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DIETARY SUPPLEMENT & COSMETICS LEGAL BULLETIN

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SHOOK HARDY & BACON

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SPOTLIGHT

British Environment Minister Presses Plastic Microbead Ban

Microbeads remain a hot issue both domestically and abroad. In a mid-June 2016 appearance before Parliament's Environmental Audit Committee, UK Environment Minister George Eustice testified in favor of aggressive movement toward a ban on plastic microbeads in toiletries and cosmetics. He indicated that Britain has been working with EU countries to bring the microbead prohibition issue to the forefront of the EU's agenda and further suggested the UK would pursue a national ban if the EU failed to take action, or if the UK exited the EU. According to Eustice, several EU member states support a ban, including the Netherlands, France, Belgium and Austria. *See The Guardian* and *Parliament Live TV*, June 14, 2016.

LITIGATION

California Federal Court Rejects Plaintiff's Class Certification Request

A California federal court has denied a class certification and consolidation request in a lawsuit alleging Pharmacare US, Inc.'s IntenseX Sexual Power & Performance® failed to provide the promised benefits. *Sandoval v. Pharmacare US, Inc.*, No. 15-0738 (S.D. Cal., order entered June 10, 2016). The plaintiffs alleged violations of a variety of California statutes, including the Unfair Competition Law, Business & Professions Code, False Advertising Law and Consumer Legal Remedies Act. The complaint also alleged breach of express warranty and implied warranty of merchantability as well as a violation of the federal Magnuson-Moss Warranty Act.

While the court found the plaintiff's allegations sufficient to support ascertainability and numerosity under Rule 23, it determined that he failed to demonstrate commonality and predominance. The court further refused to reform the class definitions to allow the plaintiffs to establish

coextensive and typical claims consistent with those of the putative classes. Based on these deficiencies, the court refused to "address the issue of Plaintiffs' adequacy as class representatives" and determined that a nationwide class was not appropriate because they could not make the requisite showing under California's *Mazza v. American Honda Motor Co.*, 666 F.3d 581 (9th Cir. 2012).

Glucosamine False-Ad Suit Survives Multiple Dispositive Motions

A California federal court denied a bevy of motions in a false advertising lawsuit asserting that Nature Made® glucosamine supplements were no more effective than a placebo. *Barrera v. Pharmavite, LLC*, No. 11-4153 (C.D. Cal, order entered June 2, 2016). The court first dispensed with the parties' various expert report objections, finding insufficient grounds to strike or exclude any of the reports, and instead assessed the methodologies employed to determine the weight of the reports as evidence. The court also rejected the defendant's motion to decertify the class, finding that the plaintiffs' classes were ascertainable and that common questions regarding reliance and value derived by customers predominate. Additionally, the court denied the defendant's motion for judicial estoppel, determining that the complaint—from the outset—had challenged the veracity of representations relating to the product's overall health benefits.

"Joint Juice" Lawsuit Class Limited to California

The U.S. District Court for the Northern District of California has denied the plaintiff's request to expand the classes to include members who purchased a glucosamine hydrochloride and chondroitin sulfate supplement referred to as "Joint Juice" in either "all fifty states" or "in ten specific states." *Mullins v. Premier Nutrition Corp.*, No. 13-1271 (N.D. Cal., order entered June 20, 2016). The court found that the consumer-protection statutes across all 50 states are not identical, and some conflict with California consumer-protection laws. The court further rejected the plaintiff's attempt to expand the classes to include "ten specific states" because the defendant had "demonstrated the existence of material conflicts and that each individual state's interest in the application of its laws outweighs California's interest in applying its laws to certain members among the proposed ten-state group."

Shook 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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LEGISLATION, REGULATIONS AND STANDARDS

FDA Continues to Issue Warning Letters to Cosmetics Manufacturers

During April and May 2016, the U.S. Food and Drug Administration (FDA) issued three warning letters to cosmetics companies addressing "drug claims made for products marketed as cosmetics."

In its May warning letter to Reviva Labs, FDA identified a number of claims it viewed as problematic, including: "ingredients that can help increase fatty tissue volume to . . . plump up . . . ," "new peptides and additional ingredients can help increase the volume of fatty tissue," "can help . . . reduce inflammation . . . " "reduces blemish-causing bacteria," and "fade dark spots."

FDA acknowledged that Reviva had responded, but was unable to evaluate the response due to "lack of documentation." The letter set a 15-day response period for the company to identify the "specific steps it has taken to correct violations."

FDA has not issued a close-out date for this letter, but sources indicate that Reviva Labs will eliminate all drug-like marketing claims from its products as a result of the warning letter. "I believe you will see that we are going beyond your Warning Letter to comply with FDA cosmetic directives for all Reviva products," owner Stephen Strassler was quoted as saying. *See New Jersey.com*, July 1, 2016.

Similarly, FDA's warning letter to Crescent Health Center, Inc., identified as problematic product label claims for the Ageless Derma Stem Cell and Peptide Anti-Wrinkle Cream and Ageless Derma Anti-Aging Skin Brightener Cream. The labels indicated the products were "proven to reduce all types of hyperpigmentation" and "improve the firmness and elasticity of the skin, removes crows feet." Claims on the company's websites relating to these products were also deemed problematic. Additionally, the agency found the products were misbranded. The 15-day response period has passed, and no further updates are yet available. FDA has not issued a close-out date for this letter.

In mid-April, FDA issued a warning letter to Hollywood Skincare International, Inc., finding that the claims on its website relating to the product DermaSet™ Stem Cell 3d Renewal Treatment established the

product as a drug, and the introduction or delivery of the product into interstate commerce violated the Federal Food, Drug, and Cosmetic Act (FDCA). Unapproved claims found on the website included assertions that the product "Removes Wrinkles Instantly." In addition, claims regarding the product ingredients included statements such as "This marine ingredient…offer[s] protection against UVB induced free radicals," and "provides amazing benefits to our skin by . . . stimulating regeneration of cell tissues. . . "

FDA sent Hollywood Skincare a close out letter on June 1 to inform the company that its (unspecified) corrective actions taken in response to the warning letter sufficiently addressed the violations cited in the letter.

The agency cautioned, however, that it expects the company to maintain compliance with the FDCA and its implementing regulations and will continue to monitor Hollywood Skincare's compliance in the future.

FDA Issues Revisions to Bacteriological Analytical Manual

In May 2016, the U.S. Food and Drug Administration (FDA) issued revisions to its Bacteriological Analytical Manual, Chapter 23, Microbiological Methods for Cosmetics. The modifications address dilution rates, screening tests for total numbers of microorganisms and identification of microbes. Among the subjects addressed methods for isolating microorganisms from cosmetic products, the equipment and materials needed for isolation and identification, and handling and testing of samples.

California's "Made in America" Legislation Withdrawn

A.B. 2827, the "Made in the U.S.A.," bill was withdrawn in California's Senate on June 15, 2016, after having been amended and passed in the Assembly. The amendment allowed for a private right of action for consumers alleging damages as a result of violations by including "Made in the U.S.A." to the list of "unfair methods of competition and unfair or deceptive acts or practices" found in the California Consumer Remedies Act.

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ABOUT SHOOK

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. We help 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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British Cosmetics Trade Group Issues Statement Regarding "Brexit" Shakeup

British cosmetics trade group CTPA recently issued a statement reassuring its members that the UK's decision to leave the European Union would not affect the "strict safety laws that govern [the UK's] cosmetics products." It noted that the transition process and exit from the EU is expected to take years, and that the current legal structure—set by the EU—will remain in place during the transition. According to CTPA, compliance with the Cosmetic Products Regulation will continue to be mandatory for cosmetics sold in the UK. *See CTPA Statement*, June 24, 2016.