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LEGISLATION, REGULATIONS & STANDARDS

FDA to Push Back Enforcement of Certain MoCRA Requirements

The U.S. Food and Drug Administration (FDA) has announced that it intends to delay enforcement of cosmetic product facility registration and product listing requirements under the Modernization of Cosmetics Regulation Act (MoCRA) of 2022.

In a November 8 Guidance for Industry, FDA said it will be ready to accept registration and listing information by the statutory deadline of December 29, 2023, and it is encouraging companies to meet the deadline if they are able to do so.

FDA said it does not intend to enforce the requirements under Section 607 of the Food, Drug, & Cosmetic Act related to cosmetic product facility registration and cosmetic product listing for an additional six months after the statutory deadline, or until July 1, 2024, to provide regulated industry with additional time to comply with the requirements.

FDA also said it does not intend to enforce the registration requirement for owners or operators of facilities that first engaged in manufacturing or processing a cosmetic product after December 29, 2022, or the listing requirement for cosmetics products first marketed after December 29, 2022, until July 1, 2024.

NY Gov. Approves Ban on Selling Weight Loss Supplements to Minors

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New York Gov. Kathy Hochul has signed a first-in-the-nation bill into law that prohibits the sale of over-the-counter weight loss and muscle-building supplements to minors. The law, which will take effect April 2024, creates age verification guidelines for retailers and delivery sellers. In a statement, Sen. Shelley Mayer, who co-sponsored the bill, said she was pleased the state is taking action to protect young people.

"As Chair of the Senate Committee on Education, I am committed to protecting and improving the health and well-being of young people," she said. "It is disheartening to see generations of young adults struggling to meet unrealistic societal expectations, leading them to trying short term, dangerous solutions."

Similar bills have previously advanced in California and New Jersey; the California bill was vetoed by Gov. Gavin Newsom in 2022, and the New Jersey bill failed to achieve final passage.

FDA to Propose Ban of Formaldehyde in Chemical Hair Straighteners

The U.S. Food and Drug Administration (FDA) has signaled plans to issue a proposed rule banning the use of formaldehyde and formaldehyde-releasing chemicals in hair products marketed in the United States. The agency's Unified Agenda entry states that the proposed rule would ban formaldehyde (FA) and other FA-releasing chemicals, such as methylene glycol, as an ingredient in hair smoothing or hair straightening products. The agency told CNN that it may request public comment on the ban, which it would review before proceeding.

"These chemicals are used in certain cosmetic products that are applied to human hair as part of a combination of chemical and heating tool treatment intended to smooth or straighten the hair," the entry said. "Use of hair smoothing products containing FA and FA-releasing chemicals is linked to short-term adverse health effects, such as sensitization reactions and breathing problems, and long-term adverse health effects, including an increased risk of certain cancers."

Proposed Senate Bill Would OK Reimbursement for Dietary Supplements

Sen. Kevin Cramer (R-ND) has reintroduced legislation that would allow consumers to buy dietary supplements using Health Savings Accounts (HSA), Flexible Savings Accounts (FSA) and Health Reimbursement Arrangements (HRA). The legislation seeks to amend the Internal Revenue Code to designate certain

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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.

over-the-counter dietary supplements and foods for special dietary uses as qualified medical expenses. The Natural Products Association (NPA) and Healthcare Nutrition Council have endorsed the bill.

In a statement, Daniel Fabricant, NPA president and CEO, said the bill is an innovative solution aimed at keeping more Americans healthy. “Senator Cramer is incentivizing healthy choices and expanding consumer choice by introducing legislation making dietary supplements eligible for reimbursement under Health Savings Accounts, Flexible Spending Arrangements, and Health Reimbursement Arrangements,” he said. “NPA is grateful for Senator Cramer’s leadership and is excited to continue working with him to expand access to nutritional supplements.”

Bipartisan Lawmakers Launch Congressional Cosmetics Caucus

A bipartisan group of U.S. lawmakers announced in September the launch of the Congressional Cosmetics Caucus. The group, co-chaired by Reps. Linda Sanchez (D-Calif.) and Nicole Malliotakis (R-N.Y.), aims to build awareness about important issues affecting the cosmetics and personal care products industry and highlighting its contributions to the U.S. economy and society, according to a news release from the Personal Care Products Council (PCPC).

PCPC President and CEO Lezlee Westine applauded the caucus in a statement, noting the personal care product industry provides nearly 4 million U.S. jobs, drives innovation and empowers women, who make up nearly 80% of the industry’s workers.

“With an unprecedented number of women in Congress, the Caucus has a unique opportunity to promote policies, programs and initiatives that support this dynamic and growing industry, addressing key bipartisan issues such as product safety, job growth, regulatory reform, sustainability, innovation, and diversity, equity and inclusion—all vital to our society’s success,” Westine said. “The Caucus will also serve as a platform to educate Congressional leaders about the industry’s scientific sophistication and commitment to sound science, dedication to safety and significant economic contributions.”

Bipartisan SHOP SAFE Act Takes Aim at Counterfeits Online

A bipartisan team of U.S. Senators has reintroduced the Stopping Harmful Offers on Platforms by Screening Against Fakes in E-

Commerce (SHOP SAFE) Act to protect U.S. consumers from harmful counterfeit products sold online. In a news release, Sens. Chris Coons (D-Del.) and Thom Tillis (R-N.C.) said that in 2022, Americans spent more than $1 trillion online, for the first time ever, making them increasingly vulnerable to harmful counterfeit goods sold on e-commerce platforms. They say the bill will incentivize platforms to engage in best practices for vetting sellers and goods and stopping repeat counterfeit sellers.

The proposed law would:

- Establish trademark infringement liability for e-commerce platforms;
- Require brand owners to provide platforms with advanced notice of their mark(s) and a point of contact so platforms can implement proactive measures to prevent sales of counterfeits; and
- Provide a safe harbor from liability for platforms that vet sellers and remove sellers who repeatedly sell counterfeits.

Dietary Supplement Company, Manager Settle Deceptive COVID-19 Marketing Claims

A nutritional supplement company and one of its managers have agreed to injunctions and the payment of civil penalties to resolve claims that they deceptively marketed dietary supplements during the COVID-19 pandemic in violation of the Federal Trade Commission Act and the COVID-19 Consumer Protection Act.

The U.S. Department of Justice (DOJ) alleged in its April 2021 complaint that Quickwork LLC and Eric Anthony Nepute made misleading and unsubstantiated advertising claims that their Vitamin D and Zinc supplements could be used to treat or prevent COVID-19 and could provide equal or better protection against COVID-19 than available COVID-19 vaccines. DOJ also alleged they mischaracterized the results of scientific studies to support some of their claims.

Quickwork agreed to an injunction and a $1 million civil penalty in an order entered in November 2022, but the order was partially suspended due to an inability to pay. In July 2023, the U.S. District Court for the Eastern District of Missouri awarded partial summary judgment against Nepute, and he agreed to an injunction and payment of $80,000 in civil penalties. The injunctions prohibit the defendants from making advertising claims that their supplements can prevent, cure, mitigate or treat

COVID-19 without competent and reliable scientific evidence to support their claims. They are also banned from misrepresenting the results of COVID-19 research in their advertising.

NPA Urges FDA to Amend Mushroom Supplement Labeling Requirements

The Natural Products Association (NPA) is urging the U.S. Food and Drug Administration (FDA) to take actions to clarify nomenclature and declaratory guidelines for dietary supplements that have fungal ingredients, including use of the terms "mushroom," "mycelia" and "fruiting bodies."

NPA submitted a petition to FDA asking that the agency:

- Amend 21 C.F.R. § 101 to incorporate labeling aspects based on the American Herbal Products Association's labeling guidance for mushrooms; and/or
- Commit to exercising enforcement discretion until FDA provides guidance or publishes a regulation concerning a standard of identity for dietary supplements or ingredients from fungal ingredients.

"Mushroom dietary supplements are extremely innovative and as the business grows, require a standard nomenclature," Daniel Fabricant, president and CEO of NPA, said in a statement. "By requesting that the FDA incorporate AHPA's labeling guidelines or exercise enforcement discretion until the Agency publishes its own standard of identity regulation, we aim to protect domestic farmers who continue to be economically harmed by foreign entities damaging the credibility of this evolving market."

Companies, Orgs Ask EPA to Expand Safer Choice Program

Personal care product companies and a dietary supplement company are among 39 entities calling on the Environmental Protection Agency (EPA) to expand its Safer Choice program to include beauty and personal care products. In a September 11 letter, the signatories—which include companies, investors and non-governmental organizations—said that adding such products to the program, including expanding the Safer Chemicals Ingredients List (SCIL), could provide "an important national pathway for consumers and commercial buyers seeking to purchase safer products."

"Not only would expanding Safer Choice make it easier for consumers and retailers to identify and purchase safer products, but it would also enable brands to market their products to consumers who are increasingly concerned about the safety of ingredients in beauty and personal care products, and wary of greenwashing," the group of entities said.

Safer Choice is a voluntary partnership program that works with companies to help them understand the chemical composition of their products and to select safer alternatives to chemicals that pose potential health or environmental concerns. The group said that the Safer Choice label helps consumers identify products that meet performance standards and are made with safer ingredients.

Groups Petition FTC to Withdraw Notices of Penalty Offenses Concerning Substantiation

Six industry trade groups have petitioned the Federal Trade Commission (FTC) to withdraw the Notice of Penalty Offenses Concerning Substantiation of Product Claims the agency sent to almost 700 companies in April. In September, the Consumer Healthcare Products Association (CHPA) sent a letter to FTC asserting that through the notices, the agency has attempted to impose a new drug-level substantiation standard for claims on food, dietary supplements, over-the-counter drugs and other consumer healthcare products. CHPA was joined by the Personal Care Products Council, United Natural Products Alliance, Food Industry Association, Natural Products Association and American Herbal Products Association.

The group asks FTC to withdraw the notices on three grounds. They argue the notices (i) attempt to impose a substantiation standard, which is prohibited by law and inconsistent with the Dietary Supplement Health and Education Act and long-standing regulatory guidance; (ii) do not establish the standard of "actual knowledge" needed to seek civil penalties under the FTC Act; and (iii) would violate due process upon enforcement.

"While the Commission's viewpoint is not new or surprising, what is surprising is to see FTC take its stance one step further by placing hundreds of companies on notice through standardless form letters that fail to provide any basis for imposing the civil penalties they threaten," CHPA Deputy General Counsel Carolyn Hermann said in a statement.

Bipartisan Delegation Reintroduces Humane Cosmetics Act

A bipartisan group of U.S. representatives has reintroduced the Humane Cosmetics Act, which seeks to end safety testing of cosmetic products on animals and prohibit the sale of products developed using animal testing in the United States. U.S. Representatives Don Beyer (D-Va.), Vern Buchanan (R-Fla.), Tony Cárdenas (D-Calif.), Ken Calvert (R-Calif.) and Paul Tonko (D-NY) reintroduced the bill, which includes exemptions for products that undergo animal testing mandated by the U.S. Food and Drug Administration and other international regulatory agencies.

In addition to animal welfare groups, the Personal Care Products Council (PCPC) issued a statement in support of the proposed legislation. "We applaud [the bill's sponsors] for driving a significant bipartisan effort that sets the stage for eliminating new cosmetics animal testing in favor of innovative, scientifically advanced safety assessments," PCPC President and CEO Lezlee Westine said. "This reintroduction builds on the decades' long effort to promote non-animal alternatives and move closer to eliminating the need for animals in product safety testing."

California Bans 26 Ingredients from Cosmetics

California Gov. Gavin Newsom has signed a bill into law that bans 26 ingredients intentionally added to cosmetics, including borate compounds, lily aldehyde, cyclotetrasiloxane, trichloroacetic acid, styrene and certain colors. Assembly Bill 496, sponsored by Assemblymember Laura Friedman (D-Burbank), would ban the manufacture, sale, delivery, hold or offer for sale in commerce any cosmetic product containing 26 intentionally added ingredients.

The Environmental Working Group, which sponsored the legislation, called the bill's passage "a significant milestone in the state's ongoing efforts to promote consumer safety and protect the health of Californians."

The Personal Care Products Council (PCPC) said in a statement that the group is committed to "global harmonization and policies based on the best available science."

"State governments increasingly make policy decisions that have a global impact affecting a wide range of industries, including the personal care and beauty sectors," the group added. "California Assembly Bill 496 aligns with ingredients banned in the European Union."

LITIGATION

Consumers Allege Culturelle Packaging Makes Unlawful Claims

Two California consumers have filed a proposed class action against the maker of Culturelle Ultimate Balance for Antibiotics, alleging the company makes misleading claims about its probiotic supplements. *Warren v. I-Health, Inc.*, No. 23-01926 (E.D. Cal., September 7, 2023). The plaintiffs allege that the defendant's representations that the products "rebuild bacterial balance lost to antibiotic use" violate federal law because they convey to consumers that they will treat diseases, including infections caused by antibiotics.

"When Defendant's claims are viewed in their totality, they are either explicitly or implicitly claiming to mitigate or prevent diseases," the plaintiff alleged in the complaint. "These claims mislead consumers into believing they can use the Products to self-diagnose and treat without the supervision of a licensed practitioner." The plaintiffs allege violations of California's Unfair Competition Law, False Advertising Law and Consumer Legal Remedies Act, as well as common law claims, and they seek class certification, damages, declaratory judgment and attorneys' fees.

Court Denies Bid to Dismiss Nordic Naturals Labeling Suit

A federal court in New York has denied a bid by Nordic Naturals, Inc., to dismiss a proposed class action alleging that its name misleads consumers into thinking its supplements are natural when they contain synthetic ingredients. *Orrico v. Nordic Naturals, Inc.*, No. 22-03195 (E.D.N.Y., filed September 28, 2023). The plaintiff alleged that the company misleads consumers by prominently displaying the word "natural" on its products when they contain synthetic ingredients such as gelatin, soy lecithin, maltodextrin and ascorbic acid, among others.

In its motion to dismiss, the defendant argued that no reasonable consumer would have been deceived by its name, noting that its products are not labeled as "all natural" or "100% natural." The court said in its opinion that the Second Circuit Court of Appeals has considered brand names in context when evaluating labeling claims. "Here, the 'Nordic Naturals' brand name is the only representation on the front label as to whether the Products' ingredients are natural or artificial, and it is not contradicted by

any other representation on the front label that the Products contain synthetic ingredients," the court said. "In this context, the Court cannot conclude that no reasonable consumer would interpret the brand name 'Nordic Naturals' to indicate that Defendant's Products were, in fact, comprised entirely of natural ingredients."

Supplement Multilevel Marketer Prevails in Court Against FTC

Multilevel marketing company Neora—formerly Nerium International—has prevailed in a Federal Trade Commission (FTC) action seeking to enjoin the company from making certain representations about its supplements. *FTC v. Neora LLC*, No. 20-1979 (N.D.T.X., filed September 28, 2023). In a 2019 complaint, FTC asserted five violations of the Federal Trade Commission Act, alleging in part that Neora misrepresented the efficacy of its eicosanoyl-5-hydroxytryptamide (EHT) product, which the company sold as EHT Brain Formula. FTC also alleged that Neora misled consumers by making claims misrepresenting that the effectiveness of EHT has been scientifically established.

Following a weeklong bench trial, a Texas federal court entered a ruling denying all relief sought by the FTC. The agency had alleged that Neora is responsible for claims made by its independent distributors, which it calls Brand Partners, or BPs. The court disagreed, finding in its opinion that FTC had not established that Neora was liable for the actions of the BPs. "In sum, the FTC seeks an order preventing Defendants from claiming that their products cure, treat, or prevent human disease," the court said. "There is no evidence before the Court that Defendants are currently making such claims, or are likely to do so in the future."

FTC Junk Fees Lawsuit Results in Lifetime Ban for Skin Cream Marketer

The owner of a several companies that charged consumers who bought skin creams millions of dollars in undisclosed and recurring subscription fees has agreed to a lifetime ban on negative option marketing and to turn over assets to the Federal Trade Commission (FTC). *FTC v. F9 Advertising LLC*, No. 19-1174 (D.P.R., filed October 10, 2023). FTC sued Gopalkrishna Pai and eight companies he owned in 2019, alleging that he marketed skin creams online with a nominal shipping and handling fee. Consumers who bought the products did not realize they would later be charged the full price of the products, plus a recurring monthly charge, FTC said in a news release.

"Our proposed order banning defendants from the subscription marketing business and ordering the return of assets is a big win for consumers, and it should send a strong message to other unscrupulous marketers," Samuel Levine, director of FTC's Bureau of Consumer Protection, said in a statement. "The FTC will continue its crackdown on junk fees and subscription traps." The order contains a total monetary judgment of $34 million, which has been partially suspended due to the defendant's inability to pay the full amount.

Proposed Class Action Alleges Banana Boat Facial Sunscreen Misleads Consumers

A California woman has filed a proposed class action against the maker of Banana Boat sunscreens, alleging the company misleads consumers into believing its line of facial sunscreens—which cost more per ounce than full-body sunscreens—are designed specifically for the face, when they are the same formula as the full-body sunscreens. *Lowe v. Edgewell Personal Care Brands LLC*, No. 23-1256 (D. Conn., filed September 26, 2023).

The plaintiff alleged that prominent representations on Banana Boat's Sport Ultra Faces lotion tout that the product is "Oil Free" and "Non-Greasy," leading consumers to believe the lotion is specifically designed for the face. She asserted that, based on that belief, consumers are willing to pay more for the product, noting that the Faces line costs more than twice as much as Banana Boat's regular Sport Ultra lotion. The plaintiff alleged that the Faces lotion is not specifically formulated for the face, however, and is the same as the Sport Ultra lotion. "Defendant is putting the same sunscreen into two different bottles with different labels, and charging more for one of them," she alleged. "Consumers are being deceived and overcharged."

The plaintiff alleges violations of state consumer protection acts in California, Illinois, Maryland, New York, Missouri, Washington and Connecticut; violations of California's Unfair Competition Law, False Advertising Law and Consumer Legal Remedies Act; and unjust enrichment. She seeks class certification, declaratory judgment, damages, restitution and attorneys' fees.

Dietary Supplements Company Ordered to Pay $1.1M, Stop Production

A California court has ordered dietary supplements maker Evig LLC to pay the state nearly $1.1 million to resolve claims that the

company deceptively advertised its Balance of Nature products. *California v. Evig, LLC*, No. 21-0242 (Napa Cty. Super. Ct., filed June 23, 2023). The lawsuit was brought by district attorneys' offices in nine counties that make up the California Food, Drug and Medical Device Task Force.

Balance of Nature sells dietary supplements that purport to be fruits and vegetables that are freeze-dried, powdered and placed in a capsule, according to a news release from the Sonoma County District Attorney's Office. The complaint alleged that Balance of Nature made representations regarding the effectiveness of its products that were not supported by competent and reliable scientific evidence, including claiming that one serving of its Fruits product contained the "nutritional equivalent of over 5 servings of fruit per dose."

In a final judgment, the court permanently enjoined Evig from making untrue or misleading statements about nutritional supplements; representing that any nutritional supplement can diagnose, mitigate, treat, cure or prevent any disease condition; and making claims that are unapproved by the U.S. Food and Drug Administration (FDA). The court ordered $250,000 in restitution, a civil penalty of $775,000 and $75,000 for investigative costs.

In a separate action before the U.S. District Court for the District of Utah, a federal judge in November ordered Evig and its manufacturer, Premium Production LLC, to stop producing and selling their products until they comply with federal regulations under the Federal Food, Drug, and Cosmetic Act, FDA announced.

FDA said Balance of Nature products are marketed as dietary supplements, but their labeling rendered them unapproved new drugs and misbranded drugs, including claims the products could be used to diagnose, cure, mitigate, treat or prevent diseases like cancer, heart disease, cirrhosis, diabetes, asthma and COVID-19. FDA further said Evig also violated current good manufacturing practice requirements, rendering its products adulterated dietary supplements.

Consumers Sue Orgain, Nestle for 'Grass-Fed' Protein Claims

Two California women have filed a proposed class action against Orgain LLC and Nestle Health Science U.S. Holdings, Inc., alleging the labels for Orgain’s nutritional shakes, protein shakes and protein powders are deceptive about the amount of grass-fed protein in its products. *Bennett v. Orgain, LLC*, No. 23-1877 (S.D. Cal., filed October 13, 2023).

The plaintiffs take issue with front label representation about the number of grams of grass-fed protein per serving in the products, pointing to the front label of the Orgain Kids Protein Shake, which states "8g GRASS-FED PROTEIN." The plaintiffs alleged that the represented protein is actually a blend of grass-fed protein and organic protein, and that organic protein is not the same as grass-fed protein because organic protein comes from cows fed grain and corn.

“From a nutritional standpoint, 100% grass-fed protein has more Omega-3s and conjugated linoleic acid (CLAs) than conventional whey protein,” they argue. “This is important to consumers as the higher level of Omega-3s is believed to fight inflammation, benefit the immune system, improve exercise performance, and prevent chronic conditions such as heart disease and diabetes. Thus, the belief that the Products are made with only grass-fed protein is material to consumers.”

The plaintiffs allege violations of California’s Consumer Legal Remedies Act, False Advertising Law and Unfair Competition Law in addition to common law claims. They seek class certification, declaratory judgment, injunctive relief, restitution, damages, attorneys' fees and pre- and post-judgment interest.

Keto Supplement Maker Sued for False Advertising

A California consumer has filed a proposed class action against Sports Research Corporation alleging that the company falsely advertises its raspberry lemonade-flavored Keto+ dietary supplement as “naturally flavored.” *Lozano v. Sports Research Corp.*, No. 23-8696 (C.D. Cal., filed October 16, 2023).

The plaintiff alleged in her complaint that while the front label of the product states that it is “naturally flavored,” the claim is false and the product contains an artificial flavoring, DL malic acid. The plaintiff alleged that independent testing has confirmed the presence of the "D" isomer in the malic acid used in the products, confirming that the malic acid used in the product is DL malic acid, a synthetic substance.

“The DL malic acid used in the Products is used to create, simulate, and/or reinforce the sweet and tart taste that consumers associate with the fruit flavors stated on the labels,” the plaintiff alleged. “Defendant uses the petrochemical-derived DL malic acid in its Products to create a sweet and tart flavor but pretends otherwise, conflating natural and artificial flavorings, misbranding the Products and deceiving consumers.”

The plaintiff alleges violations of California's Unfair Competition Law, False Advertising Law, Consumer Legal Remedies Act, unjust enrichment and breach of express warranty and seeks class certification, declaratory judgment, damages, injunctive relief, attorneys' fees and pre- and post-judgment interest.