Shook, Hardy & Bacon L.L.P.

ISSUE 2 | MAY 10, 2013

LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS
• DIETARY SUPPLEMENTS
• NUTRACEUTICALS

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INSIDE GOVERNMENT

NIOSH Sets Nanomaterials Exposure Level

The National Institute for Occupational Safety and Health (NIOSH) has set exposure guidelines (current intelligence bulletin [CIB 65]) for nanotechnology fibers at "one microgram per cubic meter of air per eight-hour workday." According to environmental health sciences experts, anything below that limit cannot be measured. While the CIB acknowledges that animal studies may not indicate "whether similar adverse health effects occur in humans following exposure to CNT [carbon nanotubes] or CNF [carbon nanofibers], or how airborne CNT in the workplace may compare in size and structure to the CNT aerosols generated in the animal studies," because adverse respiratory health effects have been observed in lab animals, NIOSH recommended an exposure limit for CNT and CNF "to help minimize the risk of occupational respiratory disease in workers." *See USA Today,* April 26, 2013.

ANSI Circulates Draft Nanotechnology Standards Panel Meeting Report

The American National Standards Institute (ANSI) has circulated a draft report of its most recent Nanotechnology Standards Panel meeting. Established in 2004, the panel facilitates nanotechnology standards development, with an initial focus on terminology and nomenclature, to develop a common language for different industry sectors. Most attendees were from government or standards agencies, although several trade group representatives and academics were also present, including a representative from the Personal Care Products Council; they discussed what it would take to increase participation by stakeholders and referred to ANSI's Standards Boost Business initiative as a model for showcasing the benefits of participation in nanotechnology standardization activities.

Other issues addressed during the meeting included (i) questions about adapting the current National Nanotechnology Initiative definition of nanotechnology to "accommodate the biological impacts of larger size particles," referred to as the "nano-bio interface"; (ii) the European Union's requirement for labeling "nano" food starting in 2014 and distinctions in the EU between the definition of "nano" in foods and the Cosmetics Directive definition; (iii) a Consumer Product Safety Commission acknowledgement that more robust

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data are needed for agencies to understand how to assess potential exposures and toxicity of nanomaterials; and (iv) the need for validated measurement methods to advance standardization efforts.

Scientists Push for Global Action on EDCs

A group of scientists has written a **letter** to the United Nations Environment Program (UNEP), World Health Organization (WHO), Organization for Economic Cooperation and Development, and Strategic Approach to International Chemicals Management, urging the agencies to take "swift action to prevent harm from a wide variety of synthetic chemicals in consumer products and pesticides that play a role in increased incidences of reproductive diseases, cancer, obesity, and type-2 diabetes worldwide." The scientists include authors of a recent WHO/UNEP report that underlines the "urgent need for global action to address the dangers of hormone or endocrine disrupting chemicals (EDCs)," according to an Endocrine Society news release. The scientists' action is part of a growing international effort to identify and control the chemicals that allegedly affect endocrine systems in humans and wildlife; more than 100 countries are reportedly engaged in a process to develop a global plan for the safe management of chemicals.

The scientists recommend several key principles to guide regulatory efforts in this area, including (i) a clear definition of EDCs—"endocrine disrupting chemicals are chemicals, or chemical mixtures, that interfere with normal hormone action"; (ii) vulnerability of living organisms—"hormones and their signaling pathways are critical for normal functioning in all vertebrates and invertebrates"; (iii) EDC effects occur at low doses—"many EDC effects occur at low doses even when high dose effects are not apparent"; (iv) EDCs can affect future generations, and timing of exposure is key—"the most sensitive period is during periods of development, from the fetal and post-natal periods, which can extend into infancy and childhood for some tissues"; (v) exposure to EDC mixtures may be different than exposure to single substances—"humans and animals are exposed to complex mixtures of hundreds of EDCs"; and (vi) the Precautionary Principle is key—"decision-making should err on the side of precaution." *See The Endocrine Society News Release,* April 23, 2013.

Supplement Associations Seek Revised Draft Guidance on NDI Ingredient Identity

Five associations representing the dietary supplement industry have reportedly asked the Food and Drug Administration (FDA) to issue revised guidance on new dietary ingredient (NDI) notifications, with a specific focus on information to identify the new dietary ingredient.

Making the request were the American Herbal Products Association, Council for Responsible Nutrition, Consumer Healthcare Products Association, Natural Products Association, and United Natural Products Alliance.

Of particular concern to the groups is that "FDA's rule on NDI notifications . . . does not specifically state what information should be provided to the agency on the identity of the ingredient that is the subject of an NDI notification. Yet the most common objection communicated by FDA in its responses to NDI notifications is that the agency 'is unable to establish the identity' of the dietary ingredient that is the subject of the notification."

"This is clearly an area in which guidance is needed by the regulated supplement industry," said AHPA President Michael McGuffin. "We are therefore requesting that FDA prioritize its attention to this specific issue and provide the industry with clarity on this matter."

Earlier comments submitted by each trade association to FDA's June 2011 draft guidance, "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues," were reportedly critical. In June 2012, FDA then informed the associations that the agency was planning to promulgate revised draft NDI guidance and would permit additional industry input.

"Other issues raised by FDA's 2011 draft NDI guidance are still concerning to the supplement industry," said Steve Mister president and CEO of the Council for Responsible Nutrition. "We will continue our active dialogue with FDA until each of these is resolved. But in the meantime, it benefits both the industry and FDA to move forward on the topics where there is agreement. What constitutes an adequate description of the ingredient in an NDI notification is one of those issues where the trade associations and FDA are likely to agree." *See Council for Responsible Nutrition Press Release,* May 6, 2013.

Minnesota House Passes Ban on Formaldehyde in Children's Products

The Minnesota House of Representatives has passed legislation (H.F. 458) that would prohibit manufacturers from "intentionally" adding formaldehyde to children's personal care products such as lotions, shampoos and bubble bath for children younger than age 8. The legislation was passed in a 113-13 vote and now moves to the desk of Governor Mark Dayton (D). If it is approved, the ban would take effect August 1, 2015.

"There's no reason for formaldehyde-releasing chemicals to be in products that children inhale and absorb through their skin" said Kathleen Schuler, co-director of Healthy Legacy, the Minnesota environmental health coalition supporting the legislation. "Safer alternatives are available and being used by some manufacturers. This bill takes an important step in protecting young children who could suffer health effects from exposure to toxic formaldehyde." *See Campaign for Safe Cosmetics News Release,* May 6, 2013.

LITIGATION & REGULATORY ENFORCEMENT

Putative Class Claims "24-Hour" Makeup Does Not Work

A woman who purchased a L'Oréal foundation product advertised to last for 24 hours has sued the company and its parent on behalf of a class of purchasers, alleging that it did not perform as promised, that is, "retouch free," "perfectly flawless" and providing "24 hour lasting perfection and comfort." *Weisberg v. L'Oréal USA, Inc.*, No. 13-2851 (U.S. Dist. Ct., S.D.N.Y., filed April 30, 2013).

Orthodox Jewish plaintiff Rorie Weisberg, who cannot apply makeup during the Sabbath, a 24-hour period from sundown Friday to sundown Saturday, reportedly hoped to be able to use the product for her son's Bar Mitzvah. She tested it from sundown Thursday to sundown Friday and "felt that the product made her skin look very cakey" when applied. She alleges, "[b]y Friday morning, plaintiff's skin was shiny, particularly around her nose. Moreover, the product that had been applied had faded significantly, making plaintiff's face look uneven. It looked like very little of the product was remaining on plaintiff's face, which was confirmed when she removed the remainder of the product at 3 p.m. with a white cotton ball, where very little of the product was found on the pad."

Claiming that she "did not receive the benefit of longwearing efficacy as claimed by Lancôme in its advertising and on the product packaging," Weisberg alleges breach of express warranty, unjust enrichment and business law violations. Meanwhile, a biochemist with a cosmetics company for customers who cannot apply makeup during the Sabbath reportedly said of the suit, "I hope a judge will look at it and throw it in the garbage. There's no way you can guarantee things on everyone's skin. All we can do is let you try the product. Everybody's skin is different, and who knows if she put it on right?" A Lancôme spokesperson reportedly indicated that the company "strongly believes that this lawsuit has no merit and stands proudly behind our products." The company plans to "strenuously contest these allegations in court." *See abcnews.go.com*, May 2, 2013; *Courthouse News Service*, May 3, 2013.

Athletic Training Supplement Allegedly Fails to Deliver Benefits

A California resident has filed consumer fraud claims against the Vitamin Shoppe, Inc., on behalf of a putative statewide class of individuals who purchased the company's True Athlete Training Formula® expecting that it would, as advertised, build muscle and enhance athletic performance. *Hodges v. Vitamin Shoppe, Inc.*, No. 13-2849 (U.S. Dist. Ct., N.D. Cal., filed April 23, 2013). According to the complaint, the product's ingredients are either useless for "enhancing athletic performance, improving cardiovascular function, or building muscle" or are present at such low levels that they cannot provide the benefits advertised even at the recommended "dosage" levels.

The ingredients on which the complaint focuses are L-Arginine Alpha Ketoglutarate (AAKG), Creatine Monohydrate (CM), Beta-Alanine (Carnosyn®), and AstraGin™. The plaintiff contends that he paid more for the product based on the "false and misleading labeling claims" and would not have purchased the product "absent these claims and advertisements." He alleges violations of the California Business and Professions Code ("unlawful, unfair or fraudulent business act or practice"), California Legal Remedies Act and False Advertising Law; breach of express warranty; and unjust enrichment. And he asserts violations of the federal Food, Drug, and Cosmetic Act and California's Sherman Food, Drug, and Cosmetic Law. Seeking to restrain and enjoin the defendant from "continuing to use these deceptive sales tactics," the plaintiff also seeks compensatory, consequential, special, statutory, and punitive damages; interest; delay damages; attorney's fees; and costs.

NAD Recommends InterHealth Modify Advertising for Supplement

According to a news source, The National Advertising Division (NAD)—an investigative unit of the Council of Better Business Bureaus—has recommended that InterHealth Nutraceuticals, Inc., discontinue claims that its Zychrome® dietary supplements promote healthy insulin levels.

Evidently, claims made by InterHealth for its Zychrome® chromium compound, also known as chromium dinicocysteinate (CDNC), were challenged by Nutrition 21, LLC, which manufactures a competing chromium picolinate product, called Chromax®. Among other things, InterHealth claimed that its product is (i) "the only form of chromium clinically shown to be twice as effective as chromium picolinate for managing insulin levels"; (ii) "2x more effective than chromium picolinate in improving insulin function;" (iii) "the most effective chromium to date"; (iv) "more effective than other chromium compounds for modulating glycemic parameters"; and (v) preferred by 88 percent of diabetic educators over chromium picolinate for insulin management.

According to NAD, InterHealth made its claims based on a single study "in which differences between the Chromax and Zychrome groups did not reach statistical significance for any variable measured and did not rely on head-to-head test results to support its comparative efficacy claims." NAD recommended that InterHealth discontinue the claims at issue. *See ASRC News Release,* April 23, 2013.

EMERGING TRENDS

Avon Shareholders Reject Request to "Ditch Toxic Cosmetics"

According to a Securities and Exchange Commission report, Avon Products, Inc. shareholders have rejected a proposal filed by Green Century Equity Fund asking the company to remove hazardous chemicals from its cosmetics. The vote garnered more than 260 million against the proposal and nearly 58 million

in favor of it. Green Century Equity Fund is an index "comprised of the stocks of approximately 400 companies selected using environmental, social and governance criteria."

According to the Campaign for Safe Cosmetics (CSC), a coalition of activist organizations, the request called on Avon to "substitute safer alternatives for dangerous chemicals used in their beauty products that have been linked to cancer, reproductive harm, and other serious diseases."

CSC noted that Avon "has taken some steps to eliminate dangerous chemicals from its products in the past," citing a 2004 announcement that the company would comply with the European Union ban on dibutyl phthalate, a 2005 announcement that it would no longer use diethyl phthalate in its fragrances and a 2010 company ban on the use of propyl and butyl parabens in new product development.

Avon products, however, "still contain chemicals linked to cancer, as well as chemicals known to disrupt hormones, which may adversely affect healthy body functioning," said CSC. "Of particular concern," noted the agency, "are parabens, a class of hormone-disrupting chemicals, and sodium laureth sulfate, which may be processed using ethylene oxide, a known breast carcinogen."

CSC also cited triethanolamine, an ingredient it found "in several Avon children's products [that] can break down into nitrosamines, carcinogenic chemicals [that are] banned from cosmetics in Europe and Canada."

Global Personal Care Products Industry Expected to Hit $630 Billion by 2017

International research firm Research and Markets has issued a report which observes that the "global personal care products industry" has experienced "good growth" during the past five years and "is expected to reach approximately $630 billion in 2017." Titled the "Top Five Global Personal Care Products Manufacturers: Performance, Strategies and Competitive Analysis," the report provides "detailed insight into the performance of the top five personal care products companies across the world, and cites rising population, [an] increase in household disposable income and changing spending habits in recent years among the reasons for the increased demand in the industry."

Meanwhile, market research firm Global Information, Inc. (GII) reports that cosmeceuticals have become the "fastest growing" segment of the cosmetics and personal care industry and are estimated to reach "$31.84 billion by 2016." In a report titled "Global Cosmeceuticals Market Outlook 2016," GII observes that several factors are contributing to the growth, including "advancements in technology and the emergence of new ingredients . . . ."

Among other things, the report finds that (i) skin and hair care represent key segments in the cosmeceuticals market; (ii) tooth whitening and lip protection products are "emerging as key segments with significant growth";

and (iii) "research into new ingredients, such as stem cell and peptides for skincare-based cosmetics" is expected to play a dominant role in the market. *See The Wall Street Journal,* May 3, 2103; *Global Information, Inc.* News Release, April 10, 2013.

ETS Exposure Assessment Expert Takes on Cosmetics Safety

University of California, Berkeley School of Public Health researchers, including environmental tobacco smoke (ETS) exposure assessment and anti-tobacco expert S. Katharine Hammond, have published a study addressing the concentrations of lead, aluminum, cadmium, cobalt, chromium, copper, manganese, nickel, and titanium in lipsticks and lip glosses. Sa Liu, S. Katharine Hammond & Ann Rojas-Cheatham, "Concentrations and Potential Health Risks of Metals in Lip Products," *Environmental Health Perpsectives*, May 2, 2013.

Concluding that "[t]his preliminary study of metal content of 32 lip products suggests that toxic metals in cosmetics should be regulated to protect women's health in the US, as has already been undertaken by the European Union through their Cosmetics Directive," the researchers apparently found that most of the products tested "contained high concentrations of titanium and aluminum." All of the products had detectable manganese, and lead was found in three-fourths of the products, "including one sample with 1.32 ppm."

Estimated average daily rates of use would result in >20 percent of acceptable daily intakes (ADIs) for aluminum, cadmium, chromium, and manganese, and average daily use of 10 products "would result in chromium intake exceeding our estimated ADI for chromium." The researchers also purportedly found that for high rates of product use "the percentages of samples with estimated metal intakes exceeding ADIs were 3% for aluminum, 68% for chromium, and 22% for manganese." Lead intakes were reportedly <20 percent of ADIs for average and high use.

The UK's Cosmetic, Toiletry and Perfumery Association (CTPA) released a statement in response to the report, claiming that the industry is "confident in the safety of our lip products," noting that the researchers "found minute levels of metals in many of the products they reviewed." According to CTPA, "[t]he levels of impurities found in the US study are exceedingly small and, despite the suggestions otherwise, they are not present at levels in the lip products that would cause harm either now or in the future." The trade organization claims that all cosmetics and personal care products "made in or imported into the UK and Europe must be safe" and that the presence of trace metals is not surprising "as these are natural elements that make up the environment in which we live." *See CTPA News Release*, May 2, 2013.

Increased Intake of Folate, Vitamin B12 and Methionine May Lower Breast Cancer Risk

A recent study has concluded that "higher intake of folate is marginally associated with a lower risk for [estrogen receptor negative] ER- breast cancer, and higher intakes of vitamin B-12 and methionine [an amino acid] are marginally associated with a lower risk of ER+ breast cancer." The study included 2,325 women from the

4-Corners Breast Cancer Study and also evaluated menopausal status, ethnicity and alcohol intake. Among other things, the study showed that (i) "women in the highest quartile of folate intake [] associated with 50 percent reduced risk for ER+ breast cancer compared with those in the lower quartile"; (ii) "those in the highest quartile of vitamin B12 intake were 27 percent less likely to develop breast cancer, compared with those in the lowest quartile"; and (iii) "among non-Hispanic women, the highest intake of vitamin B12 was associated with 51 percent reduced risk for breast cancer."

Nanoparticles in Everyday Items Inhibit Fat Storage and Accelerate Aging

New research conducted by Stony Brook University scientists reportedly reveals that "pure gold nanoparticles found in everyday items such as personal care products, as well as drug delivery, MRI contrast agents and solar cells can inhibit adipose (fat) storage and lead to accelerated aging and wrinkling, slowed wound healing and the onset of diabetes."

The researchers reportedly tested the impact of nanoparticles in vitro on multiple types of cells, including adipose (fat) tissue, to determine whether their basic functions were disrupted when exposed to very low doses of nanoparticles. They discovered "that the human adipose-derived stromal cells—a type of adult stem cells—were penetrated by the gold nanoparticles almost instantly and that the particles accumulated in the cells with no obvious pathway for elimination." They also concluded that "the presence of the particles disrupted multiple cell functions, such as movement; replication (cell division); and collagen contraction; processes that are essential in wound healing."

"Reductions caused by gold nanoparticles can result in systemic changes to the body," said lead researcher Tatsiana Mironava. "Since they have been considered inert and essentially harmless, it was assumed that pure gold nanoparticles would also be safe. Evidence to the contrary is beginning to emerge."

"We have learned that careful consideration and the choice of size, concentration and the duration of the clinical application of gold nanoparticles is warranted," she added. "The good news is that when the nanoparticles were removed, normal functions were eventually restored." *See Stony Brook University News Release,* April 24, 2013.

INTERNATIONAL DEVELOPMENTS

Germany Seeks Stricter Nanomaterial Reporting Rules Under REACH

German safety regulators have apparently sought a major nanotechnology-related revision of the European Union's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). According to representatives of the German Federal Institute for Risk Assessment (BfR), the REACH one-metric-ton reporting threshold is too high and current rules classifying what constitutes a

nano-feature are "insufficient." BfR Toxicologist Ulrike Bernauer said, "Up to now, there are no clear statements about the requirement to characterize a material to prove it is a nanomaterial." She also reportedly noted that toxicological and ecotoxicological testing requirements addressing nano-specific features have not been integrated into REACH.

Bernauer further said that revised joint proposals for amending REACH as to nanomaterials, submitted to the European Commission by Bfr, the German Federal Institute for Occupational Safety and Health and Federal Environment Agency, could provide the foundation for a new proposal from the commission later this year. The joint proposals called for an annual 100-kilogram reporting threshold, and were intended to prepare REACH for rapid developments in this sector and ensure that the "precautionary principle" will apply when assessing potential effects of nanomaterials on human health and the environment. *See Bloomberg BNA Product Safety & Liability Reporter*, April 22, 2013.

CONFERENCES & SEMINARS

McDonough to Discuss Crisis Communication Issues During PCPC Conference

Shook, Hardy & Bacon Pharmaceutical & Medical Device Practice Chair Madeleine McDonough will join a distinguished faculty in Montreal, Canada, May 22-24, 2013, to discuss crisis communications and reputation management issues during the Personal Care Products Council's (PCPC's) 2013 Legal and Regulatory Conference.

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LEGAL TRENDS REPORT

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