Shook, Hardy & Bacon L.L.P.

ISSUE 34 | OCTOBER 23, 2014

LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

CONTENTS

INSIDE GOVERNMENT

FDA Considers Action on DMBA Products; GNC Stops Selling Them

The U.S. Food and Drug Administration (FDA) has received communications from the Council for Responsible Nutrition as well as U.S. Sens. Dick Durbin (D-Ill.) and Richard Blumenthal (D-Conn.) urging the agency to take action on the dietary-supplement ingredient known as AMP Citrate or DMBA, and FDA has indicated that it will consider taking regulatory action on the stimulant.

According to a news source, GNC stopped selling Redline White Heat and OxyTHERM Pro on its Website one day after *USA TODAY* criticized the products for containing the ingredient, a "close chemical cousin of DMAA—a stimulant the FDA has warned is an illegal ingredient that contains risks of heart attacks, seizures and neurological conditions," according to the newspaper. *USA TODAY* and the senators cited a recent study examining AMP Citrate to support concerns about its safety. Pieter A. Cohen, et al., "A synthetic stimulant never tested in humans, 1,3-dimethylbutylamine (DMBA), is identified in multiple dietary supplements," *Drug Testing and Analysis*, October 8, 2014. *See USA TODAY*, October 8 and 9, 2014.

FTC Seeks Public Comments on Consent Agreements over "Slimming" Garments

The U.S. Federal Trade Commission (FTC) has published analyses of its proposed consent agreements with Norm Thompson Outfitters, Inc. and Wacoal America, Inc. to aid public comments, which must be submitted by October 29, 2014. The consent agreements, if given final approval after comment, would resolve claims that the companies violated the law by falsely claiming that their garments, "infused with microencapsulated caffeine and other ingredients," can reduce cellulite and slim and reshape the body. Additional details about the settlements appear in Issue 33 of this *Report*. *See Federal Register*, October 6, 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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California Court Nixes Suit by Dietary-Supplement Maker Against Consumer

A California appeals court has determined that a dietary-supplement maker cannot stop a consumer from filing a false-advertising claim under the Consumers Legal Remedies Act (CLRA) by bringing an action against the consumer and her attorneys, seeking a declaration that its ads were accurate and legal. *Lunada Biomedical v. Nunez*, Nos. B243205 & B246602 (Cal. Ct. App., decided October 9, 2014). So ruling, the court affirmed the trial court's grant of the consumer and attorneys' motion to strike the company's complaint under the state's anti-SLAPP (Strategic Lawsuit Against Public Participation) statute. The court further upheld the attorney's fee award to the consumer and her attorneys and remanded for calculation of fees incurred in connection with the appeal.

The court determined that (i) the declaratory-judgment action arose from a protected activity, i.e., the filing of a CLRA notice-and-demand letter, required under the law as a prerequisite to filing a CLRA lawsuit; and (ii) the company did not demonstrate a probability of prevailing on the claim because "it may not sue for declaratory relief regarding a claim for damages under the CLRA."

According to the court, the declaratory-judgment action would thwart certain important CLRA incentives and goals, including (i) mandatory attorney's fees, (ii) the possibility of avoiding litigation by providing an opportunity to remedy statutory violations after the demand letter is served but before a lawsuit seeking damages is filed, and (iii) the elimination of the class-action rights of consumers who would have joined the CLRA class action. In its view, the declaratory-relief action would undermine the CLRA. Because the plaintiff was precluded from filing the declaratory-relief claim, the court determined that it could not demonstrate a probability of prevailing on that claim. The court also found that without an actual controversy between the company and the plaintiff's attorneys, who are not consumers under the CLRA and cannot bring a CLRA claim on their own behalf, the company "cannot prevail on its claims against the law firm defendants."

CVS to Pay $225K to Settle Charges over Misleading Product Packaging

CVS/pharmacy has reportedly agreed to pay four California counties and the California Department of Agriculture $225,000 for allegedly misrepresenting product sizes "by use of oversized and non-functional slack-fill and/or false sidewalls and/or false bottoms." The company allegedly violated the California Business and Professions Code as well as health and safety provisions. Among the list of 11 affected products are Accelerated Wrinkle Repair Moisturizer, Age Refine Eye Cream, Moisturizing Face Cream Hair Remover, and Frizz-Defy Hair Serum. CVS can continue to manufacture the products until January 1, 2015, and may continue selling the products for two years.

In a statement to Fresno's ABC30, a CVS representative said, "CVS/pharmacy is committed to ensuring that its product packaging is sufficient in size to accommodate pertinent information about the product. CVS Brand products, including packaging, are generally designed to be similar to the national brand equivalents. While manufacturers generally choose the container size, CVS/pharmacy has agreed to redesign the packaging of certain CVS Brand items." *See ABC30*, October 3, 2014.

NAD Criticizes Philosophy's Study Supporting "Time in a Bottle" Anti-Aging Serum Ads

The National Advertising Division (NAD) of the Council of Better Business Bureaus has recommended that Philosophy, Inc. discontinue some advertising claims about its Time in a Bottle Age-Defying Serum because NAD found problems with the six-month clinical study the company cited to support its claims. Philosophy advertised the product as causing users' skin to look two years younger, reducing signs of aging and making skin appear "radiant," "poreless," "even," and "wrinkle-free." In the study, 117 women aged 25 to 55 used the product once daily and then answered questions about how their skin looked after four and eight weeks of use.

Among the problems NAD cited as to the study's reliability were (i) Philosophy did not account for environmental factors because it began the trial in winter, when skin is driest, and ended it in summer, when humidity is most excessive; (ii) skin-imaging analysis was used in advertising to show results but was only used on 26 of the 117 participants; (iii) the study used self-assessments rather than trained experts to determine actual results, causing a disparity between the actual improvements in anti-aging parameters and the self-reported improvements; and (iv) the self-assessment questionnaire may have been unreliable because of its length and the questions it asked, such as "Skin appears __ years younger."

In its response, Philosophy expressed respect for the process but disagreed with the determination, finding that the criticism of its study, "one of the most significant and extensive studies conducted in the cosmetics industry to evaluate product performance across a broad audience of women at different times," could "result in confusing guidance for the cosmetics industry and disincentivize manufacturers from conducting similar comprehensive studies." According to a news source, the company said it would appeal the ruling to the National Advertising Review Board. *See NAD Press Release*, October 9, 2014.

INTERNATIONAL DEVELOPMENTS

India Prohibits Imports of Cosmetics Tested on Animals

Beginning November 13, 2014, India will no longer permit the "import of cosmetics tested on animals." The government reportedly took the action

some five months after prohibiting cosmetic animal testing within the country. According to news sources, the country is the first in south Asia to take such action. India's Chapter of the Humane Society International, which along with other organizations pushed for the ban, called the action "an example for other nations to follow." An organization spokesperson said, "This is a huge achievement that could not have been possible without the compassion of our government, consumers and industry. We feel confident that if this vision is applied to other areas of product testing, this can be a defining moment in the modernization of India's safety science, with potentially hundreds of thousands more animals spared pain and suffering." *See The Times of India*, October 14, 2014; *The Hindu*, October 15, 2014.

Manufactured Nanoparticle Substances to Be Registered in Belgium

According to the Belgian Official Journal, as of January 1, 2016, manufactured nanoparticle substances, with certain exceptions, must be registered in Belgium through a Web platform. These substances are further defined and include fullerenes, graphene flakes and single-wall carbon nanotubes with one or several external dimensions less than 1 nm. Mixtures containing these substances must be registered by January 1, 2017, and products containing manufactured nanoparticle substances will be registered at a later date. Excluded from the registration mandate are biocidal products, medicines, food and feed, food contact materials, and pigments. Data on the exact use, function or applications, and the registrant will remain confidential. *See nanotechia.org News Release*, October 9, 2014.

EU Science Committee Approves UV Filter in Sunscreens

The European Commission's Scientific Committee for Consumer Safety has determined that a UV filter is safe at a concentration of up to 10 percent in sunscreen products. While the committee ruled in its revised opinion that 1,1'-(1,4-piperazinediyl)bis[1-[2-[4-(diethylamino)-2-hydroxybenzoyl]phenyl]-methanone (HAA299) does not pose a risk of systemic toxicity to humans at this concentration, the ruling does not include an evaluation of HAA299 filters composed of nanoparticles nor does it apply to inhalation exposure, due to insufficient data provided.

EMERGING TRENDS

Anti-Shampoo Product Market Expanding

In a trend some have attributed to a growing interest in the use of products with "natural" ingredients, a niche market has developed around the belief that shampoo contains chemicals detrimental to both hair and the environment. New products have been introduced to meet the "no poo" community's needs. *Fast Company* examines Purely Perfect, a "cleansing crème" made with aloe vera and various oils and without sulfates, parabens or surfactants—the

ingredient that causes shampoo to foam. Purely Perfect Founder Michael Gordon also created hair-care company Bumble and Bumble, now an Estée Lauder Cos. brand. Colin Walsh, president of DevaCurl and seller of a similar product branded as No-Poo, reportedly said, "We like to say we took the 'sham' out of the 'poo.'"

The science supporting the movement is "shaky," says *Fast Company*. The premise is that washing hair every day removes the sebum, and the scalp produces more oil to compensate, leaving hair oily. Dermatologists apparently dispute this concept; one reportedly compared it to the myth that shaving makes hair grow back more thickly. Some in the "no poo" movement have turned to a concoction of baking soda and apple cider vinegar, which caused one dermatologist to tell *Fast Company* that using something so caustic on the hair "makes commercial shampoo look like child's play."

Still, "no poo" companies have apparently been growing—DevaCurl claims that sales of No-Poo have nearly doubled in the last three years and that 2014 will be its best year yet. Walsh reportedly attributes the product's success to media attention and the expansion of the grassroots movement that pays attention to the ingredients in beauty products. *Fast Company* compares the quick growth in "no poo" popularity to the rise in sulfate-free shampoos, which it says Pureology created as a category a decade ago and are now available through retailers everywhere. *See Fast Company*, October 8, 2014; *The Atlantic*, October 21, 2014.

SCIENTIFIC/TECHNICAL DEVELOPMENTS

Two-Thirds of Recalled Dietary Supplements Still Contain Pharma Ingredients

According to a *Journal of the American Medical Association (JAMA)* research letter, 66.7 percent of dietary supplements, recalled due to adulteration with pharmaceutical ingredients between January 2009 and December 2012, that were still available for purchase at least six months after the recalls remained adulterated with banned ingredients. Pieter A. Cohen, et al., "Presence of Banned Drugs in Dietary Supplements Following FDA Recalls," *JAMA*, October 22/29, 2014. The researchers purchased the supplements in July or August 2013 directly from the Websites of supplement manufacturers or retailers rather than through e-commerce sites such as Amazon.com. They were subjected to the same type of testing used by the U.S. Food and Drug Administration (FDA), but just as to the common adulterants anticipated based on the marketing claims. The supplements remained adulterated in 85 percent of those sold for sports enhancement, 67 percent for weight loss and 20 percent for sexual enhancement.

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Researchers Identify Nanoparticle Skin-Penetrating Characteristics

Studying gold nanoparticles, University of Southampton, UK, scientists have experimented with surface charge, shape and functionality to learn how to enhance skin penetration. Rute Fernandes, et al., "Interactions of Skin with Gold Nanoparticles of Different Surface Charge, Shape, and Functionality," *Small*, October 7, 2014. Lead author Antonios Kanaras said, "By creating nanoparticles with different physicochemical characteristics and testing them on skin, we have shown that positively charged nanorod shaped, nanoparticles are two to six times more effective at penetrating skin than others. When the nanoparticles are coated with cell penetrating peptides, the penetration is further enhanced by up to ten times, with many particles making their way into the deeper layers of the skin (such as the dermis)." The research could apparently help scientists discover ways to prevent potentially toxic nanoparticles in such products as cosmetics from entering the skin. *See University of Southampton News Release*, October 9, 2014.

UPCOMING CONFERENCES AND SEMINARS

Perfumes & Cosmetics Conference Scheduled in Chartres

The 12th annual Perfumes & Cosmetics Congress will be held November 19-20, 2014, in Chartres, France, and for the first time will be simultaneously translated in English. Intended for corporate executives as well as all those involved in developing, manufacturing and promoting perfumes and cosmetics, the event will give participants the opportunity to remain current with regulatory changes, network with peers and meet with regulatory authorities. Among other items on the agenda are sessions on raw material safety, cosmetics packaging safety, allergens, ingredients, and advertising.

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