Shook, Hardy & Bacon L.L.P.

ISSUE 24 | MAY 2, 2014

LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

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INSIDE GOVERNMENT

FDA Issues Final Rule on Nutrient Content Claims for Omega-3 Fatty Acids

The U.S. Food and Drug Administration (FDA) has announced a final rule, effective January 1, 2016, prohibiting statements on food product labels, including dietary supplements, that claim products are "high in," "rich in," or an "excellent source of" docosahexaenoic acid (DHA) or eicosapentaenoic acid (EPA) as well as similar claims for alpha-linolenic acid (ALA). The rule finalizes a proposed rule the agency published in 2007 without any substantive changes.

Under the U.S. Federal Food, Drug, and Cosmetic Act (the Act), nutrient-content claims such as "high in" are allowed only for nutrients for which a reference level for the claim has been set, or, in some situations, if the requirements of the Act have been met, such nutrient levels can be based on authoritative statements published by certain types of scientific bodies, such as the Institute of Medicine of the National Academies (IOM).

FDA apparently received notifications in 2004 and 2005 asserting that IOM had issued authoritative statements that identified such nutrient levels for DHA, EPA and ALA. The agency reports, however, that multiple notifications identified multiple, and sometimes conflicting, nutrient levels for the omega-3 fatty acids, leading FDA to determine that none of the claims met the Act's requirements.

Stakeholder comments on the agency's analysis of the proposed rule's impact suggested that hundreds of product categories, including seafood, yogurt, cheese, meat, eggs, milk, juice, bread, and baby food would be affected by the rule and labeling changes would be costly and place an unfair burden on small businesses. Allowing for a transition period, FDA noted that the rule will take effect January 1, 2016, and manufacturers will have up to one year to comply and change food and supplement labels accordingly. *See CFSAN Constituent Update*, April 25, 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.

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FDA Seeks Comments on Cosmetics Labeling

The U.S. Food and Drug Administration (FDA) has **invited** public comments on its proposed extension of a current information collection request (ICR) regarding cosmetics labeling. Noting that current regulations require "cosmetics manufacturers, packers and distributors [to] disclose information about themselves or their products on the labels of their products," and failure to comply may render a cosmetic "adulterated" or "misbranded," FDA specifically seeks information about (i) whether the proposed ICR is necessary for FDA to execute its authority; (ii) whether the agency's estimate of business impacts is correct; and (iii) and how the quality, utility and clarity of the information can be optimized. Comments will be accepted until June 16, 2014. *See Federal Register*, April 17, 2014.

FDA Refuses to Re-Classify Tooth-Whitening Products as Drugs

The U.S. Food and Drug Administration (FDA) has denied a citizen petition asking the agency to re-categorize tooth-whitening products as drugs instead of cosmetics, stating that, among other things, it lacks specific information about the way peroxide-containing whiteners work to support that action.

Submitted to FDA in 2009 by the American Dental Association (ADA), the petition, which claims that tooth-whitening products can cause damage to patients' teeth and soft tissue in the mouth, and are "easily over-used and abused by individuals who assume that the products are safe since they are readily available," requested that the agency "review and establish an appropriate regulatory classification for tooth-whitening preparations that act by chemical means to lighten tooth color." Specifically, ADA asked the agency to re-classify tooth-whitening products as drugs, voicing concerns about consumers' use of the products without consulting dental professionals.

Emphasizing that to meet the drug definition, tooth whiteners must affect the structure and function of teeth or be meant to treat a disease, Director of FDA's Center for Drug Evaluation and Research Janet Woodcock wrote in an April 22, 2014, **letter**, "we would need to examine each product on a case-by-case basis to determine whether it meets the statutory definition of drug as well as the definition of cosmetic. Without further data illuminating the mechanism of action of peroxide-containing tooth whiteners that work by chemical means, or knowing the intended uses of specific products, we cannot answer the question of whether all tooth whiteners as a group meet the definition of a drug."

Previous FDA efforts in the 1990s to regulate tooth-whitening products as drugs were reportedly thwarted by strong opposition from industry representatives who argued that the products are "generally safe and correctly classified as cosmetics." *See Raps.org*, April 23, 2014.

TTB Finds that Extraction Products Contain Alcohol

The Alcohol and Tobacco Tax and Trade Bureau (TTB) has apparently discovered that some herb, flower, gem, and mineral extraction products labeled, marketed and sold as dietary supplements or "natural health remedies" in U.S. retail establishments, are mis-classified as they purportedly contain 0.5 percent or more alcohol by volume, deeming them subject to regulation and taxation as alcohol beverages. TTB has compiled an **FAQ,** available on its Website, to help "producers, distributors, or importers of extraction products [] comply with the law and regulations and ensure that their products are appropriately labeled."

Illinois Senate Passes Legislation Banning Microbeads

The Illinois Senate has approved, in a 54-0 vote, a bill (**S.B. 2727**) that would ban the use of microbeads—tiny, non-biodegradable plastic particles often added to body cleansers, facial scrubs and toothpastes—by the end of 2018. Considered an increasing environmental threat because they slip through sewage system filters and end up in rivers and lakes, the particles can apparently absorb toxic chemicals already commonly found in such waterways and pose a hazard to fish and other wildlife that mistake them for food or otherwise absorb them. Research also indicates that microbeads can pollute soil if particles running through water treatment facilities get into sewage sludge, which is often used as fertilizer.

The Illinois measure would prohibit the manufacture of microbeads effective December 31, 2017, and the sale of such products would be prohibited as of December 31, 2018. States surrounding the Great Lakes and some coastal states, such as New York and California, have considered similar bans, and lawmakers note that the Illinois legislation could serve as an example for those states because it gives the industry a few years to develop substitutes—including natural alternatives such as ground seeds, nuts, sugar, and salt—and allows retailers to sell current inventory.

According to industry sources, many leading cosmetic companies and industry groups, including the Personal Care Products Council (PCPC) consider the Illinois law fair and say it offers manufacturers sufficient time to change their products. "We believe that the 2017 deadline is one that we can meet with little marketplace disruptions for consumers," said PCPC spokesperson Lisa Powers. While waiting more than four years before the ban on sales takes effect irks some environmentalists, industry representatives counter that the process of switching to alternative materials is time-consuming and complicated, involving substance testing, clinical studies, customer surveys, and product redesign. *See ABCLocal.go.com*, April 16, 2014; *LancasterOnline.com*, April 27, 2014.

In a related development, the Tucson, Arizona-based Desert Whale Jojoba Co. has reportedly developed a biodegradable, natural-based alternative to microbeads created from a combination of castor oil and jojoba oil. According to a news source, the formulation is gentle enough to be used daily and can be customized to fit a variety of skincare product requirements. *See Cosmetics-Design-USA.com*, April 24, 2014.

OEHHA Adds Pulegone to Prop. 65 List

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has **added** pulegone to its list of chemicals known to the state to cause reproductive toxicity under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Prop. 65).

Used as a flavoring agent in perfume and aromatherapy products, pulegone is a naturally occurring organic compound obtained from the essential oils of various plants, including mint, catnip and pennyroyal. The International Agency for Research on Cancer has concluded that there is "sufficient evidence of carcinogenicity in experimental animals" to add pulegone to the Prop. 65 list. Companies making and selling products containing chemicals listed under Prop. 65 are required to disclose exposures to California consumers or face fines for failure to do so. *See OEHHA News Release*, April 18, 2014.

LITIGATION AND REGULATORY ENFORCEMENT

Settlement Reached in Hydroxycut False Advertising Class Actions

Plaintiffs, retailers and Iovate Health Sciences Inc. have reached a $14 million settlement agreement resolving false advertising class actions stemming from sales of the weight-loss supplement Hydroxycut before the U.S. Food and Drug Administration pulled the product from shelves in 2009. *In re Hydroxycut Mktg. & Sales Practices Litig.* No. 09-02087 (U.S. Dist. Ct., S.D. Cal., motion filed April 21, 2014). The settlement follows a similarly structured $25.3 million proposed deal rejected by Judge Barry Ted Moskowitz in November 2013 and a January 2014 ruling declaring that if the claims against the retailers were to succeed, the plaintiffs would have to prove that the retailers directly participated in or controlled ads for Hydroxycut. The $14 million settlement includes $7 million in Iovate products that do not include the allegedly dangerous or ineffective ingredients in Hydroxycut as well as $7 million in cash, with *cy pres* distribution of any remaining money to public health policy nonprofit Changelab Solutions.

Class Claims Weight-Loss Supplement Does Not Contain Hoodia Gordonii

A California resident has filed a putative nationwide class action against the company that makes "AdrenaLean," alleging that it is falsely advertised as containing Hoodia Gordonii, an African cactus, with appetite-suppressant and fat-incinerator capabilities. *Singleton v. Exclusive Supplements, Inc.*, No. BC542886 (Cal. Super. Ct., Los Angeles Cnty., filed April 17, 2014). According to the complaint, laboratory testing showed that the product contains no Hoodia Gordonii and thus "cannot provide the results promised, cannot perform as Defendant claims, and does not contain the active ingredients promised."

The plaintiff also alleges that the defendant promises "fast acting energy, appetite suppression, and weight loss minus the jittery side effects," despite adding caffeine and yohimbie, "both of which cause jitters," to the product and promises "'no crash' even though caffeine causes a crash." Accordingly, the plaintiff claims, "not only is Defendant falsely claiming what ingredients are actually present in its Product, but all of Defendant's claims based on the ingredient's capabilities are completely false."

Alleging violations of the state's False Advertising Law, Unfair Competition Law and Consumers Legal Remedies Act, the plaintiff seeks damages, restitution, injunctive relief, interest, attorney's fees, and costs.

Complaint Alleges Xymogen's Supplements Contain Lead

Public interest group Environmental Research Center (ERC) has sought civil penalties and an injunction against nutritional supplement manufacturer Atlantic Pro-Nutrients Inc., also known as Xymogen, in California state court for exceeding the daily dose limit on lead defined in California's Proposition 65. *Envtl. Research Ctr. v. Atlantic Pro-Nutrients Inc.*, No. RG14722249 (Cal. Super. Ct., Alameda Cnty., filed April 21, 2014). According to ERC, each daily dose of Xymogen's products contains more than the 0.5 microgram limit set by Proposition 65, the Safe Drinking Water and Toxic Enforcement Act. ERC seeks an injunction preventing Xymogen from manufacturing the products in California without providing warnings about the risk of using or handling the products as well as at least $15 million in civil penalties. ERC also implored Xymogen to contact each purchaser of their products to warn them of the risks.

Putative Class Action Filed Against Revlon Over "DNA Advantage" Claims

Two women have filed a putative class action against Revlon Consumer Products Corp. alleging that the cosmetic company's use of the term "DNA Advantage" on three of its products constitutes deceptive business practices, false advertising, misrepresentation, and breach of warranties. *Elkind v. Revlon Consumer Prods. Corp.*, No. 14-02484 (U.S. Dist. Ct., E.D.N.Y., filed April 17, 2014).

The complaint alleges that Revlon's federal trademark application for "DNA Advantage" explains that the term merely refers to sunscreen rather than ingredients that "interact with the skin's DNA, perhaps on a cellular or molecular level, to provide scientifically-enhanced therapeutic benefits that reverse, minimize, slow, or otherwise 'defy' the process of aging," as the term implies to plaintiffs. Citing the definitions in the Federal Food, Drug, and Cosmetic Act, the plaintiffs argue that the DNA Advantage products are both drugs and cosmetics and allege that Revlon has failed to abide by regulations for either. The plaintiffs seek class certification, an injunction on further sales or misleading advertisement of the products, a corrective advertising campaign, actual and punitive damages, and attorney's fees.

Class Alleges Undergarment Minerals and Nutrients Cannot Reshape Bodies

Massachusetts residents have filed a putative consumer-protection class action against the companies that sell women's undergarments made with shapewear fabric produced by a Spanish company and claim that the fabric contains minerals and nutrients which can permanently alter women's body shape and skin tone. *Bellot v. Maidenform Brands, LLC*, No. 14-11834 (U.S. Dist. Ct., D. Mass., filed April 14, 2014). Information about a similar putative nationwide class action filed against the same defendants in 2013 appears in Issue 14 of this *Report*.

According to the plaintiffs, marketing claims that the fabric's nutrients can permanently cure cellulite, destroy fat or cause weight loss are false, prey on women's body-image insecurities and allow the defendants to charge as much as 50 percent more for garments made with the fabric than for "equivalent non-nutrient infused shapewear." Alleging damages in excess of $5 million, the plaintiffs assert breach of express warranty of merchantability, breach of implied warranty of merchantability and unjust enrichment.

Beverage Co. Seeks Cancellation of Muscle Milk® Trademark Registrations

Alleging that use of the term "milk" for dietary supplement products that contain no milk from a cow constitutes false advertising under the Lanham Act, Global Beverage Enterprises Inc. has filed a complaint against the company that makes Muscle Milk®, seeking the cancellation of its trademark registrations. *Global Beverage Enters. Inc. v. Cytosport, Inc.*, No. 14-60950 (U.S. Dist. Ct., S.D. Fla., filed April 23, 2014).

According to the complaint, the companies' competing products "are placed in the same beverage cooler at The Fresh Market stores nationwide." The plaintiff contends that the defendant's use of the word "milk" on its products "deceives consumers and unfairly benefits from the good will associated with milk products or other healthy beverages." The plaintiff also alleges that Muscle Milk® marketing suggests to consumers that the products contain milk and are thus "healthier beverages when compared to competitor's products,

including the Plaintiff's products." By selling the products in "flavors traditionally associated with milk," including chocolate, chocolate malt and shake, and marketing the products as "lactose free," the defendant allegedly bolsters this deception.

The plaintiff seeks declaratory and injunctive relief, trademark registration cancellation, attorney's fees, and costs for alleged violations of the false-advertising provisions of federal trademark law. 15 U.S.C. § 1051, *et seq.*

EMERGING TRENDS

Cosmetics Market Expected to Hit $635.7 Billion by 2019

International research firm Markets and Markets has issued a report which observes that the international cosmetic products market has witnessed "significant growth" during the past few years and "is expected to reach $635.7 billion by 2019."

Titled **"**Cosmetic Products Market by Type (Skin, Hair, Sun, Oral, Fragrance, Color, Soap, Bath, Shower, Personal Hygiene), Distribution Channel (Supermarket, Pharmacy, Departmental, Specialty, Direct, Internet, Salon) & Geography—Global Trends & Forecasts to 2019," the report "defines and segments the cosmetic products market with analysis and forecasting of value and volume for cosmetic products." It also identifies market drivers, restraints, opportunities, key issues, and challenges.

Report authors attribute several key factors to the growth, including (i) an increasing demand for advanced and sophisticated cosmetic products; (ii) technological advancements in cosmetic manufacturing; (iii) economic developments in emerging markets such as China, Brazil and India; (iv) changing trends in beauty product use; and (v) increasing awarenesss about appearance.

Nu Skin Resumes Chinese Operations

Direct sale skincare company, Nu Skin Enterprises, has announced plans to immediately resume corporate-hosted business meetings and begin accepting applications for new sales people on May 1, 2014. The action follows a months-long suspension of such activities after the company came under fire from the Chinese government and was slapped with a $540,000 fine for allegedly selling unregistered products, making unsubstantiated product claims and using aggressive sales tactics.

Calling China "an important marketplace for Nu Skin," President of Sales and Global Operations Dan Chard said that the company is "committed to operating in full compliance with China's direct selling regulations" and plans to

continue working with regulatory agencies to refine training procedures and educate salespeople on local laws and company policies.

According to a company statement, Nu Skin will report first quarter 2014 results before the market opens on May 6, 2014, and will provide updated guidance at that time. Additional details about Nu Skin's Chinese sales operations appear in Issue 22 of this *Report*. *See Nu Skin News Release*, April 19, 2014.

INTERNATIONAL DEVELOPMENTS

Record-Breaking Amount of Fake Cosmetics Seized in Dubai

Dubai authorities have reportedly seized $2.6 million worth of counterfeit cosmetics after raiding a factory and its warehouse in the emirate. The goods, which included counterfeit versions of well-known brands, including 756,000 mascaras, 240,000 face powders and 120,000 lipsticks and other items, were seized by police and members of Dubai's Department of Economic Development (DED). According to a news source, the action supports an ongoing campaign by the Intellectual Property Protection Section at the Consumer Protection and Commercial Control department (CCCP) of the DED to preserve brand name products and protect consumers from counterfeit products that may contain harmful ingredients. Calling the seizure "the biggest operation with regard to body care products and cosmetics," CCCP spokesperson Adel Ahmed said, "DED seeks to protect brands and trademarks against violations in accordance with the policy of the Dubai Government to enhance economic activity and uphold intellectual property. We are determined to curb any activity that cause[s] harm to public health as well as the health of the market. *See UAEInteract.com*, April, 18, 2014.

SCIENTIFIC/REGULATORY DEVELOPMENTS

Scientists Develop Lab-Grown Skin to Replace Animal Testing

Researchers from King's College in London and the San Francisco Veteran Affairs Medical Center (SFVAMC) have reportedly developed the first ever lab-grown epidermis—the outermost layer of skin—with a functioning permeability barrier similar to human skin. While other scientists have apparently been able to grow certain parts of the skin from embryonic skin cells, until now, none could produce the outermost layer responsible for keeping moisture in the body and toxins out. The researchers say that the new epidermis, grown from human pluripotent stem cells, "offers a cost-effective alternative lab model for testing drugs and cosmetics, and could also help to develop new therapies for rare and common skin disorders."

Published in *Stem Cell Reports*, the study observes that researchers were able to produce a conceivably unending supply of keratinocytes—the major cell type in the epidermal layer—from human pluripotent stem cells and subsequently produce a three-dimensional, fully functional epidermis equivalent. Using this method, scientists believe they could produce an infinite line of skin cells from a single biopsy, allowing them to more easily research specific skin conditions.

"The ability to obtain an unlimited number of genetically identical units can be used to study a range of conditions where the skin's barrier is defective due to mutations in genes involved in skin barrier formation, such as ichthyosis (dry, flaky skin) or atopic dermatitis," said lead SFVAMC researcher Theodora Mauro. "We can use this model to study how the skin barrier develops normally, how the barrier is impaired in different diseases and how we can stimulate its repair and recovery."

The new method would also provide cosmetic companies access to a relatively inexpensive supply of human skin that would be easier and more humane to work with than the animals currently used for testing, said the researchers, noting that lab-grown epidermal layers would provide "more reliable feedback on how human skin would react to cosmetic products."

According to King's College lead researcher Dusko Ilic, the new method can be used to grow "much greater quantities of lab-grown human epidermal equivalents, and thus could be scaled up for commercial testing of drugs and cosmetics. Human epidermal equivalents representing different types of skin could also be grown, depending on the source of the stem cells used, and could thus be tailored to study a range of skin conditions and sensitivities in different populations." *See King's College London News Release*, April 24, 2014.

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