ISSUE 48 | MARCH 31, 2017

SPOTLIGHT

Personal Care Products Regulation and Litigation: Trends, 2016 and Early 2017

FDA Warning Letters on the Rise. Nearly 30 warning letters were issued by the U.S. Food and Drug Administration (FDA) regarding personal care products in 2016. These warning letters highlighted marketing claims that FDA alleged as evidence the products were intended to be used as drugs, making them unapproved and "misbranded" under the Food, Drug and Cosmetics Act. Some of the targeted marketing included claims of anti-inflammatory or healing properties; minimization of the appearance of wrinkles, spots or lines; age-defying properties; alternatives to surgery; and the promotion of regeneration of tissue or collagen production.

Citizen Petitions Push FDA to Focus Attention on Potential Dangers. In 2016, FDA announced draft guidance on recommended maximum levels for lead in cosmetic lip products and externally applied cosmetics in response to a citizen petition filed in 2011. In 2017, FDA may rescind its approval of lead acetate in hair dyes based on a petition filed by a coalition of environmental groups, including the Environmental Working Group (EWG). EWG also filed a citizen petition in 2011 alleging that formaldehyde-releasing chemicals found in products such as hair straighteners pose a health risk to consumers. The group filed suit against FDA last year alleging that the agency's failure to respond puts hair-salon workers and consumers in danger.

FTC Crackdown on "All Natural" Claims. Five personal care product companies were charged in 2016 with falsely claiming that their products were "all natural" or "100% natural" despite containing synthetic ingredients.

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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Charges against Cosmetic Companies' Sales Practices. Thirty-three cosmetic companies were charged with deceptively marketing and billing consumers for skin care products last year. The violations targeted practices of risk-free trials, online banners and pop-up ads. FTC also found that the companies failed to disclose material terms in their policies.

National Media Attention on Litigation and Personal Injuries. Cases involving personal care products and alleged injuries have drawn increased media attention. For example, WEN® by Chaz Dean hair care product manufacturers drew national media attention, including from *The New York Times*, when plaintiffs claimed that the products caused hair loss and scalp irritation.

Proposed Increase to FDA's Regulatory Authority. FDA's regulatory powers, or what some lawmakers criticize as a lack of powers or regulatory gaps, resulted in proposed legislation to strengthen FDA's authority.

Publicly Available Adverse Event Data. FDA announced at the end of 2016 that it will begin making publicly available certain data pertaining to cosmetics. Beginning in 2017, FDA will issue quarterly reports.

Thus far in 2017, FDA has issued one warning letter to a cosmetic company, Aegeia Skin Care, LLC, identifying four products from the company's website—Purifying Facial Cleanser, Refining Facial Toner, Nourishing Clay Mask and Silken Body Butter—that allegedly violate the Federal Food, Drug, and Cosmetic Act because the company's claims about the products establish that they are intended for use as drugs. Unlike the 2016 letters, which focused on general product claims, this letter targeted ingredient-specific claims such as products containing coconut oil for healing "rashes, acne and other infections."

The letter highlighted claims related to specific ingredients in the products; for example, the company claimed that the oatmeal in the cleanser could be added to baths "to treat insomnia and anxiety as well as a variety of skin conditions, including burns and eczema." Other claims centered on oils in the cosmetic products, including the use of tea tree oil for antiseptic properties and coconut oil for healing "rashes, acne and other infections."

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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.

Office of Dietary Supplements Announces Goals

The Office of Dietary Supplements (ODS) at the National Institutes of Health announced the release of its strategic plan for 2017-2021, *Strengthening Knowledge and Understanding of Dietary Supplements*. The plan reviews activities from 2010-2016 and presents goals and strategies for the next five years.

The plan outlines steps to fulfill four goals over the next five years: (i) expanding scientific knowledge of dietary supplements by "stimulating and supporting" biomedical research and "developing and contributing to" collaborative initiatives and events such as workshops, meetings and conferences; (ii) using training and career development to enhance the workforce involved in developing dietary supplement research; (iii) fostering the development and dissemination of dietary supplement research; and (iv) making dietary supplement research accessible to a broad audience, including consumers, health professionals, researchers and policymakers.

FTC Outlines Lessons from Herbalife Case

The Federal Trade Commission (FTC) recounted lessons from its $200-million settlement with Herbalife in July 2016, which resulted in the issuance of nearly 350,000 refund checks.

FTC outlined four lessons to be learned from the lawsuits: (i) false or unsubstantiated earnings claims violate the FTC Act; (ii) companies should monitor the claims their distributors are making to ensure they comply with the law; (iii) sales must be real sales to real customers, and the majority of sales should not be focused on insiders and recruits; and (iv) compensation and incentives should be tied to those real sales and real customers.

LITIGATION

Iowa Targets "Drinkable Sunscreen"

The Iowa attorney general has filed a lawsuit alleging Benjamin Johnson and his companies, Osmosis LLC and Harmonized Water LLC, fraudulently sell "ordinary water at premium prices by claiming he has treated the water in ways that imbue it with

amazing medicinal or cosmetic properties," including the abilities to "protect against cancer-causing UV rays, repel mosquitos that might carry the Zika virus, protect the body from pathogens, cure acne, reverse the aging process, and perform various other near-miraculous feats." *Iowa v. Osmosis, LLC*, No. EQCE081282 (Iowa D.C., Polk Cty., filed March 14, 2017). The complaint alleges that Johnson—"who is referred to as Dr. Johnson in advertisements without disclosure of the fact that he was forced to surrender his Colorado license to practice medicine in 2001"—markets his water products as "imprinted" with radio waves of varying frequencies to produce different benefits. Since 2012, Johnson's company Osmosis has sold UV Neutralizer, an ingestible liquid sprayed into the mouth that purportedly protects skin from sun damage "by generating scalar waves that vibrate above the skin."

The complaint argues that Johnson and his companies "used the public—adults and children alike—as guinea pigs, even though the stakes involved cancer" because they sold the products for two years before conducting clinical studies to test the claims. Further, studies conducted in 2014 and 2016 "do not provide the level of substantiation provided by law," the state asserts. The complaint also lists several other wellness products sold by Osmosis for $26-$40 per 100 milliliters that "appear to have water as the sole ingredient," including a facial mask; a hangover reliever; a treatment for rosacea, eczema and psoriasis; a menstrual-discomfort reliever; an energy booster; a digestive-discomfort reliever; a sleep enhancer; and a hormone balancer treating infertility, hair loss, menopause and thyroid deficiencies. The state seeks $40,000 per alleged violation of Iowa's Consumer Fraud Act as well as $45,000 for each violation targeted at older persons, who are "substantially more vulnerable to such conduct on account of age and other factors," per the state's Older Iowans Law.

Permanent Injunction Issued Against Dietary Supplement Cos. Following FDA Complaint

A Colorado federal court entered a consent decree of permanent injunction against three dietary supplement companies owned by Michael Floren—EonNutra LLC, CDSM LLC and HABW, LLC—after the U.S. Food and Drug Administration (FDA) determined the companies' products were misbranded and unapproved new drugs as well as misbranded and adulterated dietary supplements. *U.S. v. EonNutra, LLC*, No. 17-0633 (D. Colo., order entered March 13, 2017).

According to the complaint, Floren's companies marketed dietary supplements as drugs by claiming the products could treat or prevent medical conditions or diseases such as heart disease, depression, diabetes, hypertension and osteoporosis. Additionally, the businesses did not follow Good Manufacturing Practice regulations, including the failure to properly list the serving size and servings per container as well as failure to list all ingredients and the parts of the plant from which the ingredients were derived. Under the consent decree, Floren's businesses will stop operations until the products comply with federal law, including requirements that the companies issue a product recall and hire experts in labeling and good manufacturing practices.

"Companies that market their products with unproven health claims and also continue to violate manufacturing regulations put consumers' health in jeopardy," FDA Associate Commissioner for Regulatory Affairs Melinda Plaisier said in a March 14, 2017, press release. "The FDA will take the enforcement actions necessary to protect consumers from this undue risk."

FTC Settles Spam Suit Against Florida Weight-Loss Cos.

The Federal Trade Commission (FTC) has reached a $1.3-million settlement with three defendants who allegedly sent spam e-mails containing phony weight-loss claims and fictitious celebrity endorsements and sold bogus weight-loss products to consumers nationwide. *Fed. Trade Comm'n v. Tachht, Inc.*, No. 16-1397 (M.D. Fla., order entered March 3, 2017). The suit alleged that Colby Fox, through his companies Tachht, Inc. and Teqqi, LLC, violated the FTC and CAN-SPAM acts by sending unsolicited emails to consumers misrepresenting the companies' weight loss products, including sending emails under a materially false or misleading email header and claiming endorsements from Oprah Winfrey, Rachael Ray and the television show "The Doctors," which the defendants had never obtained. The companies' products include "Original Pure Forskolin," "Original White Kidney Bean," and "Mango Boost Cleanse."

Three of the four defendants stipulated to the settlement, which includes (i) an immediate payment of $500,000 to the FTC that suspends the remainder of the judgment if the defendants comply with a permanent injunction barring them from making false and unproven weight-loss claims about their products; (ii) the requirement to obtain competent and reliable scientific evidence before making future health or efficacy claims; (iii) financial reports about business activities and financial conditions to the

FTC; and (iv) full cooperation in further investigations. Litigation is continuing against a fourth defendant, Christopher Reinhold, a manager of Teqqi, LLC.

Plaintiff Files Same Complaint Against PhD Fitness in Multiple Federal Courts

California-based PhD Fitness is facing two separate but nearly identical putative class action complaints in South Carolina and Michigan filed by the same plaintiff. *Johnston v. PhD Fitness LLC*, No. 16-14152 (E.D. Mich., filed March 16, 2017); *Sandviks v. PhD Fitness LLC*, No. 17-0744, (D.S.C., filed March 17, 2017) Both complaints allege "false, fraudulent and misleading" labeling of PhD Fitness' Pre-JYM and Post-JYM sport supplement products, sold online and in retail stores nationwide. The plaintiffs claim (i) the products do not contain the "proper" doses of the ingredients listed on the labels; (ii) the labeling does not accurately represent the product ingredients; and (iii) in an Instagram post, the company owner called the omission of sodium from the product label a "misprint." In both actions, the plaintiffs seek class certification, damages, restitution, injunctive or equitable relief and attorney's fees for breach of warranties, misrepresentation and unjust enrichment.

Plaintiff Claims GNC Aloe Vera Gel Contains No Aloe Vera

GNC is facing a putative class action alleging that the company's Aloe Vera Skin Gel, marketed as containing "99% Aloe Vera Gel," actually contains no aloe vera. *Lambert v. Gen. Nutrition Corp.*, No. 17-2149 (N.D. Ill., filed March 21, 2017). The plaintiff claims the ingredient label says the gel contains aloe barbadensis leaf juice, but independent lab testing of the product allegedly showed no "detectable amount" of aloe vera plant components. Further, the plaintiff alleges, the product couldn't contain 99 percent aloe vera gel because aloe barbadensis leaf juice is listed third on the ingredient label, behind water and polysorbate 20, a surfactant and emulsifier. For violations of the Federal Food, Drug, and Cosmetics Act, the Illinois Consumer Fraud and Deceptive Business Practices Act, and breach of warranties, the plaintiff seeks class certification, damages, restitution and attorney's fees.

Class Action Against Lush Cosmetics Dismissed for Lack of Standing

A federal court has dismissed a putative class action alleging that the terms of use on Lush Cosmetics' website violate New Jersey consumer-protection laws, holding that because the plaintiff had not actually read the terms—which were "buried" at the bottom of the website's pages in a font size smaller than adjacent text—she was not bound by the terms as a matter of law, suffered no cognizable harm and therefore had no standing to sue. *Hite v. Lush Internet Inc.*, No. 16-1533 (D.N.J., order entered March 22, 2017).

The plaintiff alleged the terms of use and terms of service on the Lush website violate the New Jersey Truth in Consumer Contract, Warranty and Notice Act (TCCWNA) because they claim the retailer has no liability for any claim arising out of the use of its website, ranging from issues with the cosmetic products to cybersecurity problems. In addition, the suit alleged that the terms impose provisions containing one-sided, exculpatory language barring consumers from bringing suit under the TCCWNA and shortening the time to bring claims.

However, the plaintiff admitted that she had not seen nor read the terms before buying a product on the website, so the court held that she had failed to assert an injury sufficient to establish standing. The court said the plaintiff was seeking only to bring Lush's terms into accord with what she believes New Jersey law requires, not to recover damages from actual harm. "Based upon the allegations in the amended complaint, the harm that plaintiff has suffered from the allegedly unlawful limitations of liability in the terms of use is metaphysical at best," the court found. "Her strongest allegation of harm is that she was present and made a purchase on a website that, unbeknownst to her, had terms that she now claims are objectionable."

Seniors Claim Unfair Targeting by Skincare Companies

Two California plaintiffs have filed a putative class action against a group of companies selling a line of facelift creams and serums, claiming that their "false, misleading and deceptive practices" unfairly target seniors. *Young v. Nature's Elite, Inc.*, No. 17-0421 (E.D. Cal., filed February 24, 2017).

The plaintiffs, both seniors, allege they were offered free skincare consultations at an Infinite Beauty store but were persuaded by a

Gold Elements sales representative to sign up for a year of monthly facials, regular purchases and use of Gold Elements "face-lift serum" and "face-lift cream," which totaled more than $4,000. They claim the sales rep promised that the skincare products were "capable of providing a non-surgical facelift" and that the results would "last for fifteen years." The plaintiffs also allege that seniors are "particularly susceptible" to such sales claims and suffer greater injury when spending sums of money "otherwise designated to maintain the health and welfare" of seniors.

For alleged violations of California's consumer-protection statutes, including a subsection awarding civil penalties where conduct is directed at persons over age 65, the plaintiffs are seeking class certification, an injunction, corrective advertising, restitution, damages and attorney's fees.

Permanent Injunction Entered Against Distributor of Supplements Containing DMAA

A California federal court entered a consent decree of permanent injunction against VivaCeuticals, Inc. (Regeneca Worldwide) and the company's CEO following allegations that the company was in violation of the Federal Food, Drug, and Cosmetic Act (FDCA) because it was adding unsafe ingredients to its products, including 1, 3-dimethylamylamine (DMAA). *U.S. v. VivaCeuticals, Inc.*, 15-1893 (C.D. Cal., order entered February 8, 2017).

The U.S. Food and Drug Administration (FDA) sent Regeneca a warning letter in August 2012 after its products were found to contain DMAA, which is classified as a new dietary ingredient. New dietary ingredients render a supplement adulterated under the FDCA unless they have either been "present in the food supply as an article used for food in which the food has not been chemically altered" or if there is a history of use or other evidence of safety and FDA has been properly notified with evidence establishing the safety of the ingredient.

Regeneca assured FDA that it was taking corrective action, but it continued to distribute the DMAA-containing supplement. Under the decree, the company is prohibited from marketing unapproved new drugs as well as and adulterated and misbranded dietary supplements.

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