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DIETARY SUPPLEMENT & COSMETICS LEGAL BULLETIN

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SHOOK HARDY & BACON

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SPOTLIGHT

FTC Cracks Down on Cosmetics Companies' Sales Practices

The Federal Trade Commission (FTC) has secured orders against 29 defendants whom it claims deceptively marketed and billed consumers for skin care products. The products sold by the California-based defendants include Auravie, Dellure, léOR Skincare and Miracle Face Kit brands.

Filed in June 2015, the original complaint, alleged violations of the Federal Trade Commission Act (FTC Act), Restore Online Shoppers' Confidence Act (ROSCA), and Electronic Funds Transfer Act (EFTA) by 22 defendants. The complaint was amended in October 2015, adding 11 defendants.

The alleged FTC Act violations target defendants' practices of offering "risk-free trials" on websites, and online banner and pop-up ads. Consumers who signed up for the trials were required to enter their billing information for nominal shipping and handling charges, but were evidently charged full cost of the product 10 days later. FTC also alleges the defendants failed to disclose material terms of their return policies. Further, defendants employed negative option features, including enrolling consumers in continuity plans without properly disclosing the material terms and obtaining consumers' express informed consent. FTC pointed to defendants' false Better Business Bureau accreditation and ratings claims as further violations of the FTC Act.

Twenty-nine of 33 defendants have either agreed to court orders or had default orders entered against them by the court. Those orders together total more than $72.7 million in monetary judgments against the defendants. Litigation is ongoing for the remaining four defendants.

Jessica Rich, director of FTC's Bureau of Consumer Protection, was quoted as saying the agency "will continue to attack scams that rely on supposed 'free trial' offers and unauthorized credit card charges." *See FTC Press Release*, October 13, 2016.

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LITIGATION

FTC Reaches Agreement with Marketers in Joint Supplement False Advertising Case

The Federal Trade Commission (FTC) has announced an agreement with the marketers of Supple®, a liquid supplement containing glucosamine and chondroitin. FTC had charged the Wisconsin company and principals with making false advertising claims. *FTC v. Supple, LLC et al.*, 16-cv-01325 (E.D. Wis., order entered October 4, 2016).

The complaint, filed in early October 2016, included charges of false or unsubstantiated efficacy claims based on the defendants' advertisements and online chats. Defendants were alleged to have promoted Supple as providing long-lasting joint pain relief, including pain experienced as a result of rheumatoid arthritis, fibromyalgia and osteoarthritis. They also made claims about the supplement's ability to repair or rebuild cartilage and joints, provide pain relief comparable to drugs and surgery, and restore mobility and joint function. Count two of the complaint, a false establishment claim, was based on defendants' representation that Supple is clinically proven to eliminate joint pain. Count three alleged false or unsubstantiated expert endorsement by Monita Poudyal, M.D., the former wife of Supple CEO Peter Apatow.

Additional counts involved FTC's claims that the infomercials promoting Supple represented Poudyal as an independent and impartial medical expert, failing to reveal that she was married to Apatow at the time of her endorsement, and that her website endorsements also failed to disclose their relationship.

The stipulated settlement agreement requires that any future claims made by the defendants about pain relief, treatment of diseases and health benefits be supported by competent and reliable scientific evidence. Additionally, defendants may not represent that endorsements by individuals with close personal or financial ties to the product are independent or objective. Most of the more than $150 million judgment has been suspended based on the financial condition of the defendants.

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.

For additional information about Shook's capabilities, please contact

Laurie Henry
816.559.2421
lhenry@shb.com

Madeleine McDonough
816.559.2342
202.783.8400
mmcdonough@shb.com

If you have questions about this issue of the *Bulletin* or would like to receive supporting documentation, please contact Mary Boyd at mboyd@shb.com.

Preliminary Settlement Granted in WEN Hair Loss Litigation

A California federal judge recently granted class certification and preliminary approval of a class settlement in litigation against WEN By Chaz Dean and Guthy-Renker, LLC. *Amy Friedman v. Guthy-Renker, LLC*, 2:14-cv-06009 (C.D. Cal., order entered October 28, 2016).

The lawsuit, originally filed in January 2014, maintains that consumers using WEN hair care products have experienced hair loss and scalp irritation; a second amended complaint was filed in June 2015.

The court order also granted plaintiffs leave to file a third amended complaint, which the plaintiffs completed soon after the ruling. The amended complaint adds two additional plaintiffs to the action and broadens the class definition. It also broadens the number of WEN products at issue in the case.

An estimated 6 million people could be eligible for compensation under the settlement, which includes two tiers for claims. The first tier allows any class member to submit a claim for $25 and does not require supporting documentation. The intention is to compensate these consumers for the false advertising claim, rather than for a bodily injury. Five million dollars of the settlement fund would be available for these claims. In the second tier, class members can seek a larger payment, but must provide supporting documentation for their injuries. The maximum award for tier two claims would be $20,000 and is dependent on the amount of hair loss and type of documentation provided.

The parties must file a motion for the final approval of the settlement by May 1, 2017, including the number of members filing tier-one and tier-two claims, with an estimate of the amount of funds going to tier-two claims. A hearing for the final approval of the class certification and settlement is set for June 5, 2017.

LEGISLATION, REGULATION AND STANDARDS

FDA Sends Warning Letters to Skin Care Companies

The Food and Drug Administration (FDA) recently posted two warning letters to topical skin care companies over the companies promotion of products for uses that qualify them as drugs under the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The agency's letter to PhytoCeuticals, Inc., lists 17 products and highlights label and website claims which indicate that they are intended for use as drugs. Some of these claims include language such as, "assists in skin regeneration," "Anti-Inflammatory," "Promotes extraordinary healing capabilities," and "Restores skin pigment." The letter also warns that two of the company's products are misbranded drugs under the Act. Additionally, the letter warns that even if the products did not state claims that made them unapproved drugs, they are still in violation as adulterated cosmetics. FDA inspections apparently revealed that the company failed to protect ingredients from contamination with foreign materials, which is a violation of section 301(a) of the Act.

FDA's letter to Bioque Technologies, Inc. and Vouray, Inc. also warns that these companies' skin care products are in violation of the Act because their claims indicate the products are intended for use as drugs. The serums and creams identified by FDA are promoted by language such as "Banish bruises and prevent unsightly scars," "Promotes the production of collagen and elastin," and "Works all day to protect your skin from harmful…DNA damage." This letter also identifies problems revealed in FDA inspections, making the products adulterated cosmetics under the law.

GLOBAL

Health Canada Proposes Overhaul of Health Products and Dietary Supplement Regulatory Rules

Health Canada recently issued a consultation document describing three proposals for a new regulatory framework for self-care products.

Health Canada currently divides self-care products into three categories: (1) cosmetics used to clean, improve or alter complexion, skin, hair, or teeth; (2) natural health products, which encompasses vitamins, supplements, probiotics, herbal products, homeopathic remedies, and traditional medicines; and (3) non-prescription drugs. Under Canadian law, all of these products are regulated under the Food and Drugs Act, but three sets of regulations govern them—cosmetic regulations, natural health products regulations, and food and drug regulations—resulting in different rules for bringing self-care products to market.

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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.

Under the agency's first proposal, products would be characterized by three risk profiles—lower, moderate and higher.

Lower-risk products would not require Health Canada's review or licensing, but manufacturers would have to meet certain requirements to sell them. Examples of such products would include cosmetics, toothpaste, mouthwash, diaper rash products, homeopathic products, and many vitamin and mineral products.

Products in the moderate-risk category would be subject to some review and licensing requirements, and Health Canada would approve claims based on scientific evidence. Companies would be required to meet quality standards, but full review would not be necessary. The moderate-risk category would include topical and oral pain relievers, cough and cold products, laxatives, and allergy relief products.

The higher-risk category would require full review of product claims by Health Canada, and companies would be required to provide evidence of safety, quality and effectiveness. Product examples in this category would include products moving from prescription to non-prescription status, those containing new medicinal ingredients and products for cardiovascular health.

Under the agency's second proposal, regulatory evaluators would review product health claims based on a new definition requiring companies to provide scientific evidence to support such claims. Health Canada would review claims pertaining only to "diagnosis, treatment, prevention, cure, or mitigation of a disease or serious health condition."

Under the third proposal, Health Canada would continue to take a risk-based approach to compliance and safety monitoring.