Shook, Hardy & Bacon L.L.P.

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# LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS
• DIETARY SUPPLEMENTS
• NUTRACEUTICALS

CONTENTS



## INSIDE GOVERNMENT

### Industry Issues Statement on Proposed Safe Cosmetics and Personal Care Products Act

The Independent Cosmetic Manufacturers And Distributors (ICMAD) association has issued a statement in response to the Safe Cosmetics and Personal Care Products Act of 2013 (H.R. 1385) recently introduced by Reps. Edward Markey (D-Mass.) and Jan Schakowsky (D-Ill.). The proposal aims to close "major loopholes in the federal law that allow companies to use ingredients in cosmetics and personal care products known to damage human health and the environment."

Among other things, key provisions in the bill include (i) cosmetic and ingredient testing and safety, including the establishment of a list of ingredients prohibited from use in cosmetics, such as carcinogens and reproductive and developmental toxins; (ii) "post market testing requir[ing] the Secretary of Health and Human Services to conduct annual random sample tests for pathogens or contaminants in cosmetic products"; (iii) market restrictions that would provide the Food and Drug Administration (FDA) with recall authority for products that are misbranded, adulterated, or otherwise fail to meet safety standards; and (iv) mandatory reporting of adverse health effects requiring cosmetic manufacturers, packagers and distributors to provide FDA with reports of adverse health effects associated with the use of a cosmetic.

"While we agree with Representatives Schakowsky and Markey that certain provisions of the Food, Drug and Cosmetic (FD&C) Act should be modernized to keep pace with evolving science and the growth of the personal care industry," ICMAD said, "we believe our industry's approach . . . is practical and science-based. We are working with Members of Congress and the FDA to propose changes to the law that will make meaningful enhancements to cosmetics regulation without overburdening FDA or imposing costly and unnecessary restrictions on American businesses."

To that end, ICMAD suggests that the following measures would "enhance FDA oversight and and give the agency the information and flexibility it

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needs to continue to ensure consumer safety and safeguard public health": (i) enhanced FDA registration requirements, including facility registrations, product ingredient reports and adverse event reports; (ii) a process to set safety levels for trace constituents; (iii) an FDA ingredient review process; (iv) new FDA oversight of cosmetic ingredient review findings; and (v) FDA-issued, industry-wide good manufacturing practices.

ICMAD said that it "will continue to support Congress and FDA in their efforts," adding that "[its] goal is that an agreement on cosmetics legislation will be reached quickly with FDA and that legislation that enhances FDA's regulatory authority can be passed on a bipartisan basis." *See ICMAD News Release,* April 15, 2013.

### FDA Announces Public Meeting to Discuss Cosmetics Regulation

The Food and Drug Administration (FDA) has scheduled a May 8, 2013, **public meeting** in College Park, Maryland, "to invite public input on various topics pertaining to the regulation of cosmetics." The agency said that information from the meeting, titled "International Cooperation on Cosmetics Regulation (ICCR)—Preparation for ICCR–7 Meeting," may be used "to help us prepare for the ICCR–7 meeting" that will take place July 8 in Japan. The ICCR, a "voluntary international group of cosmetics regulatory authorities from the United States, Japan, the European Union, and Canada," is working toward a "convergence of regulatory policies and practices" that will remove "regulatory obstacles to international trade while maintaining global consumer protection." *See Federal Register,* April 5, 2013.

### NTP *Ginkgo Biloba* Report Draws Energy Drink Warning from CSPI

The National Toxicology Program (NTP) recently **released** its peer-reviewed report on the toxicology and carcinogenesis of *Ginkgo biloba,* "an herbal remedy and dietary supplement purported to improve memory and brain function." Based on long-term studies in which researchers "deposited solutions of *Ginkgo biloba* extract in corn oil directly into the stomachs of male and female mice and rats five times a week for two years," the report concluded that animals exposed to *Ginkgo biloba* extract "experienced increased rates of a variety of lesions in the liver, thyroid, and nose" as well as "increased incidences of cancers of the thyroid gland… in male and female rats and male mice and liver cancers in male and female mice."

Citing these studies, the Center for Science in the Public Interest (CSPI) has since issued a warning to consumers, advising them to avoid a number of products, including energy drinks, that list ginkgo as an ingredient. According to CSPI, the Food and Drug Administration has already sent "warning labels [sic] to several drink companies…, stating that ginkgo is not generally recognized as safe, or GRAS, for use in food, though it is legal as an herbal supplement."

"Ginkgo has been used in recent years to let companies pretend that supplements or energy drinks with it confer some sort of benefit for memory or concentration," said CSPI Executive Director Michael Jacobson. "The evidence for those claims has been dubious, at best. The pretend benefits are now outweighed by the real risk of harm." Meanwhile, the American Herbal Products Association (AHPA) strongly criticized the report for failing to distinguish between the extract used in the study and products sold commercially, which, the organization contends, are not chemically similar. American Botanical Council founder and executive director Mark Blumenthal observed that the dosage levels administered in the lab were significantly higher than levels ordinarily used by consumers. *See CSPI* and *AHPA News Releases,* April 18, 2013.

## LITIGATION & REGULATORY ENFORCEMENT

### Eleventh Circuit Upholds Findings in FTC Contempt Action Against Supplement Maker

The Eleventh Circuit Court of Appeals has rejected most of the Federal Trade Commission's (FTC's) claims that a dietary supplement manufacturer was in contempt of a stipulated final order and permanent injunction under a 2006 consent agreement; the court remanded one claim—that Garden of Life "misrepresented the six-month results of a bone density study in an advertisement for Grow Bone system"—for the district court to address. *FTC v. Garden of Life, Inc.*, No. 12-12382 (11th Cir., decided April 15, 2013) (unpublished).

The consent agreement, which settled a dispute over alleged advertising misrepresentations, apparently prohibited unsubstantiated claims "about absolute or comparative health benefits, efficacy, performance, safety, or side effects" and misrepresentations about "the existence, contents, validity, results, conclusions, or interpretations of any test or study." Garden of Life contracted with ISS, a consulting firm headed by a clinical pharmacologist with 20 years of experience evaluating advertising claims, to comply with its obligations under the FTC agreement.

FTC brought contempt claims over ads for products the company launched in 2009, calcium supplements RAW Calcium® and Grow Bone System®, and an omega-3 supplement for children Oceans Kids Chewables®. While the district court rejected FTC's contempt claims, it failed to expressly address an advertisement for the company's Grow Bone System® alleged to have falsely reported six-month increases in bone density that were in fact annualized figures that doubled a study's six-month findings. The Eleventh Circuit found that the district court's order did not provide a sufficient record on this issue for its review, so it remanded the case for the court to "specifically address whether [Garden of Life's] false description of the bone density study's results constituted a violation of §2," that part of the consent agreement barring misrepresentations of study results.

### ITC Initiates Imported Omega-3 Extracts Patent-Infringement Investigation

The U.S. International Trade Commission (ITC) has issued a notice regarding its decision to launch an investigation into the amended complaint filed by two Canadian companies alleging violations of section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, based on U.S. imports of "certain omega-3 extracts from marine or aquatic biomass and products containing the same by reasons of infringement of certain claims of U.S. Patent No. 8,278,351 and U.S. Patent No. 8,383,675." Requesting exclusion and cease and desist orders are complainants Neptune Technologies & Bioressources, Inc. and Acasti Pharma Inc. Respondents include omega-3 extract suppliers from Canada, Israel, New Zealand, Norway, and the United States. *See Federal Register*, April 17, 2013.

### FDA Consent Decree Addresses Dietary Supplement Maker's Manufacturing Practices

A federal court in New York has entered a consent decree of permanent injunction against Kabco Pharmaceuticals, Inc. and its CEO to enjoin them from violating the federal Food, Drug, and Cosmetic Act in manufacturing, packing and distributing dietary supplements. *United States v. Kabco Pharms., Inc.*, No. 12-3468 (U.S. Dist. Ct., E.D.N.Y., entered April 4, 2013). Food and Drug Administration (FDA) inspectors apparently found that the company distributed products, including Brewers Yeast Tablets®, Dandelion Root Capsules®, Night-Time Herb Capsules®, Inositol Calcium & Magnesium Capsules®, Vitamin C-500 with Rose Hips Time Released Tablets®, and Joint All Capsules®, "that did not meet product specifications."

FDA found that the company did not investigate product complaints, failed to prevent product mix-ups and included unlabeled raw ingredients in their supplements, including whey polio, an undeclared allergen that can cause a reaction in those allergic to milk. Previous inspections had apparently uncovered a history of violations and warnings. The company has agreed to stop manufacturing and distributing dietary supplements until it demonstrates to FDA "that it is meeting the quality, safety and labeling standards required by law." Kabco must also engage independent third-party oversight to ensure compliance. *See U.S. Department of Justice News Release*, April 8, 2013.

### NAD Finds Anti-Wrinkle Serum's Prescription Comparison Unsupported

The National Advertising Review Board, a self-regulatory appellate unit of the advertising industry's National Advertising Division (NAD), has reportedly recommended that skin care product maker Origins Natural Resources, Inc. cease claiming that its Plantscription® anti-aging serum "rivals an anti-wrinkle prescription" and has "88% of the visible wrinkle-reducing power of a prescription." The board agreed with NAD that these messages were not supported by the record. While the company disagreed with the board's conclusion

regarding these advertising statements, it agreed to take the decision into account and expressed pleasure that "the panel agreed with Origins that the data generated in Origins' clinical testing could be relied on to support [other] comparative claim[s]." *See Advertising Self-Regulatory Council Press Release*, April 9, 2013.

### Consumer Fraud Claims Filed Against GNC Corp. over Flexibility Supplements

A California resident has filed a putative multi-state class action against GNC Corp., alleging that the company falsely advertises some of its dietary supplements as products that will "help promote mobility and flexibility, improve joint comfort and cushion joints." *Lerma v. GNC Corp.*, No. 13-933 (U.S. Dist. Ct., S.D. Cal., filed April 18, 2013). According to the complaint, the primary active ingredients in the company's TriFlex® Products are glucosamine and chondroitin, which studies have purportedly shown to be ineffective. Claiming that he relied on the "joint health benefit representations on the front, back and sides of the label" when making his purchase, the plaintiff claims that he would not have done so had he known "the Product was not effective as represented by Defendant." The plaintiff alleges lost money as his injury.

Seeking to certify a multi-state or alternative California class, the plaintiff alleges violations of California's Unfair Competition Law (unlawful, fraudulent and unfair business practices) and Consumers Legal Remedies Act. He requests a judgment awarding restitution and disgorgement, injunctive relief, a corrective advertising campaign, attorney's fees, and costs.

### Putative Class Charges Skin Cream Maker with Deceptive Ads

In a case that began in a New Jersey state court in 2006 and has been cycling through jurisdictional disputes in state and federal courts, a state resident alleges consumer fraud on behalf of a putative class against companies that make, market and distribute a stretch mark repair cream later claimed to be a "miracle" or "breakthrough" product that can eliminate facial wrinkles. *Morgan v. Gay*, 13-2470 (U.S. Dist. Ct., D.N.J., filed April 17, 2013). Now acknowledged under *Standard Fire Insurance Co. v. Knowles*, No. 11-1450 (U.S., decided March 19, 2013), to meet the federal jurisdictional threshold under the Class Action Fairness Act, the case has been removed to federal court.

According to the complaint, claims about Stri-Vectin-SD are unsupported by any study or scientific data. The plaintiff seeks to certify a state-wide class of product purchasers and alleges violation of the New Jersey Consumer Fraud Act, fraud, unjust enrichment, breach of warranty, and injunctive relief. She asks for compensatory, treble and punitive damages in excess of $5 million and an order enjoining the defendants from marketing the product "through use of any representations concerning the safety or efficacy of the product" and ordering them to "immediately take all steps necessary to effectuate a recall" of all products distributed or sold. *See Law360*, April 22, 2013.

## EMERGING TRENDS

### Cruelty Free International Campaign Focuses on U.S. Animal-Testing Practices

Following the European Union's (EU's) recent ban on animal testing for cosmetics, "Game of Thrones" star Peter Dinklage has joined forces with animal rights group Cruelty Free International (CFI) to call for an end to cosmetics tests on animals in the United States as part of the non-profit's mission "to end product testing on animals worldwide."

"I am so pleased to support Cruelty Free International and be part of the global campaign to end cosmetics tests on animals," Dinklage said. "It is unacceptable that animals continue to suffer around the world, including the United States of America, for the sake of beauty. I appeal to the USA to follow the European Union's lead and end animal testing for cosmetics."

Industry sources report that it is unknown how many animals are used for cosmetics testing, because most companies do not publicize this information. But CFI estimates that "thousands of animals are used in cruel tests for beauty and personal care products, from soap, deodorant and toothpaste to fragrance, make-up and moisturizer, every year." Ban supporters contend that not only are there safer, cheaper and more effective alternatives to animal tests that can be used, including in-vitro tests, computer modeling programs and tests on human skin donated from cosmetic surgery, but the newer methods are reportedly more relevant to humans and have been found to predict human reactions better than traditional animal tests. *See crueltyfree-international.org,* April 11, 2013.

## INTERNATIONAL DEVELOPMENTS

### EFSA Rejects Omega-3 Health Claim for Children with ADHD

The European Food Safety Authority (EFSA) has **rejected** health claims submitted by Belgian omega-3 supplements manufacturer, Minami Nutrition Health, purportedly linking omega-3 form EPA (eicosapentaenoic acid) and reduced risk of ADHD in children.

According to a news source, the claims suggested that "attention deficit-hyperactivity disorder (ADHD) could be reduced by improving the ratio between arachidonic acid (AA) and EPA in the body." EFSA disagreed, stating "No evidence was provided by the applicant to substantiate that the AA/EPA ratio plays a role in the development of ADHD, that the AA/EPA ratio can predict the incidence of ADHD, or that lowering the AA/EPA ratio can lower the risk of ADHD."

The only "approved health claim for EPA in the European Union is an article 13, general function health claim for, 'Maintenance of normal cardiac function,'" according to a news source. *See Nutraingredients.com,* April 15, 2013.

### Dutch State Secretary Calls for Ban on Microplastics in Cosmetic Products

Dutch State Secretary Wilma Mansveld has called on the House of Representatives to adopt a European-wide ban on microplastics in personal care products to ensure that these particles no longer penetrate into surface water via wastewater. The tiny, plastic non-biodegradable particles are purportedly harmful to the marine environment and one of the pollutants contributing to "the problem of plastic soup in the North Sea."

"A large proportion of products of this type on the Dutch market are produced by foreign manufacturers," Mansveld said in a government news release. "This makes a European ban the most effective measure … [Dutch consumers] should know if a tube of toothpaste or a bottle of bath foam contains microplastics. I would also like to offer consumers a sustainable option by asking the cosmetics sector to find alternatives to microplastics. The sector is already heading in the right direction."

Evidently, a large proportion of Dutch cosmetics companies are re-evaluating the use of microplastics in their products to see if they can be replaced by other materials. "The sector expects that in eighteen months' time 80% of its members will have replaced microplastics with other materials," concluded the news release. *See Government of the Netherlands News Release,* April 16, 2013.

### Malaysia Joins OECD Effort to Coordinate Non-Clinical Safety Data

The Organization for Economic Co-operation and Development (OECD) recently **announced** that Malaysia has joined its system for the Mutual Acceptance of Data (MAD), a multilateral agreement that "allows participating countries to share the results of various non-clinical safety tests done on chemicals and chemical products, such as industrial chemicals and pesticides."

According to OECD, MAD system participants agree to follow OECD Test Guidelines and Principles of Good Laboratories when assessing chemicals, including those used in cosmetics, in the interest of human health and the environment. In addition to Malaysia, the MAD system includes all 34 OECD countries as well as Argentina, Brazil, India, Singapore, and South Africa, and reportedly saves governments and chemical producers an estimated €150 million annually.

"Governments participating in the MAD system have confidence that chemical safety test data generated in other countries is of high quality and can be used for regulatory assessments. This reduces duplicative testing, saves laboratory costs, promotes work-sharing by countries assessing the same data and removes a potential non-tariff trade barrier," said OECD Secretary-General Angel Gurría. "Malaysia's participation in this system highlights the mutual

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LEGAL TRENDS REPORT

ISSUE 1 | APRIL 25, 2013

benefit of the partnership between OECD and major emerging economies." *See OECD News Release,* April 10, 2013.

## NEWS BYTES

### FDA Issues Warning About Popular Stimulant

The U.S. Food and Drug Administration (FDA) has issued a public warning about the stimulant dimethylamylamine—or DMAA—that is evidently commonly found in workout-boosting and fat-burning dietary supplement products.

FDA said that as of April 13, 2013, it "had received 86 reports of illnesses and death associated with supplements containing DMAA." The majority of these were voluntary reports from consumers and healthcare practitioners, FDA indicated, and the illnesses reported include "heart problems and nervous problems or psychiatric problems." The warning places the United States behind eight other countries that have already banned the stimulant, reported a news source. *See redorbit.com,* April 16, 2013.

## CONFERENCES & SEMINARS

### McDonough to Discuss Crisis Communication Issues During PCPC Conference

Shook, Hardy & Bacon Life Sciences & Biotechnology Practice Co-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

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 procure¬ment; 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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