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LEGISLATION, REGULATIONS & STANDARDS

Senate Committee Proposes Cosmetics Regulation Amendment

The Senate Committee on Health has released a discussion draft of a proposed amendment to the Federal Food, Drug and Cosmetic Act (FDCA) that would establish greater oversight of cosmetic product manufacturing and mandate adverse event reporting. The Modernization of Cosmetics Regulation Act of 2018 would apply to facilities that manufacture or process cosmetic products but would exempt most retailers, salons and research and testing facilities. The Senate committee, led by Sens. Lamar Alexander (R-Tenn.) and Patty Murray (D-Wash.), indicated in a press release that it will work to enact the amendment before the end of 2018.

The amendment would require manufacturers and distributors to report "serious adverse events"—including death, hospitalization, persistent disability, or significant disfigurement—to the U.S. Department of Health and Human Services (HHS) within 15 days. Minor reactions, such as "transient" allergic reactions and skin irritations, are expressly excluded from the definition.

The amendment would also require HHS to establish standard manufacturing practices and labeling requirements for cosmetic products and proposes annual safety assessments of at least 10 "ingredients or non-functional constituents." Products would be deemed safe if "a reasonable certainty that the cosmetic or cosmetic product is not injurious to health" can be established when the ingredient is used as recommended.

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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FDA, CDC Advise Consumers to Avoid Kratom Supplements

The U.S. Food and Drug Administration (FDA) and the Centers for Disease Control (CDC) have advised consumers to avoid kratom products after linking the substance to an outbreak of Salmonella that has sickened at least 28 people in 20 states. FDA has also reviewed its studies and mortality reports on kratom, including reports of 44 deaths associated with its use, concluding the data contains "stronger evidence" of kratom's opioid properties. FDA has previously seized kratom products and placed kratom supplements on import alert, and the agency reports that several states, cities and foreign countries have banned the substance.

"The extensive scientific data we've evaluated about kratom products provides conclusive evidence that compounds contained in kratom are opioids and expected to have similar addictive effects as well as risks of abuse, overdose and, in some cases, death," said FDA Commissioner Scott Gottlieb in a press release.

FDA also announced that it warned Industrial Chemicals LLC that it has made "inaccurate and misleading statements" about its Mitrasafe kratom supplement, which is "intended to be used as a drug, even though the product has not gone through the required FDA approval process." The company advertised the supplement as relief for the symptoms of opioid withdrawal. In addition, FDA announced a voluntary recall and destruction of kratom supplements manufactured and distributed by Divinity Products Distribution LLC under the names Botany Bay, Enhance Your Life and Divinity. In cooperation with FDA, the company has also agreed to stop selling all products containing kratom.

U.S. Rep. Introduces Bill to Ban or Label Asbestos in Children's Cosmetics

Responding to news reports alleging Claire's Stores Inc. sold cosmetics contaminated with asbestos, U.S. Rep. Debbie Dingell (D-Mich.) has introduced the Children's Product Warning Label Act of 2018, which would require that "all cosmetics marketed to children are demonstrated to be free of asbestos or otherwise carry a warning label," according to a press release. Dingell specifically named the Claire's incident as her inspiration and called on her colleagues in Congress to review and revise the U.S. Food and Drug Administration's (FDA's) regulatory authority for related products.

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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.

"A broad overhaul of FDA's authority over cosmetics and personal care products is long overdue and is the best way to address this problem. We need to pass comprehensive legislation to create a user fee program for cosmetics and give the FDA the authority to review the most dangerous ingredients so they can keep people safe," Dingell said. "But if Congress is unwilling to consider this approach, we should start taking common sense steps to protect our children by passing my legislation to ensure consumers have all the facts about the products they purchase. Congress must make this a priority in 2018."

Proposed California Bill Seeks to Ban Animal-Tested Cosmetics

California Sen. Cathleen Galgiani (D-Stockton) has introduced a bill that aims to prohibit the sale of cosmetics tested on animals. The bill would prohibit cosmetic manufacturers from knowingly importing or selling cosmetics as well as personal hygiene products such as deodorant or hair products in the state if any component of the product was tested on animals after Jan. 1, 2020. A violation would result in a fine of up to $500 initially and up to $1,000 for each subsequent violation.

"California has long been a leader in promoting modern alternatives to animal tests," Galgiani said, according to a February 16, 2018, press release. "Inaction at the federal level compels California to lead the way in ensuring a cruelty-free cosmetics market for its citizens by barring any new ingredients or cosmetics that are tested on animals."

Ad Authorities Recommend Companies Discontinue Supplement Claims

The National Advertising Division (NAD) has referred advertising claims to the Federal Trade Commission after Pharmavite LLC refused to discontinue marketing its NatureMade Omega-3 Xtra Blend as able to be absorbed four times faster than similar products. Noting that omega-3 fatty acids are poorly absorbed by the body unless taken with a high-fat meal, NAD reviewed Pharmavite's claim that the supplement is made with "self-microemulsifying drug delivery systems" and agreed that the technology has been demonstrated to enhance absorption. However, NAD determined that Pharmavite could not support its extrapolation of the results of the study to support its "4x better absorption" claim and recommended that the claim be discontinued.

The U.K. Advertising Standards Authority (ASA) has upheld three complaints that Source Ltd.'s direct mail advertising for the Meristem Dietary Supplement violated the CAP Code by including (i) health claims not authorized by the EU Register; (ii) claims that the supplement could prevent, treat or cure disease; and (iii) health claims referring to recommendations of individual health professionals. Source Ltd. claimed the supplement would "replace and renew every cell in the human body, completely rejuvenating . . . your 11 vital systems, restore your youth and recover perfect health as quickly as possible." The advertising also claimed the product was "specially recommended" for a wide range of medical conditions and diseases, including cardiovascular illness, depression, gastrointestinal disorders, eye diseases, erectile dysfunction, Alzheimer's and arthritis. ASA ruled that the ad could not appear again in its current form.

CRN Launches Effort to Educate About SARMs

The Council for Responsible Nutrition (CRN) has announced the launch of a "consumer education initiative" to warn against use of selective androgen receptor modulators (SARMs). CRN's press release asserted that the U.S. Food and Drug Administration considers SARMs to be "unapproved drugs illegally marketed as dietary supplements" and that their use is prohibited by the World Anti-Doping Agency. SARMs, often listed as ostarine or andarine on product labels, reportedly increase the risk of heart attack, stroke and liver damage.

GLOBAL

EC Announces Survey Results on Websites Selling Unauthorized Supplements

The European Commission Directorate-General for Health and Food Safety has announced the results of a test of the first EU-coordinated control plan to identify cross-border offers, promotions and sales of products that fail to comply with national or EU food and nutrition legislation.

Conducted in September 2017, the test searched for websites marketing supplements claiming to prevent, treat or cure bone and joint diseases or that referred to such properties with "disease-related expressions, pictures or symbols." The

participants were also asked to search for novel foods containing four ingredients not authorized in the EU: agmatine (4-aminobutyl) guanidine sulfate, acacia rigidula, epimedium grandiflorum and hoodia gordonii.

The review of nearly 1,100 websites found 251 supplements with unauthorized medicinal claims and 428 offers of novel foods; about 15 percent of the total offers were from third countries, primarily the United States and China. According to the Commission, “Experience shows however that the response of third countries in case of food supplements and novel foods which are non-compliant with EU legislation is poor and that cooperation and mutual support need to be improved especially on eCommerce cases. The Commission will discuss this issue with the respective US and Chinese authorities.”

LITIGATION

Anti-Aging Co. Settles FTC Charges

The U.S. Federal Trade Commission (FTC) has reached an agreement with Telomerase Activation Sciences Inc. and its CEO Noel Patton to settle administrative charges alleging the company lacked evidence to support anti-aging and other health claims made in its marketing. The agency asserted that TA Sciences claimed its products provided anti-aging benefits by lengthening short telomeres and thus lengthening the cellular lifespan of normal cells. The products, which were sold in powder, capsule and topical cream forms, retailed between $100 and $600, according to the complaint. Under the agreement, TA Sciences will not make claims unsupported by competent and reliable scientific evidence; the agreement specifically targets claims that a product reverses human aging, prevents or repairs DNA damage, or prevents or reduces the risk of cancer.

Lawsuits Allege Ulta Sells Used Makeup

Ulta Beauty Inc. allegedly sells cosmetics misrepresented as new to "unsuspecting consumers," according to multiple putative class actions. *Smith-Brown v. Ulta Beauty Inc.*, No. 18-0610 (N.D. Ill., E. Div., filed January 26, 2018); *Devries v. Ulta Beauty Inc.*, No. 18-1723 (Ill. Cir. Ct., Cook Cty., filed February 8); *Ogurkiewicz v. Ulta Beauty Inc.*, No. 18-3006 (Ill. Cir. Ct., Cook Cty., filed March 7, 2018).

The lawsuits were spurred by former Ulta employees' social media posts that asserted the store "routinely doctored used beauty

products, many of which had been used and returned to the store, in order to deceive consumers into believing the products were new and unused," according to one complaint. The social media posts allegedly claim that Ulta managers instructed their employees to clean returned products "with cotton swabs 'to make [them] look [like] new.'"

"Consumers expect that Beauty Products are new and unused when purchased from retailers, such as Defendant, because, by nature, used Beauty Products are unsanitary and unhygienic, and place them at a risk of contracting disease," one of the complaints asserts. Alleging a variety of unjust enrichment and strict product liability claims as well as consumer-protection statute violations, the plaintiffs each seek class certification, injunctions, damages and attorney's fees.

Marketing Firm to Pay $2 Million to Settle FTC Claims

The Federal Trade Commission (FTC) has announced a $2 million settlement with Marketing Architects Inc. (MAI) to resolve allegations that the firm disseminated deceptive radio advertisements for client Direct Alternative's weight-loss products, including Puranol, PH Plus, Acai Fresh and Final Trim. FTC settled deceptive advertising and illegal billing claims with Direct Alternative in 2016. According to FTC's announcement, "MAI developed and disseminated fictitious weight-loss testimonials and created radio ads for weight-loss products falsely disguised as news stories." Further, the company's inbound call scripts failed to disclose to consumers that they would be enrolled in an automatically renewing program following their purchase. The $2 million settlement will be paid to FTC and Maine and "may be used to provide refunds to consumers harmed by MAI's allegedly deceptive conduct."

Putative Class Action Alleges Monat Products Cause Hair Loss

Monat Global Corp. faces a putative class action brought by consumers alleging the company’s products caused their hair to fall out. *Whitmire v. Monat Global Corp.*, No. 18-20636 (S.D. Fla., filed February 20, 2018). The plaintiffs contend that Monat promotes its hair products as “naturally-based” and “safe” and responds to consumer complaints by referring to hair loss and scalp irritation as part of a “detox” period that provides sales representatives an opportunity to suggest “still more expensive

products." The complaint further alleges that Monat represents the products as free of sulfates and petrochemicals despite purportedly containing both compounds. Claiming violations of Florida's consumer-protection statute, negligence, strict product liability and unjust enrichment, the plaintiffs seek class certification, damages, injunctive relief, attorney's fees, and orders mandaing the removal of misleading claims and inclusion of material safety information.

In addition, Monat has filed a defamation suit against a former sales representative who quit because she allegedly lost her hair after using the products. *Monat Global Corp. v. Harrington*, No. 18-0008 (E.D.N.C., filed January 26, 2018). The sales rep apparently started a closed Facebook group in which she and others—who assert the products caused "scalp sores and abrasions, hair loss, balding, and are dangerous for pregnant women, or individuals receiving cancer therapy"—could post criticisms about Monat and photos of their alleged injuries. According to *BuzzFeed News*, more than 12,000 people have joined the Facebook group since November 2017. Claiming commercial disparagement/trade libel/injurious falsehood, defamation and tortious interference with prospective economic advantage, Monat seeks an injunction and an order that the sales rep "release public statements in appropriate forums to ameliorate the negative effects and consumer confusion" caused by her statements.

Court Dismisses Weight-Loss Labeling Claim Against Vitamin Shoppe

A California federal court has dismissed a putative class action against Vitamin Shoppe Inc., holding that state consumer-protection statutes do not provide a private right of action for lack of substantiation claims. *Nathan v. Vitamin Shoppe Inc.*, No. 17-1590 (S.D. Cal., entered February 12, 2018). The plaintiff alleged that the label of Vitamin Shoppe's Garcinia Cambogia Extract contained the statements "Weight Management" and "Appetite Control," which led her to believe it was a weight-loss product. The plaintiff had previously filed a lawsuit alleging that the same product was misleadingly marketed because studies have purportedly shown that consumption of garcinia cambogia does not assist with weight loss, but she dismissed that lawsuit before filing a second. Additional details appear in Issues 50 and 51 of this *Bulletin*.

In addition to holding that she had no private right of action under state consumer-protection laws, the court noted that the "first problem" with the complaint was the assertion that the label

statements were equivalent to a representation that the product provided weight-loss benefits. The second problem, the court held, was that the single study cited by the plaintiff that did directly address the label statements used qualifying language that made its conclusion an insufficient basis to raise a plausible claim of falsity or misrepresentation.

Drunk Elephant Eye Cream Violates FDCA, Lawsuit Alleges

A consumer has filed a putative class action alleging Drunk Elephant LLC's Shaba Complex Eye Serum fails to deliver the advertised structural and functional changes to skin. *Nguyen v. Drunk Elephant LLC*, No. 18-1051 (S.D.N.Y., filed February 6, 2018). The complaint alleges that Drunk Elephant misleads consumers into believing the product will "smooth skin roughness" and "decrease glycation" with several ingredients, including niacinamide, "a potent skin-identical, cell-communicating ingredient that improves skin's elastic feel." Alleging the product is "worthless," the plaintiff asserts that members of the putative class deserve a refund of the full purchase price. She further argues that Drunk Elephant's marketing makes drug claims in violation of the Federal Food, Drug, and Cosmetic Act (FDCA) because the company claims the product will change skin structure. Alleging fraud and false advertising, the plaintiff seeks class certification, an injunction and damages.

Grisi Soaps, Jason Shampoos Targeted in "Natural" Lawsuits

Consumers have filed putative class actions alleging Midway Importing Inc. and Jason Natural Products advertise their products as “natural” despite containing synthetic ingredients. *Rivera v. Midway Importing, Inc.*, No. 18-1469 (C.D. Cal., filed February 22, 2018); *Li v. Jason Natural Products, Inc.*, No. 18-1127 (S.D.N.Y., filed February 8, 2018).

Midway Importing, which sells Grisi soaps, advertises its products as “natural,” but the products contain several allegedly unnatural compounds, including sodium lauryl sulfate, citric acid, titanium dioxide and calcium carbonate. The complaint contends that reasonable consumers would not understand that the four ingredients are synthetic and that the plaintiffs would not have paid a premium for the products had they known of the ingredients. Alleging violations of state consumer-protection laws

and the Magnuson-Moss Warranty Act as well as breach of warranties, the plaintiffs seek class certification, injunctive relief, damages and attorney's fees.

The plaintiffs alleging Jason's hair products are falsely advertised as "extra gentle" or "all natural" rely in part on the Environmental Working Group's Skin Deep Cosmetics Database to allege that the products contain "toxic" and synthetic ingredients. The complaint also states that, according to the Federal Trade Commission, "it is false and deceptive to advertise or package a product as 'All Natural' or '100% Natural' if it contains one or more synthetic ingredients." Claiming violations of New York consumer-protection statutes, the plaintiff seeks class certification, injunctive relief, damages and attorney's fees.

Putative Class Action Alleges Target Cleansing Towelettes Cause Allergic Reactions

A consumer has filed a putative class action alleging that Target Corp.'s Up & Up Makeup Remover Cleansing Wipes caused swelling, blotches and a burning sensation in her skin, requiring the use of medicine to relieve. *McAteer v. Target Corp*., No. 18-0349 (D. Minn., filed February 7, 2018). The complaint asserts that Target describes its cleansing wipes as "gentle" and "hypoallergenic" but are "so harsh that they cause users' skin to develop an allergic reaction." Citing the Environmental Working Group's Skin Deep Cosmetics Database, the plaintiff alleges that the products contain "harsh chemicals and known human allergens," including fragrance, hexylene glycol and tocopheryl acetate. The complaint also lists a number of negative online reviews on Target's website and MakeupAlley. Alleging a violation of the Magnuson Moss Warranty Act, negligence, fraud and unjust enrichment, the plaintiff seeks class certification, an injunction, damages and attorney's fees.

SCIENCE

JAMA Op-Ed Calls for Activism Transparency in Nutrition Research

In a *JAMA* Viewpoint article, researchers from Stanford University have argued that nutrition studies should be transparent about their authors' financial and non-financial conflicts of interest, including their dietary preferences and activism work.

Noting that “the puritanical view that accepting funding from the food industry ipso facto automatically biases the results is outdated,” the authors briefly call for a financial disclosure registry before shifting to focus on non-financial conflicts of interest. “Advocacy and activism have become larger aspects of the work done by many nutrition researchers, and also should be viewed as conflicts of interest that need to be disclosed,” they assert.

“Therefore, it is important for nutrition researchers to disclose their advocacy or activist work as well as their dietary preferences if any are relevant to what is presented and discussed in their articles,” the researchers argue. “This is even more important for dietary preferences that are specific, circumscribed, and adhered to strongly. For example, readers should know if an author is strongly adherent to a vegan diet, the Atkins diet, a gluten-free diet, a high animal protein diet, specific brands of supplements, and so forth if these dietary choices are discussed in an article.”

“As a general rule, if an author’s living example could be reasonably expected to influence how some readers perceive an article, disclosure should be encouraged,” the article concludes. “Authors who have strong beliefs and make highly committed choices for diet or other behaviors should not hesitate to disclose them. Doing so may help everyone understand who is promoting what and why.”