ISSUE 15 | DECEMBER 6, 2013

LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

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INSIDE GOVERNMENT

Sunscreen Approval Process Still in Debate

The House Committee on Energy and Commerce recently held a U.S. Food and Drug Administration (FDA) oversight hearing at which U.S. Reps. Ed Whitfield (R-Ky.) and John Dingell (D-Mich.) reportedly pressed Janet Woodcock, director of FDA's Center for Drug Evaluation, about the status of pending sunscreen applications. As discussed in Issue 9 of this *Report*, FDA has faced criticism over its long-delayed approval of the use of eight sunscreen ingredients available in many foreign countries, but not in the United States.

"We are all well aware the workload is heavy at the FDA and that resources are limited, but myself and other senators have drafted legislation to try to expedite the approval process, which we have submitted to you for technical assistance," U.S. Rep. Whitfield said. Whitfield apparently then asked if the FDA director was aware of the submitted legislation and if so, when he and his colleagues could expect a response. "We hope you will get a prompt response," Woodstock reportedly said, adding that the agency is "more frustrated than the manufacturers and you all are about this situation. The problem is that we have to do regulations to get these ingredients into monographs and they are backlogged and slow to get through." *See Cosmeticsdesign.com,* November 25, 2013.

LITIGATION AND REGULATORY ENFORCEMENT

Court Approves Consent Decree Setting Deadlines for FDA Triclosan Monographs

A federal court in New York has approved the consent decree entered by the Natural Resources Defense Council (NRDC) and the U.S. Food and Drug Administration (FDA) obligating the agency to complete by certain dates monographs "establishing conditions for use of certain products containing triclosan as the active ingredient." *NRDC v. FDA*, No. 10-5690 (U.S. Dist. Ct., S.D.N.Y., order entered November 21, 2013).

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Without admitting any of NRDC's claims that FDA violated the Administrative Procedure Act, the agency agreed to finalize the "Consumer Antiseptic Hand Wash Products Monograph" by September 15, 2016; the "Healthcare Antiseptic Products Monograph" by January 15, 2018; and the "Consumer Antiseptic Hand Rub Products Monograph" by April 15, 2019. The agreement binds successors to Health and Human Services Secretary Kathleen Sebelius and FDA Commissioner Margaret Hamburg and accounts for the possibility of delay due to government shutdowns.

According to an NRDC press release, "FDA first proposed in 1978 to remove triclosan from certain consumer products. Because it took no further action, the chemical has been widely used in antimicrobial soaps sold in the United States." NRDC attorney Mae Wu stated, "It's outrageous that FDA has waited 35 years to protect the public from this harmful chemical. This final rule should prohibit triclosan from use in soaps. Washing your hands with soap containing triclosan doesn't make them cleaner than using regular soap and water. In fact, not only do soaps containing triclosan fail to provide benefits consumers might expect, they carry potential health risks." *See NRDC Press Release*, November 22, 2013.

Federal Court Approves Class Settlement in "Risk-Free Trial" Suit

A federal court in New Jersey has granted final approval to the settlement of class claims in litigation alleging that Hydroxatone deceived consumers by offering beauty products with risk-free trial offers and auto-shipment programs that, in fact, consisted of customer-service practices that failed to credit product returns or to cancel membership in the auto-shipment programs. *Sabol v. Hydroxatone, LLC*, No. 11-4586 (U.S. Dist. Ct., D.N.J., decided November 22, 2013). Additional information about the motion for preliminary approval of the settlement appears in the February 14, 2013, **issue** of Shook, Hardy & Bacon's *Product Liability Litigation Report*.

In approving the settlement, the court overruled objections filed by the named plaintiff in a rival action. Lisa Margolis apparently refused to participate in the *Sabol* negotiations, and, instead, sought to consolidate her case with Sabol's and revise the alleged facts in her dispute with the defendants. Margolis also added defendants and alleged that their free-trial program differed in some respects from the programs offered by the *Sabol* defendants. She also objected to the amount of the settlement. Analyzing her arguments under Third Circuit precedent, the court concluded that Margolis's claims were included in the *Sabol* settlement agreement and characterized her objection as "at least in part, the continuation by other means of a struggle among counsel for control of the litigation."

Each class member will be eligible for awards between $40 and $100 or for replacement products. The settlement's total value is approximately $10 million.

Court Preliminarily Approves $5-Million Muscle Milk® Class Settlement

A federal court in California has given preliminary approval to the settlement of a nationwide class alleging that Cytosport, Inc. misleads consumers by representing that its Muscle Milk® Ready-to-Drink products are healthy and nutritious when they actually contain the same amount of calories and almost as much fat as a doughnut. *Delacruz v. Cytosport, Inc.*, No. 11-3532 (U.S. Dist. Ct., N.D. Cal., order entered November 18, 2013). Under the agreement, the company denies any wrongdoing, but agrees to establish a $5.3-million fund for class members who purchased Muscle Milk® beverages and bars throughout the United States between July 2007 and December 2012. The court has scheduled a May 15, 2014, final approval hearing. Additional information about the settlement and litigation appear in Issue 475 of Shook, Hardy & Bacon's *Food & Beverage Litigation Update*.

Putative Class Action Claims Glucosamine/Chondroitin Supplements Ineffective

A New York resident has filed a putative class action against Rite Aid Corp. alleging that the company falsely advertises and labels its house-brand line of joint-health dietary supplements containing glucosamine sulfate and chondroitin sulfate as effective in addressing joint pain or stiffness. *Lastres v. Rite Aid Corp.*, No. 13-6550 (U.S. Dist. Ct., E.D.N.Y., filed November 25, 2013).

Seeking to represent a class of consumers who purchased any of a number of these Rite Aid supplements in New York, plaintiff Louis Lastres claims that the company's representations about the efficacy of the products "are totally contradicted by all credible scientific evidence." He claims that he purchased one of the products relying on the company's claims that they would "help rebuild cartilage & lubricate joints." According to the complaint, the company made its product representations "through a variety of media including its website and online promotional materials and the labeling/packaging of the Supplements themselves." Lastres alleges that he received no benefit from the product and that he would not have purchased it if he had been aware that "Rite Aid had both misrepresented the benefits of the Supplements and, in addition, concealed its knowledge of studies demonstrating the lack of efficacy of those products."

The plaintiff alleges unfair or deceptive acts and practices, false advertising and breach of express warranty under New York law. He seeks restitution and disgorgement, injunctive relief, corrective advertising, statutory and punitive damages, attorney's fees, and costs.

Skin-Whitener Company Denies Seeking Dismissal of Product Liability Suit

According to a news source, Kanebo Cosmetics Inc. has denied that it asked a court to dismiss a consumer's claims that the company's skin-whitening product with 4HPB, or Rhododenol, caused her to develop itchy skin and white blotches on her face, neck and arms. The claimant is apparently demanding ¥48 million under product liability law and other legal theories. She reportedly claims that her symptoms worsened because the company delayed recalling the product or issuing warnings. Additional details about Kanebo's purported delay in recalling the product appear in Issue 7 of this *Report*.

The company apparently hopes to negotiate individual compensation awards with some 14,000 affected customers, but news sources say that the likelihood of additional lawsuits is increasing. Kanebo may also be subject to penalties imposed by the government for failure to report alleged product side effects in compliance with the law. Taiwan, evidently the company's largest overseas retail market, has reportedly prohibited the sale of any products containing Rhododenol and has recalled any beauty item with the ingredient from store shelves. A team of lawyers retained by Kanebo reportedly issued findings in September critical of the company's delayed product recall, claiming that Kanebo should have taken steps to address the problem a year earlier. *See The Japan Times*, September 16, 2013; *Cosmeticsdesign-asia.com*, November 27, 2013.

EMERGING TRENDS

Cosmetics Companies Join WWF to Encourage Responsible Development of Plant-Based Plastics

Eight leading consumer brand companies, including Procter & Gamble, have joined with the conservation group World Wildlife Fund (WWF) to form the Bioplastic Feedstock Alliance (BFA), which aims to "encourage the responsible development and growth of plastics made from plant material and build a more sustainable future for the bioplastics industry." The group will focus primarily on "guiding the responsible selection and harvesting of feedstocks—sugar cane, corn, bulrush, and switchgrass—used to make plastics from agricultural materials."

Noting that consumers across the world are increasingly looking for more sustainable products, including those made from plant-based plastics, BFA observes that as development of these renewable materials has grown, so has the opportunity to address their potential impacts on land use, food security and biodiversity. BFA intends to bring together leading experts across various

industries and organizations to help guide the evaluation and sustainable development of bioplastic feedstocks. The Alliance will be supported by academic experts, supply chain partners, suppliers, and technology development companies. *See BFA News Release,* November 19, 2013.

Kansas City Officials Warn of Potential Lead Poisoning Risk from Imported Makeup

A makeup product marketed as improving skin texture, healing acne, protecting from sun exposure, and evening skin tone has reportedly been linked to two cases of lead poisoning in children in Kansas City, Missouri. Called Thanakha, the product is a traditional cosmetic in Myanmar (formerly known as Burma) and sold predominantly in ethnic stores or online, where, according to news sources, it is marketed to a broad audience of consumers looking for natural skin care products. Its packaging apparently often lacks information about the product's manufacturer or distributor. Although Thanakha—a yellowish paste made from tree bark—is natural, the tools used to grind it and some of the metal containers used to store it reportedly contain high levels of lead. Amy Roberts, manager of the Kansas City Health Department's Childhood Lead Poisoning Prevention Program, noted that the product is sold in a number of Kansas City-area stores and cautioned consumers who have it to "stop using it, throw it away, and only use products with ingredients clearly labeled on the container." Roberts also urged people who have been exposed to get a blood lead test. *See Kansas City Health Department News Release,* November 26, 2013.

INTERNATIONAL DEVELOPMENTS

EFSA's Ephedra Opinion Considered a Significant Step

In what is reportedly considered a significant step forward in European Union botanical regulation, the European Food Safety Authority (EFSA) has concluded that the herb ephedra and its extracts are unsafe for use in food supplements. Noting that (i) the use of ephedra and its preparations in food supplements may result in exposure to total ephedra alkaloids or ephedrine that exceeds therapeutic dose ranges in medicinal products, and (ii) such exposure could lead to severe adverse effects, which may be enhanced when combined with caffeine, EFSA's Food Additives and Nutrient Sources (ANS) Panel has determined that ephedra and its preparations containing ephedra alkaloids used as food supplements pose "significant safety concern at the estimated use levels." According to a news source, the move represents "real progress" in the Panel's herbal-safety assessment methodologies, referring to the so-called "yohimbe non-opinion" where the agency stated that it could not determine the safety of the supposedly aphrodisiac herb. Referring to the

"long, well-reasoned and well-researched opinion," the source indicated that EFSA has now shown that it can apply its botanical methodology in a way that is "meaningful for regulators and consumers." *See Nutra-Ingredients.com,* December 2, 2013.

Japanese Government to Update Reporting System After Skin-Whitening Product Scandal

In light of the July 4, 2013, recall of some 4.6 million skin-whitening products that purportedly caused patchy skin lightening, de-pigmentation and vitiligo-like symptoms, the Japanese Ministry of Health, Labor and Welfare (MHLW) reportedly plans to amend its Pharmaceutical Affairs Law to improve its adverse effects reporting system for cosmetic products. The move follows the government's criticism of manufacturer Kanebo Cosmetics Inc.'s handling of the recall; sources indicate that Kanebo was notified in mid-May that some consumers had experienced de-pigmentation after using the company's skin-whitening products, but the cosmetics maker evidently neither reported those cases to the government until the end of June nor issued the recall until July. The law will reportedly be amended to require that Japanese cosmetic companies report severe adverse reactions to relevant authorities within 15 days of notification by consumers. Information about pending litigation against the company appears elsewhere in this *Report*. *See ChemLinked.com* and *MHLW News Release,* November 29, 2013.

Norwegian Government Says Further Studies Needed to Confirm Vitamin A Safety in Cosmetics

At the request of the Norwegian Food Safety Authority, the Norwegian Scientific Committee for Food Safety (VKM) has conducted a **risk assessment** of local adverse effects, such as skin irritation, induced by vitamin A (retinol and retinyl esters) in skin care products and concluded that relevant data to accurately judge safe usage levels is insufficient. According to VKM, the use of retinol and retinyl esters in cosmetic products had been restricted under Norwegian cosmetics regulations, with maximum allowed concentrations of 0.3 percent retinol and 0.55 percent retinyl palmitate. As a result of the July 11, 2013, European Cosmetics Regulation, however, national regulation of these compounds ceased, and the Norwegian Food Safety Authority has been working with VKM to identify the upper concentrations of vitamin A that may be safely used in cosmetics in relation to the ingredients' ability to irritate the skin. "There are not enough relevant studies with the necessary data on association between concentrations and adverse effects in the skin to define safe upper concentrations for the use of retinol and retinyl esters (retinyl palmitate and retinyl retinoate) in cosmetics," noted VKM in the assessment. "However, the present available data indicates that local adverse effects in human skin

may appear after application of retinol at concentrations of 0.075% and above. For retinyl esters, no conclusion can be drawn from the available data." *See VKM News Release,* November 28, 2013.

SCIENTIFIC/TECHNICAL DEVELOPMENTS

Americans' Caffeine Intake Driven by Coffee Consumption

Results of a study said to be the first population-based research to estimate human caffeine intakes in more than 10 years suggest that overall mean caffeine intakes in the United States remain driven by the consumption of coffee and, to a lesser extent, tea and carbonated soft drinks. Diane Mitchell, at al., "Beverage Caffeine Intakes in the U.S.," *Food and Chemical Toxicology,* November 1, 2013. The study, which analyzed data from seven-day diet records of 37,602 Americans, indicated that caffeine intakes from so-called energy drinks—shots and beverages—contributed "minimally," or less than 2 percent, to total caffeine intakes.

The study showed that the greatest proportion (9-10 percent) of caffeinated beverage consumers consuming energy drinks were teenagers (13-17 years old) or young adults (18-24 years old); only 5 percent of total caffeine intake, however, was attributable to energy drink consumption in these groups. Meanwhile, the mean daily intake of those who did consume caffeine was 165 mg/day and mean intakes were highest in the 50-64-year age range at 226 mg/day. According to the study, even the heaviest caffeine consumers were not drinking huge amounts; intakes at the 90th percentile from all caffeinated beverages were slightly above 400 mg/day for adults age 35 years and older. Although the United States has no specific recommendations for caffeine intakes, the U.S. Food and Drug Administration has indicated, that for healthy adults, caffeine intake up to 400 mg/day is not associated with adverse health effects.

Magnesium May Lessen Mortality Risk in Individuals with CV Risks

A recent Spanish study has purportedly revealed that increased intakes of magnesium may decrease mortality rates as much as 34 percent in adults with high cardiovascular risk. Marta Guasch-Ferré, et al., "Dietary Magnesium Intake Is Inversely Associated with Mortality in Adults at High Cardiovascular Risk," *The Journal of Nutrition,* November 20, 2013. Using a database of 7,216 men and women ages 55 to 80 from the Prevención con Dieta Mediterránea study, participants at a high risk of cardiovascular disease were randomly assigned to Mediterranean diets supplemented with nuts or olive oil—high in magnesium—or a low-fat control diet. According to data collected during a five-year period, 323 total deaths, 81 cardiovascular deaths and 277 cardiovascular events such as stroke, heart attack and heart disease, occurred. The

data also revealed that the highest average intakes of magnesium (442 mg/day) were associated with a 59-percent reduction in cardiovascular mortality, a 37-percent reduction in cancer mortality and a 34-percent reduction in all-cause mortality, compared to the lowest average intakes of approximately 312 mg/day.

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LEGAL TRENDS REPORT

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