Shook, Hardy & Bacon L.L.P.

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LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

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INSIDE GOVERNMENT

FDA Asserts *Park* in Vicarious Liability Context

A recent warning letter issued by the Food and Drug Administration (FDA) against a dietary supplement distributor cited *United States v. Park*, 421 U.S. 658 (1975), and *United States v. Dotterweich*, 320 U.S. 277 (1943), to support the agency's contention that the distributor is responsible for the current good manufacturing practice violations of its contractor manufacturers.

Under the *Park* doctrine, the government may press misdemeanor charges against company officials for their companies' alleged violations of the Food, Drug, and Cosmetic Act (FDCA) without showing that the official participated in or was aware of the violations. By citing both *Park* and *Dotterweich* (involving an officer's vicarious liability for the acts of third party manufacturers), FDA may have signaled by implication its intent to hold distributor officers in positions of responsibility or authority strictly criminally liable for a contractor's FDCA violations.

CSPI Calls on FDA to Ban Ginkgo Products

In a letter to the U.S. Food and Drug Administration (FDA), the Center for Science in the Public Interest (CSPI) has urged the agency to ban the use of the herbal ingredient Ginkgo biloba in foods and dietary supplements, citing a National Toxicology Program (NTP) report which states that the ingredient causes cancer in lab animals. The watchdog group calls on FDA to give the industry a "reasonable time" to comply with the directive and then "seize whatever products remain on shelves to protect consumers."

Industry groups, including the Council for Responsible Nutrition (CRN), have challenged CSPI's action and claim that the doses administered to the laboratory animals were much too high to show whether Gingko biloba is unhealthy for humans. "Ginkgo biloba has literally been used for thousands of years, and this attempt by CSPI to discredit this safe and beneficial dietary supplement demonstrates an irresponsible misinterpretation of both the science and the

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intent of the National Toxicology Program (NTP) in reviewing ginkgo," said CRN President and CEO Steve Mister. "This premature evaluation from CSPI reveals an abuse of its position, a lack of understanding about the regulation of food by FDA, and presents a true disservice to consumers."

According to CSPI, the NTP report found "clear evidence" that Ginkgo caused liver cancer in mice and "some evidence" that it caused thyroid cancer in rats. NTP researchers reportedly told *The New York Times* that the number of cancers found in the mice exceeded numbers previously seen in their lab. Supplement industry representatives argued that NTP used ginkgo extract not used in supplements sold in the United States, but NTP evidently claimed that the composition of the extract it tested falls within the range of what is sold.

"It used to be the case that the only problems associated with Ginkgo were the unfounded and deceptive claims by manufacturers that it helped memory," said CSPI Executive Director Michael Jacobson. "Now we know these make-believe benefits are far outweighed by a real risk of cancer." *See CPSI News Release,* June 3, 2013; *CRN News Release,* June 4, 2013.

LITIGATION & REGULATORY ENFORCEMENT

Settlement Approved in Homeopathic Remedy False Ad Suit

A federal court in California has reportedly granted preliminary approval to the settlement of class claims involving allegedly false ads for a Boiron Inc. homeopathic cold remedy. *Delarosa v. Boiron USA Inc.*, No. 10-1569 (U.S. Dist. Ct., C.D. Cal., order entered May 31, 2013).

California residents who purchased Children's Coldcalm® for personal use since August 2006 may receive refunds for the full purchase price of $12.99 per purchase with a receipt or product packaging. Those without proof of purchase are capped at recovering $16 per household. The agreement will resolve claims that Boiron misled consumers by advertising its product as an effective cold remedy despite its alleged inability to relieve cold symptoms. The deal also includes product label and packaging modification requirements and $750,000 in attorney's fees and costs.

According to a news source, several other Children's Coldcalm® class actions that settled for $12 million raised questions about collusion between the parties. Counsel for the plaintiffs in *Delarosa*, however, said that "this case is the antithesis of a collusive case." *See Law360*, May 31, 2013.

Fraud Claims to Proceed Against Dietary Supplement Maker

A federal court in Florida has denied the defendant's motion to dismiss putative class claims alleging that the company's representations about the effects of "5-hour ENERGY®"—five hours of energy without the crash of related products—are false and misleading. *Feiner v. Innovation Ventures, LLC*, No. 12-62495 (U.S. Dist. Ct., S.D. Fla., decided May 29, 2013). According to the court, the plaintiff sufficiently pleaded the elements of his consumer-fraud and unjust-enrichment causes of action.

The court also disagreed with the defendant that the name of its product could not be misleading because it is a trade name. The court said, "This argument fails because Defendant has not established that 5-hour ENERGY®'s status as a trade name—or lack thereof—has any bearing on whether that name is misleading. Therefore, the Court has no reason to disregard Plaintiff's allegation that the name 5-hour ENERGY® conveys to the reasonable consumer that the product will provide five (5) hours of energy."

JPML Centralizes 5-Hour ENERGY® Lawsuits

The Judicial Panel on Multidistrict Litigation (JMPL) has transferred nine actions pending in eight federal courts against Innovation Ventures, LLC, the company that makes 5-Hour ENERGY®, to the Central District of California. ***In re 5-Hour ENERGY Mktg. & Sales Practices Litig.*, MDL No. 2438 (JPML, order entered June 5, 2013)**. According to the panel, the "actions share factual questions arising out of allegations that Innovation Ventures, LLC, used false advertising and deceptive marketing to mislead consumers concerning the benefits of its 5-Hour Energy 'energy shot' product, particularly vis-à-vis other caffeinated stimulants." Among the cases transferred for pre-trial proceedings was *Feiner v. Innovation Ventures, LLC*, discussed elsewhere in this *Report*.

JPML Denies Transfer in Cosmetics Marketing and Sales Litigation

The Judicial Panel on Multidistrict Litigation (JPML) has denied the request of defendant cosmetics companies in putative class actions pending in California and New York federal courts to centralize the consumer-fraud litigation in the Southern District of New York to coordinate pre-trial proceedings. ***In re Maybelline N.Y. & L'Oréal Cosmetic Prods. Mktg. & Sales Practices Litig.*, MDL No. 2447 (JPML, order entered June 6, 2013)**.

While all of the plaintiffs have alleged that "the defendants' lip products do not remain on wearers' lips for the durations advertised," the JPML notes that the "products are not the same across all actions. In the Southern District of New York and Northern District of California actions, the involved lip products are Maybelline's SuperStay 10HR Stain Gloss and SuperStay 14HR Lipstick. In the Southern District of California and Eastern District of California actions, the

involved product is SuperStay 24HR Lip Color. In addition, two of the actions implicate products not found in any other action. Specifically, the Northern District of California action involves allegations concerning certain mascara products, and the Eastern District of California action involves allegations concerning a foundation product."

According to the panel, voluntary cooperation and coordination among the parties and courts can minimize the risk of duplicative discovery and inconsistent pre-trial rulings "[t]o the extent that there is factual overlap among the actions."

EMERGING TRENDS

Environmental Groups Pressure Companies to Ban Cosmetics Microbeads

Environmental groups have called on cosmetics and personal care products companies to ban the use of microbeads—used as exfoliants in skincare scrubs, soaps and shower gels—claiming that the micro-plastic particles can move through water filtration systems to oceans and lakes, which harms marine life and disrupts ecosystems. Microbeads have reportedly become popular in the cosmetics market only during the past decade, as manufacturers began using them as an exfoliating alternative to ground walnut shells, which can have sharp edges and pose allergy risks to some consumers.

According to advocacy group 5 Gyre, which conducted a soon-to-be-published study of water in the Great Lakes, microbeads are one of the most "egregious sources" of plastic pollution because they are designed to be washed down the drain. Stiv Wilson, a 5 Gyre spokesperson who reportedly took the samples for the Great Lakes study said, "We didn't even know we had them, at first. You can't really see them and it's not like they float on the surface. But you run the water through a coffee filter and you can see them with the naked eye…up to 10 milliliters of a 100-milliliter sample was plastic. Trillions and trillions and trillions of these beads are going into the water."

The group has asked cosmetic manufacturers to use natural alternatives, such as apricot shells and cocoa beans, as a sustainable alternative to plastic microbeads. It has also sought to (i) pressure retailers to stop selling products that contain microbeads, (ii) encourage manufacturers to stop using microbeads in cosmetic and personal care products, (iii) raise awareness about the issue and encourage consumers to boycott companies that use microbeads, and (iv) ask legislators to ban the use of microbeads in consumer products. *See Plastics News,* June 7, 2013; *5gyres.org.*

Formulating Dietary Supplements with Non-GM Ingredients Presents Major Challenges

Although dietary supplement manufacturers face mounting pressure from consumers to use non- genetically modified (GM) ingredients in their products, doing so presents significant challenges that dietary supplement companies may not fully understand, reports a news source. Key among the challenges is "education in the supply chain," said United Natural Products Alliance (UNPA) Executive Director Loren Israelson. "We sense that the issue is substantially more significant than dietary supplement companies think. There is not the practice of testing in-bound materials for [GM] status. If you look at the core [GM] crops and their derivatives, then it could be a difficult situation. The standard is very high to play in the realm, and the supply community is not there with us yet."

Additional challenges reportedly identified include (i) a lack of incentive for suppliers to include non-GM certification in their ingredient process, (ii) rigorous standards from non-GM advocacy groups, (iii) the complexity of many dietary supplement formulations, (iv) the fact that many vitamins and nutrients are products of fermentation and a lot of microorganism feedstocks come from GM crops, and (v) the reluctance of enzyme manufacturers to disclose their fermentation processes. *See NutraIngredients-usa.com,* June 5, 2013.

INTERNATIONAL DEVELOPMENTS

SCCS Says Parabens in Cosmetics Are Safe

The European Union's (EU's) Scientific Committee on Consumer Safety (SCCS) has updated its **opinion** on propyl- and butylparaben—chemical substances that are widely used in sunscreen and other products and purportedly disrupt the human endocrine system—and ruled that the parabens do not pose any health risk in the amounts currently used.

Parabens are approved as preservatives in the EU's Cosmetics Directive at a maximum concentration of 0.4 percent when used individually or 0.8 percent when used as a mixture of esters. Despite numerous reviews of the chemical, concerns about the parabens still evidently exist. Environmental health research and advocacy organization Environmental Working Group (EWG) rates propyl-paraben as highly hazardous and states that parabens "mimic estrogen and can act as potential hormone (endocrine) system disruptors."

Sylvia Maurer, safety and environment senior policy officer at the European Consumers' Organisation, has said that calling parabens safe underestimates the overall quantity to which consumers are exposed. "We use on average 10 to 20 cosmetics a day. Such potentially harmful substances, in lipsticks, creams

and shampoos, can add up in our bodies. We are concerned that this 'mixture effect' has been ignored by the EU legislation."

The human risk associated with other parabens, including isopropylparaben, isobutylparaben, phenylparaben, benzylparaben, and pentylparaben, has not evidently been evaluated due to lack of data. *See EurActiv.com,* June 5, 2013; *Environmental Working Group's Cosmetics Database*.

EU to Restrict More Hair Dyes

According to a notification **document** sent to the World Trade Organization, the European Union (EU) plans to restrict the use of 22 hair dyes, including 1,4-benzenediamine, 2-methyl, 2,5-diaminotoluene sulphate, and 1,3-benzenediol, by adding them to Annex III of the EU Cosmetics Regulation, No. 1223/2009. Annex III will also be amended to include 10 hair dye substances and the use of hydrogen peroxide in products intended for coloring eyelashes by establishing "strict" use conditions and obligatory warnings, such as "for professional use only."

According to the new amendments, the presence of benzyl alcohol must be indicated in the list of a cosmetic product's ingredients when its concentration exceeds 0.001percent in leave-on products and 0.01percent in rinse-off products. *See government chemist.wordpress.com,* May 30, 2013.

EU Firms to Step Up Investment in Chinese Cosmetics Companies

European Union (EU) cosmetics companies reportedly intend to expand investment in China despite some concerns about rising labor costs, sluggish economic growth and escalating competition. According to a news source, the increased interest in expansion follows China's central government's promise to spur economic growth through a series of finance, taxation, agriculture, and technology reforms.

A recent business confidence survey conducted by the EU Chamber of Commerce and Roland Berger Strategy Consultants, showed that of 550 European companies with a presence in China surveyed, 86 percent have considered expanding investment in China and 41 percent have planned merger and acquisition deals in 2013. The survey also revealed that more than half of the companies surveyed will expand their business from first-tier cities in China to second- and third-tier cities, with interest growing in the country's western region.

"European cities are expanding operations and geographical reach to achieve greater economies of scale and are strengthening in areas where they already hold advantages in order to maintain an edge over local competition," said Roland Berger Senior Partner Kang Yang. Topping the list of firms that evidently consider China a priority market are European consumer goods

and service firms. "Domestic daily necessities and cosmetic companies are becoming more competitive," noted Kang. *See EU Chamber of Commerce,* May 30, 2013; *chinadaily.com,* May 31, 2013.

Argentina's ANMAT Revises List of Color Additives Permitted in Cosmetics

The Administración Nacional de Medicamentos, Alimentos y Tecnologia Medica (ANMAT), the authority responsible for regulating Argentina's cosmetic industry, has updated the list of color additives permitted for use in perfumes, personal care products and cosmetics. According to a news source, several substances that were previously banned will now be permitted, provided that they are tested for insolubility. These include insoluble barium, strontium and zirconium, which are used to make pigment dyes.

The resolution will reportedly be adopted by the Mercosur's Common Market Group and will be enacted in all member states (Argentina, Brazil, Paraguay, Uruguay, and Venezuela) 30 days after Mercosur's Secretariat officially indicates that the text has been transposed into each national law. *See premiumbeautynews.com*, June 6, 2013; *cosmeticsdesign.com,* June 10, 2013.

Illegal Cosmetics Discovered in UK Contain Toxic Ingredients

Birmingham, England, officials have reportedly cracked down on businesses selling cosmetics, including skin-lightening creams, lipstick and eye make-up, that purportedly contain potentially harmful levels of banned substances, such as lead, copper, mercury, barium peroxide, and arsenic. According the *Birmingham Mail,* Birmingham City Council's Trading Standards officers have discovered dozens of shops selling cosmetics with toxic ingredients that cause blood poisoning, cancer, infertility, brain damage, and death.

Apparently at issue are banned Asian and Middle Eastern imports sold in stores that target ethnic minorities. Harmful ingredients have also reportedly been found in counterfeit versions of designer make-up products available in shops and online. "The manufacture of genuine cosmetics is strictly controlled and products are rigorously tested before they go on sale," said a Trading Standards Institute spokesperson. "But the counterfeiters churning out the cheap versions do not abide by any of these rules, so along with potentially harmful metals, other banned substances may be used. Paint stripper and nail varnish remover have been found in fake mascara and liquid eyeliners and a batch of counterfeit perfume contained urine." *See Birmingham Mail,* June 3, 2013.

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LAW FIRM NEWS

Croft Addresses Regulatory and Litigation in Connection with Dietary Supplements

Shook, Hardy & Bacon International Litigation & Dispute Resolution Partner Sarah Croft has authored an article titled "Product liability and dietary supplements" appearing in the May 2013 issue of *The In-House Lawyer*. Croft discusses how these products are regulated in Great Britain and the European Union, as to both ingredients and labeling, and the standards that apply to marketing and advertising. Noting that "product liability litigation related to dietary supplements has not yet arisen this side of the Atlantic," she reports on wrongful death litigation involving a supplement containing DMAA currently pending in the United States.

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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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