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DIETARY SUPPLEMENT & COSMETICS LEGAL BULLETIN

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SHOOK HARDY & BACON

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SPOTLIGHT

FDA Approves Retinoid Acne Gel for OTC Use

The U.S. Food and Drug Administration (FDA) has approved Differin Gel 0.1% (adapalene) for over-the-counter (OTC) treatment of acne. FDA has not approved an OTC acne treatment ingredient in the last three decades and this once-a-day topical gel is the first-ever retinoid acne treatment approved for OTC use in the United States.

Prescription adapalene is currently approved in a variety of formulations, including a 0.1% solution, 0.1% lotion, 0.1% cream, 0.3% gel and 0.1% gel. It is also available as a topical gel in combination with benzoyl peroxide for treating acne in those aged 9 years and older. Differin Gel 0.1% was originally approved in 1996 for the treatment of acne vulgaris in consumers aged 12 and older.

In reviewing the application for the topical gel's OTC use, FDA considered post-marketing safety data from 1996 to 2016, consumer studies and data from a maximal use trial. Galderma, the distributor of Differin Gel 0.1%, conducted three consumer studies, including a label comprehension study, a self-selector study in pregnant and lactating women and an actual use study.

Lesley Furlong, the deputy director of the Office of New Drugs IV in FDA's Center for Drug Evaluation and Research, commented in a July 8, 2016, news release, "Millions of consumers, from adolescents to adults, suffer from acne. Now, consumers have access to a new safe and effective over-the-counter option."

FDA approved the marketing of containers containing up to 45 grams of Differin Gel 0.1% with no more than two 45 gram tubes per package. The agency's approval letter noted that "usage and exposure were key review issues" in evaluating the risks in "nonprescription marketing," and that if Galderma wanted to market containers of more than 45 grams or package together more than two 45 gram tubes, the company should justify that in a subsequent application or request a pre-submission meeting.

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LITIGATION

GNC Requests Dismissal of Investors' Dietary Supplement Lawsuit

GNC Holdings Inc., a global retailer of health and wellness products, has filed a motion to dismiss a proposed class action pending in Pennsylvania federal court. *Martin v. GNC Holdings, Inc.*, No. 15-1522 (W.D. Pa., filed July 11, 2016). Oregon Attorney General Ellen Rosenblum originally filed the case in November 2015 alleging that the company had sold third-party supplements containing illegal substances.

After the case was filed, GNC's stocks fell by 14 percent, then another 26.9 percent after the release of its third quarter 2015 report. In the complaint, investors allege that the company misled shareholders about nutritional supplements containing illegal substances shortly before stock prices dropped.

In May 2016, GNC responded with a motion to dismiss, reportedly arguing that the investors' complaint was deficient and that they were required to plead the particular facts of their case rather than rely on the attorney general's allegations. In response, investors claim former employees' interviews and emails to executives prove that the company knew about the risks related to third-party supplements.

GNC's reply brief in support of its motion to dismiss maintains that the plaintiff bears the burden of pleading particularized facts showing a strong inference that the defendants intended to deceive investors, that the statements were materially false or misleading at the time they were made, and that the truth of the allegedly concealed facts was revealed to the market in a corrective disclosure. The company maintains that the documents introduced by the plaintiffs do not prove defendants had specific knowledge or intent. Oral argument on the motion to dismiss is scheduled for August 10, 2016.

California Court Agrees to Stay Lipozene Class Certification

A California federal court judge has granted an application to stay class certification proceedings in a lawsuit against The Obesity Research Institutes, LLC , and its owner. *Bozic v. Den Uijl*, No. 16-0733 (S.D. Cal., order entered July 14, 2016). The suit claims that the defendants violated consumer-protection laws and a 2005 injunction by making efficacy claims about their supplement.

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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The plaintiffs argue that the defendants have violated and will continue to violate a permanent injunction, granted to the Federal Trade Commission (FTC) in 2005, prohibiting them from marketing a dietary supplement with unsubstantiated weight loss claims. They allege violations of the Unfair Competition Law and the Consumer Legal Remedies Act as well as breach of express warranty; breach of the implied warranty of merchantability; intentional misrepresentation, fraud and deceit; negligent misrepresentation; quasi-contract/unjust enrichment; and false advertising.

The defendants filed a motion to dismiss on the grounds that plaintiffs lack standing, arguing that the FTC stipulated judgment does not allow a private right of action. They also argue that plaintiffs failed to state a claim because their lack of substantiation claim is not actionable under California law. In addition, the defendants maintain that (i) the claims are barred by the doctrine of *res judicata* since they were previously adjudicated in putative class actions and (ii) the plaintiffs fail to state a claim because nationwide class claims cannot be based on California laws because consumer-protection laws vary by state.

Defendants applied for the stay of class certification pending resolution of their motion to dismiss. After reviewing the practical circumstances of the case, the court agreed, finding it appropriate in the interest of promoting judicial economy. *See Law360,* July 12 and 14, 2016.

LEGISLATION, REGULATIONS, AND STANDARDS

FDA Issues Three Warning Letters to Marketers of Skin Care Products

The U.S. Food and Drug Administration (FDA) has issued three warning letters to companies marketing topical skin care products. According to these letters, the three companies make claims on their websites that indicate they sell products which would be classified as "drugs" under the Federal Food, Drug, and Cosmetic Act (FDCA). FDA referenced statements from the websites that establish these products are drugs according to the FDCA "because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or articles intended to affect the structure or any function of the human body." The companies that received these letters are Annmarie Gianni Skin Care, Ageless Aesthetics, Inc. and Be Green Bath and Body.

In the July 15, 2016, letter to Annmarie Gianni Skin Care, FDA provided examples of claims from three products sold on the skin-care site including Repair Serum, Anti-Aging Eye Cream and Anti-Aging Serum. Noted claims from the Repair Serum included, "Using vegan stem cells…a new way for your skin to build collagen, repair itself and prevent aging" and "Ideal for treating: Sun spots, age spots, acne scarring, Hyperpigmentation."

The July 18, 2016, letter to Ageless Aesthetics, Inc. also identified three products with claims indicating that the products are intended for use as a drug, including Growth Factor, White Balance Click Intense Brightening Serum, and White Balance Click Oxy-R Ultra Brightening Serum. FDA noted claims on each of the products. For Growth Factor, the agency identified two statements including, "Stimulates production of collagen and elastin (fibroblasts)" and "sh-Oligopeptide-1 (EGF): obtained by biotechnology, triple-filtered and liposome stabilized. Activates the skin receptors stimulating…skin regeneration."

Be Green Bath and Body received a letter dated July 15, 2016, identifying four products with claims in violation of federal law, including Rose Hip Scar Oil Treatment, Evening Primrose Healing Oil, Organic Shea Butter Tin and Calendula Cream. Example statements from Rose Hip Scar Oil Treatment included, "[H]eal damaged skin from scars and burns" and "[R]educe scar tissue and stimulate the growth of new skin tissue," as well as "'Scar Oil Treatment is beneficial for many skin conditions such as rosacea, dermatitis, eczema, acne and psoriasis.'" FDA also noted that the Rose Hip Scar Oil Treatment is intended to treat a disease or diseases that "are not amendable to self-diagnosis or treatment without the supervision of a licensed practitioner," meaning that it is not possible to include directions for a layperson to use the oil for the intended purpose. The FDA letter said the product is thus misbranded under the FDCA, and introduction or delivery into interstate commerce of a misbranded drug also violates the act.

All three letters noted that FDA has not provided an all-inclusive list of violations nor have they listed all of the products promoted by each company's website that may violate the FDCA. The companies were advised to review their websites and product labeling and encouraged to quickly correct all violations.

FDA Releases Guidance for Industry on Declaring Small Amounts of Nutrients and Dietary Ingredients on Nutrition Labels

The U.S. Food and Drug Administration (FDA) has announced the availability of *FDA's Policy on Declaring Small Amounts of Nutrients and Dietary Ingredients on Nutrition Labels: Guidance for Industry*, which addresses how the agency intends to exercise enforcement discretion in instances where a conflict exists between complying with Title 21 of the Code of Federal Regulations (21 CFR) sections 101.9(c) and 101.9(g).The final rule amending 21 CFR Part 101 was announced on May 27, 2016, with an effective date of July 26, 2016; the compliance date is July 26, 2018, for manufacturers with at least $10 million in annual food sales, and a year later for those with less.

The final guidance contains minor editorial changes to the draft guidance published in August 2015 and provides recommendations for how manufacturers of conventional foods and dietary supplements should declare small amounts of dietary ingredients and nutrients on their labels. FDA recommends that when there is a conflict between complying with the two sections, 101.9(c) and 101.9(g), manufacturers declare the dietary ingredients and nutrients in accordance with 101.9(c)(1)-(8), which provides specifications on the increments and units of measure to be used when declaring values. *See Federal Register,* July 1, 2016.

Additional Safety Data Requested for Active Ingredients in Consumer Hand Sanitizers and Wipes

The U.S. Food and Drug Administration (FDA) has announced a proposed rule amending the 1994 tentative final monograph for over-the-counter antiseptic drug products. The 1994 monograph proposed that certain active ingredients in antiseptic consumer rubs should be generally recognized as safe and generally recognized as effective.

Due to changes in use and because of scientific developments, FDA suggests that additional safety data are needed to support recognition of the active ingredients as safe and effective. The agency notes, however, that its request for more data "is intended to help the agency ensure that regular use of these products does not present unknown safety and efficacy concerns, and does not mean the FDA believes these products are ineffective or unsafe." Currently, the rule does not require any consumer hand sanitizers to be removed from the market.

The consumer antiseptic rubs addressed in this proposed rule refer to rubs, leave-on products, hand sanitizers and wipes that are not rinsed off with water and are intended to be used when soap and water is unavailable. It does not address products used by health care professionals or used in a health care setting.

"Today, consumers are using antiseptic rubs more frequently at home, work, school and in other public settings where the risk of infection is relatively low," Director of FDA's Center for Drug Evaluation and Research Janet Woodcock commented. "These products provide a convenient alternative when hand washing with plain soap and water is unavailable, but it's our responsibility to determine whether these products are safe and effective so that consumers can be confident when using them on themselves and their families multiple times a day. To do that, we must fill the gaps in scientific data on certain active ingredients."

Beyond increased usage, FDA's proposal was prompted by an independent advisory committee's input on scientific data gaps. FDA is requesting data on three active ingredients in consumer antiseptic rubs, including alcohol (ethanol or ethyl alcohol), isopropyl alcohol, and benzalkonium chloride. In addition to the safety data, the proposal suggests obtaining in vitro data about the ingredients' antimicrobial properties as well as in vivo clinical studies logging reductions in bacteria.

FDA's proposed rule is open for public comment until December 27, 2016. Companies that plan to continue marketing products must provide data within one year of this proposal. After the data is submitted, comments on the information will be accepted for 60 days. A final monograph will be published following FDA's evaluation of the data and comments. *See FDA Press Release,* June 29, 2016, and *Federal Register,* June 30, 2016.

FDA Investigates WEN by Chaz Dean Cleaning Conditioners after Adverse Event Reports

The U.S. Food and Drug Administration (FDA) posted a July 19, 2016, safety report warning of adverse event complaints concerning WEN by Chaz Dean Cleansing Conditioner products.

According to an FDA statement, the agency has received 127 adverse event reports from consumers, the largest number of adverse events

reports ever received about a cosmetic hair cleansing product. Consumers have reported hair loss, balding, hair breakage, itching and rashes.

During inspections of manufacturing and distribution facilities, FDA also discovered that there have been more than 21,000 complaints reported to Chaz Dean, Inc. and Guthy Renker, LLC. According to the safety report warning, FDA has asked the company to "provide any data that might help us to better understand the reports of hair loss associated with the use of Wen by Chaz Dean Cleansing Conditioner Products."

FDA also posted a concurrent Dear Health Care Provider Letter asking physicians with patients who have used the products and experienced adverse events to submit a report to the agency. It also asks health care providers to share with those patients FDA's statement and FDA's Information for Consumers.

FTC Approves Final Consent Orders against Four Personal Care Product Companies

On July 13, 2016, the Federal Trade Commission (FTC) announced a unanimous vote approving final consent orders against four companies charged with falsely claiming that their personal care products were "all natural" or "100% natural" when they contained synthetic ingredients.

FTC reported in April 2016 that the four companies had agreed to proposed settlements and that the commission had accepted the proposed agreements, which were to be followed by public comment and a decision on whether to make the orders final. In that news release, Director of FTC's Bureau of Consumer Protection Jessica Rich commented, "'All natural' or '100 percent natural' means just that—no artificial ingredients or chemicals. Companies should take a lesson from these cases."

All four companies promoted their products online with the claim of being natural while they contained ingredients such as dimethicone, ethyhexyl glycerin, or phenoxyethanol. Trans-India Products, Inc., as Shikai, marketed "All Natural Hand and Body Lotion" as well as "All Natural Moisturizing Gel." Erickson Marketing Group, as Rocky Mountain Sunscreen, promoted products such as "Natural Face Stick." ABS Consumer Products, LLC, as EDEN Body Works, marketed products such as "Jojoba Monoi All Natural Shampoo." Beyond Coastal sold "Natural Sunscreen SPF 30," described as "100% natural."

UL Retained by CRN to Develop and Administer a Dietary Supplement Product Registry

The Council for Responsible Nutrition (CRN), a trade association representing dietary supplement and functional food manufacturers, has reportedly retained UL, a global independent safety science company, to develop and administer a dietary supplement product registry.

According to CRN's press release, the supplement product registry "will help create a fuller picture about the dietary supplement industry for industry regulators and serve retailers as a one-stop shop to help compare product labels." CRN President and CEO Steve Mister stated, "We are confident that the dietary supplement product registry will provide a viable, adaptable product registry that will serve regulators, retailers, manufacturers, and ultimately consumers, over time."

General Manager for UL Global Nutraceuticals Mike O'Hara also commented, "We know the industry and we understand the sensitivities, complexities and determination involved in developing the right product registry that will allow for a core product accompanied by customization. We take our responsibility here very seriously and look forward to working with CRN, its members and any company that wants to bring the industry to a higher level of accountability for its customers."

UL will begin immediate development of the registry with a beta version of the database to be tested starting this summer. For the beta testing, roughly six companies will input their labels into the database. CRN will require all member companies to put their product labels into the registry by July 2017; the association also encourages non-member dietary supplement companies to input their labels as well.

At a June 2016 conference, CRN apparently explained that the group plans for the database to have two tiers. The first tier will be accessible to anyone interested in obtaining information and companies will not have to pay to provide basic product information. Tier two will offer companies the opportunity to provide more detailed information for a fee; this tier will have restricted access. *See National Law Forum,* July 6, 2016.

AMA Adopts New Policy on Nootropics

At its annual meeting held June 10-13, 2016, the American Medical Association (AMA) adopted a new policy targeting nootropics. Nootropics—sometimes referred to as "smart drugs"—include prescription drugs, supplements and substances claiming to enhance cognitive functions.

The new policy is aimed at discouraging the nonmedical use of these prescription drugs and also calls for additional research on the use, risks and benefits of dietary supplements and herbal remedies claiming to enhance cognitive abilities.

AMA's June 15, 2016, news release noted, "Only a limited amount of information is available on the patterns of dietary supplements and herbal substances used for cognitive enhancement. More than 100 substances from amino acids to botanical preparations are advertised on websites as having the ability to improve cognitive performance, and their safety and efficacy have not been systematically examined." AMA also plans to encourage the Federal Trade Commission to evaluate dietary supplement and herbal remedy advertisements that make these claims.

GLOBAL

European Commission Publishes EU Cosmetics Proposal During Trade Talks with the U.S.

As part of a push for more transparent trade policies, the European Commission has published nine proposals from the 14th round of trade agreement talks with the United States. The proposals stem from the Transatlantic Trade and Investment Partnership (T-TIP), an agreement aimed at prompting international competitiveness, jobs and growth.

The nine proposals detail the European Union's (EU's) negotiating position for regulatory cooperation in the areas of cosmetics, financial services, chemicals, engineering, medical devices, textiles, motor vehicles, climate, energy and raw materials, and institutional general and financial provisions. While the EU and United States have separate systems for regulating cosmetics, the EU has noted that T-TIP could potentially benefit both the industry and consumers by allowing regulators to collaborate in areas such as product safety.

The *EU Proposal for an Annex on Cosmetics* includes general principles and objectives including "improving, and not reducing, undermining or otherwise compromising the level of protection" in areas such as consumer and public health. The objectives include promotion of the following: "a) convergence of technical requirements and relevant standards applicable to products falling under the scope of this Annex; b) alignment of ingredients labelling; c) use of validated alternative methods to animal testing; d) existing multilateral and bilateral regulatory cooperation relating to regulation of products falling under the scope of this Annex; e) cooperation on the review and assessment of ingredients subject to market authorization; f) cooperation on new and emerging issues and on any other matter of common interest to the Parties" and "g) cooperation related to safety assessment methodologies."

Published July 14, 2016, the Annex defines "cosmetic product" as, "any substance or mixture intended to be placed in contact with the external parts of the human body…or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours." The EU and United States must reach an agreement before it is finalized.

European Industry Associations Publishing Environmental Guidelines for Essential Oil Producers

European industry associations are publishing new guidelines to assist essential oil producers in determining the environmental effects of their products. Based on the European Chemicals Agency's (ECHA's) Guidance on Information Requirements and Chemical Safety Assessment, the guidelines seek to aid producers in the completion of their legal requirements for classification and labeling.

According to a June 27, 2016, ECHA announcement, the guidance will also help companies assess "the potential persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) properties of their substances." The guidelines will be available in select EU languages by the end of 2016.

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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.

Health Canada Updates Search Capabilities of the Natural Health Products Database

As part of its website migration to Canada.ca, Health Canada has updated the Licensed Natural Health Products Database (LNHPD). Under Canada's Natural Health Products Regulations, natural health products (NHPs) are required to be safe for use without a prescription.

The LNHPD contains searchable information on licensed NHPs. Products include homeopathic medicines, vitamin and mineral supplements, traditional medicines, herb and plant-based remedies, probiotics, omega-3 and essential fatty acids, and some consumer products (certain toothpastes, deodorants, shampoos, face products and more). The database includes information pertaining to the product's name, license holder, identification numbers, ingredients, dosage, recommendations for use or purpose, and risk information.