's cosmetic imports reportedly grew more than 10 percent from the year before to $1.7 billion in 2013. A Lush spokesperson said, "Lush and other cruelty-free companies are still unable to trade in China currently, as this legislation does not allow for fully non-animal tested cosmetics to come to market. We look forward to further progressive legislation in this area which . . . would allow Chinese cosmetics companies to trade into Europe and allow us to operate cruelty free in China." *See The New York Times*, June 30, 2014; *Humane Society International News Release*, July 1, 2013; *CosmeticsBusiness.com*, July 8, 2014.

SCIENTIFIC/TECHNICAL DEVELOPMENTS

MI in Cosmetics Raises Allergen Concern

A French researcher has apparently found that methylisothiazolinone (MI), an antimicrobial widely used in cosmetics and in occupational and household products, is responsible for contact allergies in Europe at a 5.6 to 6-percent prevalence rate. F. Giordano-Labadie, "Methylisothiazolinone: An emerging allergen," *Revue Française d'Allergologie*, June 2014. According to the study abstract, "For these reasons, MI at a concentration of 2000ppm in water has recently been included in the European baseline series. Regulatory measures concerning cosmetics are now being discussed at the European level."

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