Shook, Hardy & Bacon L.L.P.

ISSUE 26 | JUNE 6, 2014

LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

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INSIDE GOVERNMENT

Senators Join FDA Sunscreen Fight

Joining a bipartisan group of lawmakers that aims to streamline the U.S. Food and Drug Administration's (FDA's) approval process for sunscreen ingredients, some of which have reportedly been awaiting review for 12 years, U.S. Sens. Kelly Ayotte (R-N.H.) and Sheldon Brown (D-Ohio) have recently announced their support for the Sunscreen Innovation Act.

Disappointed with what they deem a "lethargic review process," the senators note that the last over-the-counter sunscreen ingredient was approved in the 1990s and eight ingredients have been awaiting approval for more than 10 years. Most of the ingredients have apparently been widely used for years in Europe and Asia and are generally considered safe and effective. In many cases, the senators observe, sunscreen products available in other countries protect against UVA rays far better than many American products. "It is unconscionable that better sunscreen products, made in America, are not available to help our citizens avoid skin cancer," said Brown. "The FDA's review backlog of more than a decade is unacceptable and puts lives at risk. This bipartisan legislation would eliminate the red tape that hurts the health and well-being of Americans and limits economic opportunity for our local businesses."

If passed, the Sunscreen Innovation Act would require FDA to decide on new sunscreen applications within 11 months or less, depending on whether they are new or existing applications. Under current law, there is no mandatory timeline for this process. *See TheHill.com*, May 21, 2014; and *Time.com*, May 30, 2014.

Meanwhile, U.S.-based company Osmosis Skincare claims to have invented the world's first drinkable sunscreen that allegedly provides protection comparable to an SPF 30 lotion by making water molecules beneath the skin "vibrate" to cancel out harmful rays. The product, called Harmonized H20, purports to grant sun protection for approximately three hours. *See Time*, May 27, 2014.

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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.

For additional information on SHB's Health, Wellness & Personal Care Products capabilities, please contact

Debra Dunne
215-278-2555
ddunne@shb.com

Laurie Henry
816-559-2421
lhenry@shb.com

Madeleine McDonough
816-559-2342
mmcdonough@shb.com

If you have questions about this issue of the Update, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.

FDA to Require Warnings on Tanning Beds

The U.S. Food and Drug Administration has **issued** a final order, effective September 2, 2014, reclassifying sunlamp products such as tanning beds and booths, and ultraviolet (UV) lamps, from low-risk (class I) to moderate-risk (class II) devices.

Aimed at reducing rising rates of skin cancer purportedly linked to the radiation-emitting devices, the order will also require sunlamp products to bear warnings explicitly stating that the product should not be used by people younger than age 18. In addition, manufacturers must (i) provide warnings in marketing materials, such as pamphlets, catalogs and Websites, about cancer risks and caution that the devices should not be used by people who have had skin cancer or have a family history of the disease; and (ii) conduct premarket testing to show that products meet "certain performance requirements and address certain product design characteristics." *See Federal Register*, June 2, 2014.

Legislation Banning Microbeads Passes California Assembly

The California Assembly has approved legislation that would prohibit the manufacture and sale of personal care products that contain plastic microbeads—tiny, non-biodegradable plastic particles often added to facial scrubs, body cleansers and toothpastes—beginning January 1, 2019. The move follows similar actions already taken by personal care product manufacturers and other state legislatures (New York and Illinois—details about which appear in Issues **20** and **24** respectively, of this *Report*) to ban the use of microbeads in cosmetics. Sponsored by Assemblyman Richard Bloom (D-Santa Monica), the "Microplastic Nuisance Prevention Law," (**AB 1699**) passed in a 45 to 10 vote and will next move to the state Senate. If passed, the bill would fine violators $2,500 per day.

Considered an increasing environmental threat because they can slip past water treatment filters and end up in rivers and lakes, studies have shown that microbeads can absorb toxins such as polychlorinated biphenyls, phenanthrene and triclosan, and be passed on to fish and other wildlife, as well as humans. Dozens of California-based organizations were reportedly involved in the bill's passage, including advocacy groups 5 Gyres Institute, Clean Water Action and the Campaign for Safe Cosmetics. *See EcoWatch.com*, May 24, 2014.

LITIGATION AND REGULATORY ENFORCEMENT

China Asks U.S. State Department for Support in Vitamin C Price-Fixing Appeal

The Chinese government has asked the Second Circuit Court of Appeals to take judicial notice of a diplomatic note its embassy sent to the U.S. State Department voicing China's concerns about a vitamin C price-fixing case and urging the U.S. government to file an amicus brief asserting that foreign governments' formal statements about the interpretation of their own laws should be conclusive in U.S. courts. *Animal Sci. Prods. Inc. v. HeBei Welcome Pharm. Co. Ltd.*, No. 13-4791 (2nd Cir., motion filed May 23, 2014).

The class action stems from claims that Chinese vitamin C manufacturers fixed prices and limited supply through an illegal cartel. China's Ministry of Commerce (MOFCOM) has been involved in the 10-year case since 2008, arguing to U.S. courts that the defendant companies were participating in a Chinese trade group system required to maintain their export licenses. Despite MOFCOM's argument and the companies' invocation of the foreign sovereign compulsion doctrine, a U.S. district court allowed the case to proceed. A jury awarded the plaintiffs $54.1 million, which the court later trebled to $153.3 million plus an additional $4 million in attorney's fees. On appeal, MOFCOM filed an amicus brief arguing that the trial court failed to follow U.S. Supreme Court precedent on the interpretation of foreign law, and, in its note to the State Department, the embassy "urges the U.S. administration also to file a brief in the court of appeals in support of China's positions."

Putative Dietary-Supplement Class Dismissed for Pleading Deficiencies

A federal court in California has dismissed claims filed against GNC Holdings because the plaintiff failed to allege under the Class Action Fairness Act that she is a citizen of a state different from any defendant and because she failed to establish that the amount in controversy exceeded the $5-million jurisdictional minimum; the complaint alleges that the company deceives consumers by making false claims about the effects on human health of the L-Arginine in its Pro Performance Rapid Drive Arginine 5000 product. *Hirmez v. GNC Holdings, Inc.*, No. 13-1828 (U.S. Dist. Ct., S.D. Cal., order entered May 27, 2014).

In granting the defendant's motion to dismiss with leave to amend, the court explained how the complaint sets forth the plaintiff's residency but not her citizenship, "a fatal flaw by itself, if not corrected." It also noted that the complaint failed to specify the day of her purchase, the price of the product and how much she paid. A screen shot of products attached as an exhibit is not further elaborated in the complaint, according to the court. Even so, it reflects two prices: $39.99 and $23.97. And because the plaintiff alleges only that the class is composed of "thousands of persons geographically dispersed,"

the court observed that, without more, and assuming 2,000 class members and a product without any value, "the aggregate amount in controversy would be only $79,980" at the $39.99 price. Nine thousand class members would bring the amount in controversy to just $359,910, "still well below the jurisdictional minimum of $5,000,000."

With these issues dispositive, the court declined to address the parties' remaining arguments. An amended complaint, if any, must be filed by June 20, 2014.

London Court Rejects Claim That Glucosamine Supplements Are Medicinal

The Administrative Court of the U.K. High Court of Justice, Queen's Bench Division, has determined that the Medicines and Healthcare Products Regulatory Agency (MHRA) has acted appropriately in denying the request of drug makers to classify all glucosamine-containing products (GCPs) as medicines under the Medicines Directive. ***Blue Bio Pharms. LTD v. MHRA*, No. [2014] EWHC 1679 (Admin., decided May 22, 2014)**.

The court also denied the drug makers' request that all GCPs with a daily recommended dose of 1500 mg be declared medicines, MHRA's decision not to take enforcement action against all such GCPs be quashed and MHRA's policy "of failing to conduct any case by case analysis as to whether unauthorized GCPs fall within the functional limb of the definition of medicinal products" be declared unlawful.

According to the court, unauthorized GCPs have been sold as food supplements throughout the United Kingdom and Europe for many years and currently account for some one-fifth of all sales of GCPs dispensed by pharmacists in response to GCP prescriptions. The drug makers, whose GCP products are regulated as medicines with MHRA's approval, first brought the unauthorized GCP issue to MHRA's attention in 2010; the agency thereafter noted that it had taken action against 186 products that made medicinal claims, but refused to take action against other unauthorized GCPs that did not make medicinal claims. Approached by the drug makers again in 2012, MHRA issued a "decision letter" in March 2013 rejecting the claim that all GCPs with the same active ingredient and dosage as their drug are necessarily medicines or that MHRA had acted illogically or unlawfully. According to MHRA, "our powers do not extend to requiring non-medicinal products to be labelled with statements that they are non-effective or that they are not medicines." MHRA also emphasized that any individual product considered to be a medicinal product "will be subjected to appropriate and proportionate regulatory action."

Examining the relevant medicines and food law requirements, the court determined that MHRA had acted appropriately because it was required to determine whether a product falls within the medicines definition

on a case-by-case basis and "cannot apply a 'general rule . . . applicable without distinction' or 'applied systematically to all products.'" Among other matters, the court noted that "the purpose for which a product is used and/or marketed ('the manner in which it is used') is often a critical factor in distinguishing between medicinal and non-medicinal products." If a GCP product is sold as a "food supplement" and does not claim to prevent, treat or cure a human disease, it cannot be regulated as a medicine, in the court's view. It further noted that all relevant characteristics must be considered in "borderline" cases, and MHRA is best positioned to apply the appropriate multi-factorial test in each case based on "a mixture of factual and scientific considerations."

The Health Food Manufacturer's Association (HFMA) executive director said, "We are very pleased with the outcome of this highly significant case, which had a very real capacity to have a profound impact on the future for our members, this industry and, perhaps most significantly, consumer choice. We have argued vigorously throughout the case that the current food supplement status for glucosamine should be maintained." *See HFMA Statement*, May 20, 2014.

Online Marketer Accused of Sharing Supplement Company's Trade Secrets

Dietary supplement maker Lepton Labs LLC has reportedly filed a lawsuit in California state court against its former marketer, W4 LLC, alleging that the marketing company shared all of Lepton's creative materials with a direct competitor. *Lepton Labs LLC v. W4 LLC*, No. BC546011 (Cal. Super Ct., Los Angeles Cnty. Central Dist., filed May 16, 2014).

Lepton claims that following an agreement making W4 the sole promoter of Lepton's AllDaySlim supplement, W4 "breached numerous contractual obligations and undertakings owed to plaintiffs when they elected to assist and work directly with" Gulf Rayz Media LLC to market its SlimBlastFast supplement, a direct competitor of AllDaySlim. W4 allegedly emailed Gulf Rayz all of Lepton's creative work, and Gulf Rayz then mimicked Lepton's logos, designs and satisfied customer quotations. Lepton learned of the alleged infringement because W4 failed to remove the Lepton customer service number from the Gulf Rayz Website, resulting in Lepton receiving calls from customers inquiring about SlimBlastFast. Lepton asserts several antitrust, breach of contract and intellectual property claims and seeks $2 million in damages and injunctive relief.

Legal Malpractice Claims Arise Out of Chinese Herb Products-Liability Suit

Companies and individuals sued in an Illinois state court (Drury Litigation) as the manufacturers of Chinese herbs that allegedly contained aristolochic acid (AA) and caused the kidney failure and death of a consumer have filed a legal malpractice action against the firm and attorneys they retained to defend them. *Life Rising Corp. v. Probst*, No. 2014L005633 (Cook Cnty. Cir. Ct., Ill., filed May 27, 2014).

Alleging legal malpractice, breach of fiduciary duty and fraud, the plaintiffs contend that the attorneys incorrectly designated them as the product manufacturers in pleadings; ignored a motion to compel discovery responses; failed to respond to requests to admit, a motion for discovery sanctions or a motion for partial summary judgment; and engaged in mediation and signed a $2.5-million settlement agreement, all without allegedly informing the plaintiffs. They have, to date, been unable to reverse any of the adverse rulings entered against them and seek to recover the costs incurred in that effort.

According to the complaint, "Any liability in the Drury Litigation is solely the result of Defendants' malpractice. Plaintiffs had viable defenses in the Drury litigation that are now foreclosed by the sanctions and orders described above. . . . None of the defendants are the manufacturers of the products at issue and should have been dismissed from the product liability counts under the distributor statute. Post-suit testing by Plaintiffs of their products shows no AA present in any product, and while the Drury plaintiff claims to have one lab result showing the presence of AA, Plaintiffs are now foreclosed from testing that claim in any way much less disproving it." The plaintiffs also allege that one of the attorneys they have sued said under oath that she had never handled product-liability litigation before and she was "overwhelmed by pressure and froze."

INTERNATIONAL DEVELOPMENTS

India to Ban Import of Animal-Tested Cosmetics

India's Ministry of Health & Family Welfare has reportedly introduced a draft rule, further amending the country's Drugs and Cosmetics rules, which were revised June 2013 (details about which appear in Issue 6 of this *Report*) to prohibit the testing of domestically produced cosmetics and their ingredients on animals. If passed, the new rule would ban the import of any cosmetic, or any article intended for use as a cosmetic component, that has been tested on animals. The rule was drafted in consultation with India's Drugs Technical Advisory Board and, if implemented, will make India the first country in South Asia to do so. The action aligns India with the European Union, which has banned animal-testing and the sale of animal-tested cosmetics regardless of where the tests have been conducted. *See DeccanChronicle.com*, May 11, 2014.

EC Issues Report on Labeling and Reporting Regulations for Nanomaterials

The European Commission's (EC's) Joint Research Center (JRC) has **issued** a report outlining concerns related to labeling and reporting regulations for nanomaterials in consumer products, including cosmetics, in the European Union (EU). Although the safety of products containing nanomaterials is regulated by several EU legal acts that address chemicals and products in general, including the Nanomaterial Annexes to the regulations governing the Registration, Evaluation, Authorisation and Restriction of Chemicals, the Classification and Labeling of Products Regulation and the General Products Safety Directive, several stakeholders—the European Parliament and some EU member states and non-governmental organizations—have requested more transparency and traceability concerning potential risks.

Noting that (i) information requirements and transparency measures (labeling/product register) should be based on an (internationally) harmonized definition of nanomaterial for legal clarity and enforceability, and (ii) accurate labeling and affordable monitoring is "complicated," the report suggests, among other things, that "further developments and standardization in nanomaterial detection and characterization methods are needed and reference materials for reliable metrology at the nanoscale are necessary.

Australian Advocacy Group Calls for Ban on Nanomaterials

Australian environmental group Friends of the Earth (FOE) has **issued** a report that calls for a ban on the sale of all products, including cosmetics, that contain nanomaterials until "adequate regulation is in place to manage the health and environmental risks of nanotoxicity."

Noting that the number of products in Australia containing nanomaterials is rapidly growing, despite scientific evidence suggesting that such materials could potentially harm humans, and that Australian companies have "virtually no restrictions" on the import of nanomaterials or the products containing them, report author Jeremy Tager said that "in order to protect the health of the public you [need to] treat new technologies with a level of precaution until you've established they're safe."

Among other things, the report recommends (i) a moratorium on the production and sale of new products containing nanomaterials until further research is conducted and regulations to protect human health and the environment are in place; (ii) a mandatory and public register of all nanomaterials and all products containing nanomaterials produced, imported and sold or used in Australia; (iii) a "comprehensive and precautionary regulatory regime" whereby all nanomaterials are subject to environmental health and safety assessments as new substances; and (iv) all products containing nanomaterials for sale in Australia be labeled as such. *See TheSydneyMorningHerald.com*, May 22, 2014.

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SCIENTIFIC/TECHNICAL DEVELOPMENTS

Scientists Study Nanoparticles in Areosol Products

A study by Swiss and Dutch researchers has called for the development of higher standards to evaluate the potential risks posed by consumer aerosol sprays—often used in personal care products—containing nanoparticles. Sabrina Losert, et al., "Human Exposure to Conventional and Nanoparticle-Containing Sprays—A Critical Review," *International Journal of Nanomedicine*, April 29, 2014.

Noting that the number of products containing manufactured nanoparticles and their agglomerates and aggregates has increased during the past 10 years from a few to several hundred, the researchers observe that while numerous studies examining pesticide release from aerosol products exist, there are fewer studies concerning nanoparticle release even though such studies are "critical" for consumers because inhalation exposure to potentially toxic nanoparticles can occur.

The scientists contend that, although there has been some focus on regulations related to cosmetic aerosol products, generally, there has been a shift away from labeling nanoparticles across all consumer spray products. Among other things, the researchers recommend (i) improved techniques for determining the size of nanoparticles inside spray droplets; (ii) improved reporting, including more information on the experimental setting and on the types of spray cans used; and (iii) a "standardized" experimental setup.

OFFICE LOCATIONS
Denver, Colorado
+1-303-285-5300
Geneva, Switzerland
+41-22-787-2000
Houston, Texas
+1-713-227-8008
Irvine, California
+1-949-475-1500
Kansas City, Missouri
+1-816-474-6550
London, England
+44-207-332-4500
Miami, Florida
+1-305-358-5171
Philadelphia, Pennsylvania
+1-215-278-2555
San Francisco, California
+1-415-544-1900
Seattle, Washington
+1-206-344-7600
Tampa, Florida
+1-813-202-7100
Washington, D.C.
+1-202-783-8400

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Shook, Hardy & Bacon attorneys counsel consumer product manufacturers on FDA, USDA and FTC regulatory compliance and risk management issues, ranging from recalls and antitrust matters to facility inspections, labeling, marketing, advertising, and consumer safety. The firm helps these industries develop early legal risk assessments to evaluate potential liability and develop appropriate policies and responses to threats of litigation or product disparagement. The firm's lawyers also counsel manufacturers on labeling audits and a full range of legal matters such as U.S. and foreign patent procurement; licensing and technology transfer; venture capital and private financing arrangements; joint venture agreements; patent portfolio management; research and development; risk assessment and management; records and information management issues and regulations; and employment matters, including confidentiality and non-compete agreements.

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