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HIGHLIGHTS IN 2023 DEVELOPMENTS

FDA Takes Steps to Implement MoCRA

In 2023, the U.S. Food and Drug Administration (FDA) took several steps to implement the Modernization of Cosmetics Regulation Act (MoCRA), which was signed into law in December 2022. The law requires cosmetic manufacturers to register each of their facilities and give FDA information about product ingredients. The law also gives FDA the authority to issue mandatory product recalls.

FDA Proposes Moving Cosmetics Regulation to Office of Chief Scientist

In late February 2023, FDA Commissioner Robert Califf announced the agency's plans to restructure its Human Foods Program and Office of Regulatory Affairs. The agency said the proposed reorganization will help prepare for MoCRA implementation by moving cosmetics regulation and color certification out of the Center for Food Safety and Applied Nutrition and into the Office of Chief Scientist. Califf provided an update in December 2023 that FDA's proposed reorganization package is now under review at the U.S. Department of Health and Human Services, which begins the formal external review process. In a release, he said the agency hopes to implement the reorganization in 2024.

FDA Issues Draft Guidance on Cosmetic Product Facility Registrations and Product Listings

In August 2023, FDA issued draft guidance on cosmetic product facility registrations and product listings. FDA issued final

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guidance for industry in December 2023 that explains the statutory requirement to submit cosmetic product facility registrations and product listings, definitions, details of submission requirements and methods of submission.

FDA Announces MoCRA Enforcement Delay

In November 2023, FDA issued guidance to industry delaying enforcement of MoCRA's requirements regarding cosmetic product facility registration and cosmetic product listing requirements until July 1, 2024. FDA also will not 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.

FDA Announces Launch of Electronic Submission Portal

In December 2023, FDA announced the launch of its Cosmetics Direct electronic submission portal. The portal is dedicated exclusively to cosmetic product facility registration and cosmetic product listing electronic submissions. In preparation for the new portal, FDA announced in March 2023 that it had stopped accepting and processing submissions to the Voluntary Cosmetic Registration Program.

GAO Issues Report on MoCRA Implementation Process

The Government Accountability Office (GAO) released a December 2023 report reviewing FDA oversight of cosmetic safety. "Cosmetic Safety: Better Planning Would Enhance FDA Efforts to Implement New Law" examined research on the safety of selected substances in cosmetics and FDA actions to implement its new authorities and the extent to which these actions addressed selected leading practices for agency reforms. The agency found that FDA had not fully addressed leading practices that would help ensure the success of FDA's reforms, including the development of an implementation plan for MoCRA or a strategic workforce plan to ensure FDA has the necessary personnel to exercise its new authorities. GAO made seven recommendations to strengthen FDA's efforts to implement its new cosmetic safety oversight responsibilities, and FDA concurred with the recommendations.

Legislators Propose and Pass New Cosmetics Regulations

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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.

In 2023, lawmakers at both the state and federal levels made strides toward implementing new regulations governing cosmetics. At the federal level, a bipartisan group of U.S. Representatives 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. The bill includes exemptions for products that undergo animal testing mandated by the U.S. Food and Drug Administration and other international regulatory agencies. At the year's end, the bill had not progressed beyond introduction in the House.

At the state level, two states passed laws restricting ingredients that could be used in cosmetics sold within their boundaries. In May, Washington Gov. Jay Inslee signed into law the state's Toxic-Free Cosmetic Act, HB 1047. The law is the first state law on cosmetics and personal care products to ban ortho-phthalates, all formaldehyde-releasing agents and triclosan; restrict lead; require state agencies to assess the hazards of chemicals used in products that can affect vulnerable populations; and provide support for small businesses and independent cosmetologists to transition to safer products. The bans take effect in 2025, except for formaldehyde releasers, which have a phased-in approach beginning in 2026.

In October 2023, California Gov. Gavin Newsom signed a law banning 26 ingredients intentionally added to cosmetics, including borate compounds, lily aldehyde, cyclotetrasiloxane, trichloroacetic acid, styrene and certain colors. AB 496 bans the manufacture, sale, delivery, hold or offer for sale in commerce any cosmetic product containing any of the 26 intentionally added ingredients.

In other activity, a bipartisan group of U.S. lawmakers announced in September 2023 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.

Lawmakers Propose Legislation Affecting Personal Care Products, Supplement Industries

State and federal lawmakers proposed legislation that would the affect the cosmetics and dietary supplement industries. In September, a bipartisan team of U.S. senators 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. The bill's sponsors, Sens. Chris Coons (D-Del.) and Thom Tillis (R-N.C.), say the bill will incentivize platforms to engage in best practices for vetting sellers and goods and stopping repeat counterfeit sellers.

Sen. Kevin Cramer (R-ND) reintroduced legislation in October 2023 that would allow consumers to buy dietary supplements using Health Savings Accounts, Flexible Savings Accounts and Health Reimbursement Arrangements. The legislation seeks to amend the Internal Revenue Code to designate certain over-the-counter dietary supplements and foods for special dietary uses as qualified medical expenses.

In March 2023, the Idaho State Senate narrowly rejected a bill seeking to preserve access to dietary supplements that were legal in Idaho as of July 2022, despite any subsequent regulatory changes at the federal level. The Idaho Dietary Supplement Act, HB 82, failed by one vote.

Companies Seek Clarity, Face Enforcement on Mushrooms in Supplements

As mushrooms gain popularity as a dietary supplement ingredient, companies seek clarity on how they are labeled and face enforcement from governments on how they are marketed. In April 2023, the United Kingdom's Advertising Standards Authority (ASA) upheld a series of complaints that Dirtea, which makes mushroom powder supplements, made unlawful claims in a series of social media ads that stated or implied that a food prevented, treated or cured human disease. ASA said the ads must not appear again in similar form, and instructed the company to ensure its future advertising did not make claims that their products could prevent, treat or cure human illness.

North American Reishi Ltd. (NAMMEX), a mushroom wholesaler, petitioned the U.S. Food and Drug Administration (FDA) in June 2023 to take actions that would ensure dietary supplements and food products containing fungi are properly labeled to identify the fungal part/growth stage of the ingredient and disclose the presence of any substrate on which the fungal ingredient is grown. In December 2023, NAMMEX indicated that it received a 180-day interim response from FDA stating that the agency had not yet reached a decision.

In August 2023, the Natural Products Association submitted a petition urging FDA to clarify nomenclature and declaratory

guidelines for dietary supplements that have fungal ingredients, including use of the terms “mushroom,” “mycelia” and “fruiting bodies.” The group asked FDA to incorporate the American Herbal Products Association’s labeling guidelines for mushrooms 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 fungi.

New York Bans Sales of Weight-Loss Supplements to Minors

State lawmakers in a handful of states considered legislation prohibiting the sale of weight-loss supplements to minors. In October 2023, New York Gov. Kathy Hochul 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. The Natural Products Association filed a lawsuit challenging the constitutionality of the bill in December 2023.

Lawmakers in Maryland considered, but did not advance, HB 634, which would have required consumers purchasing weight-loss supplements to provide proof that they are 18 or older and would have required Maryland retailers to restrict access to weight loss supplements.

Additionally, dietary supplement groups claimed victory in Colorado, where legislative language that would have restricted and in some cases prohibited access to dietary supplements was stricken from SB 176 before the Colorado Health and Human Services Committee. The bill’s original language would have prohibited retail establishments “from selling, transferring, or otherwise furnishing dietary supplements for weight loss or over-the-counter diet pills to any individual under 18 years of age without a prescription.”

Federal Agencies Enforce Laws Banning Deceptive COVID-19 Claims

Multiple federal agencies have pursued actions against companies making COVID-19 claims in their marketing. In one case, three distributers for multi-level marketing company doTERRA International LLC agreed to pay $15,000 in civil penalties to resolve allegations that they made deceptive COVID-19 claims while marketing essential oils and nutritional supplements. They are enjoined from making COVID-19 prevention, treatment or

cure claims for any product or service, except for claims specifically approved by the U.S. Food and Drug Administration. In August 2023, a nutritional supplement company agreed to injunctions and payment of civil penalties to resolve claims that it deceptively marketed dietary supplements during the COVID-19 pandemic in violation of the Federal Trade Commission Act and the COVID-19 Consumer Protection Act. In another case, the U.S. Department of Justice alleged that Quickwork LLC made misleading and unsubstantiated advertising claims that its 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 vaccines.

FDA Issues Consumer Warnings for Range of Supplements

The U.S. Food and Drug Administration (FDA) issued consumer warnings about products containing Apetamin, tianeptine and selective androgen receptor modulators (SARMs). In April 2023, FDA warned that it continues to receive adverse event reports related to SARMs, chemical substances that mimic the effects of testosterone and anabolic steroids. SARMs are not FDA-approved, but, according to the agency, online vendors and social media influencers are using social media to describe them as safe and effective. FDA said SARMs cannot be legally marketed in the United States as a dietary supplement or drug. In June 2023, the agency sent a warning letter to Warrior Labz SARMS, identifying several products as unapproved new drugs. In another case, an Idaho man was sentenced to two years in federal prison for selling at least $4.4 million worth of products containing SARMs.

In November 2023, FDA warned consumers against using Neptune's Fix products or other products containing tianeptine, an unapproved substance sold with claims of improving brain function and treating anxiety, depression, pain, opioid use disorder and other conditions. FDA reportedly received severe adverse reports after individuals used the products, including seizures and loss of consciousness leading to hospitalization. The products can be purchased online and at gas stations, vape or smoke shops, and other locations.

FDA warned consumers that it had reviewed several serious adverse event incidents associated with the use of Apetamin, which is allegedly being marketed illegally for weight gain and figure augmentation. The agency has also issued warning letters to Amazon for male energy supplements containing sildenafil.

FTC Accuses Supplement Maker of Online Review Hijacking

In the first enforcement action of its kind, the Federal Trade Commission (FTC) filed a complaint alleging that the Bountiful Co, which sells Nature's Bounty and Sundown supplements, abused a feature of Amazon.com to deceive consumers into believing its newly introduced supplements had product ratings and reviews, high average ratings and "#1 Best Seller" and "Amazon's Choice" badges. FTC alleges that Bountiful engaged in review hijacking—when a marketer steals or repurposes reviews of another product—by merging its new products with different well-established products that had more ratings, reviews and badges. FTC voted 4-0 to accept the proposed consent agreement, which also prohibits the company from making similar misrepresentations and using other deceptive review tactics.

FTC Warns Companies to Backup Claims

The Federal Trade Commission (FTC) sent warning letters to 670 companies that market over-the-counter drugs, homeopathic products, dietary supplements or functional foods, warning that the agency will target companies that deceive consumers with advertisements that make product claims that cannot be backed up or substantiated. FTC warned companies that they could incur significant civil penalties for failing to adequately substantiate their product claims. Six industry trade groups, spearheaded by the Consumer Healthcare Products Association (CHPA), petitioned FTC to withdraw the letters. CHPA asserted in a letter 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.

LEGISLATION, REGULATIONS & STANDARDS

FDA Issues Guidance for New Dietary Ingredient Notifications

The U.S. Food and Drug Administration (FDA) has issued final guidance on new dietary ingredient notification procedures. "Dietary Supplements: New Dietary Ingredient Notification Procedures and Timeframes: Guidance for Industry" is intended to help manufacturers and distributors of new dietary ingredients and dietary supplements prepare and submit new dietary ingredient notifications (NDINs) to FDA, the agency said in a constituent update March 5, 2024. The guidance includes

details on who must submit an NDIN, how the information should be organized and presented, where an NDIN should be submitted, and what happens after an NDIN is submitted.

Legislators, FDA Respond to Adverse Tianeptine Reports

Months after the U.S. Food and Drug Administration (FDA) warned consumers against using Neptune's Fix products or other products containing tianeptine, the *New York Times* published an article noting an increase in case reports involving tianeptine exposure. Soon after, five lawmakers wrote to FDA Commissioner Robert Califf urging the agency to "take immediate action to research and provide guidance on tianeptine use." The day after the *Times* article, FDA urged convenience stores, gas stations and other retailers to stop selling Neptune's Fix and other products containing tianeptine. FDA also reportedly received severe adverse event reports—including seizures, loss of consciousness and death—after use of Neptune's Fix products. The company agreed to voluntarily recall all lots of its Elixer, Extra Strength Elixer and Tablets.

In Congress, Reps. Jimmy Panetta (D-Calif.) and August Pfluger (R-Tex.) announced the Scheduling Tianeptine and Analogues Now to Defend Against Emerging Opioids Act (STAND Against Emerging Opioids Act), which would add tianeptine and its analogues to Schedule III of the Controlled Substances Act. "Tianeptine, a potent opioid-like drug, poses alarming risks, and the ease of acquiring it—like candy—is a public health threat," Pfluger said in a statement.

FDA Warns Against Certain Tejocote Root Supplements

The U.S. Food and Drug Administration (FDA) warned consumers against ingesting certain dietary supplements labeled as tejocote root after testing identified yellow oleander in 18 tejocote root supplement products sold on Amazon.com and other websites. Yellow oleander can cause severe adverse health effects and can potentially be fatal, FDA stated. Two manufacturers have initiated recalls in response to FDA's safety alert: World Green Nutrition, Inc., recalled its ELV Alipotec supplements and Backstage Center recalled its Alipotec King products.

GAO Report Finds Inaccurate Amounts of Nutrients in Prenatal Vitamins

Eleven of 12 prenatal supplement products tested for a Government Accountability Office (GAO) report contained at least one tested nutrient with an average amount outside acceptable deviations from the label value, according to "Prenatal Supplements: Amounts of Some Key Nutrients Differed from Product Labels." The study organized its analysis of six nutrients into two groups: key nutrients recommended for beneficial pregnancy outcomes—folic acid, iodine and iron—and three nutrients recommended in small doses but with harmful effects to a pregnancy if the doses are too high or are in certain combinations—vitamins A, C and E. The testing found that the first group of nutrients most frequently matched the label amounts, although four supplements had average folic acid levels below the amount on their labels. The latter group of nutrients was the most variable in measured amounts compared to product labeling, the agency found.

GAO concluded that the limited reach of FDA oversight over dietary supplements could lead to unfavorable health outcomes for vulnerable populations and argued that Congress should consider measures for allowing FDA sufficient authority to carry out its oversight of dietary supplements, including pre-market notification or registration.

The Council for Responsible Nutrition pushed back on the report, noting GAO did not disclose testing methods or laboratory vendors. "This report strikes an unnecessarily alarmist note when the vast majority of prenatal supplements are not only safe, but vital to the health of mothers and their babies," a spokesperson said in a statement.

Texas Company Pleads Guilty to Distributing Misbranded Supplements

The U.S. Department of Justice (DOJ) has announced that Defyned Brands, also known as 5 Star Nutrition LLC, has pleaded guilty to distributing misbranded dietary supplements marketed as workout aids that failed to accurately include all ingredients on the product label. As part of the plea agreement, the company will forfeit $4.5 million and meet the terms of a compliance program. "Consumers deserve to know what is in the dietary supplements they take," a DOJ spokesperson said in a statement. "We will continue to investigate dietary supplement manufacturers and distributors who sell products that do not comply with the law, including through criminal enforcement where appropriate."

California Assembly Passes Bill Banning Sale of Weight-Loss Supplements to Minors

The California Assembly has passed a bill that would prohibit retailers from selling minors weight-loss or over-the-counter (OTC) diet pills without a prescription. AB 82 would also require the California Department of Public Health (CDPH) to develop a notice for display by retailers stating that certain dietary supplements for weight loss or OTC diet pills may contribute to specified health conditions or death. The bill, which would take effect July 1, 2024, also outlines a $1,000 civil penalty for each violation and exempts retail clerks from disciplinary action for violating the provisions. Gov. Gavin Newsom vetoed similar legislation in 2022, asserting that the proposed bill would require CDPH to evaluate every individual weight-loss and dietary-supplement product for safety, which is beyond the scope of its capabilities.

LITIGATION

Balance of Nature Supplement Maker Sued for Marketing Claims

A consumer has filed a putative class action alleging Evig LLC, which sells Balance of Nature dietary supplements, misleadingly marketed its products as promoting health despite their composition of 40% sugar. *Spivey v. Evig LLC*, No. 24-0781 (N.D. Ill., filed January 30, 2024). The plaintiff disputes the accuracy of labeling claims such as “real nutrition,” “real food” and “real science,” as well as the names of the company's product blends. “By representing that the Balance of Nature veggie and fruit products contain blends called ‘maintain’, ‘protect’ and ‘repair’ Defendants are falsely or deceptively representing that the Balance of Nature products maintain, protects/fend and repair one’s health when it is not possible for these products to do anything at all other than lighten the pocketbooks of consumers,” the plaintiff alleges. For purported violations of the Illinois Consumer Fraud Act, the plaintiff seeks class certification, damages, disgorgement of defendants’ revenues, attorney's fees and costs.

Nature’s Bounty Manufacturer Sued for Cardiovascular Health Claims

A consumer has filed a proposed class action against Nestlé Health Science U.S. alleging the product packaging for Nature's Bounty Fish Oil displays misleading claims about supporting heart health. *Fasce v. Nestlé Health Science U.S., LLC*, No. 24-1009 (S.D.N.Y., filed February 9, 2024). The plaintiff alleges that while the consumption of fish lowers one's risk of heart attack and stroke, the consumption of fish oil supplements does not. Nature's Bounty Fish Oil bottles are prominently labeled "Heart Health" and make claims about supporting heart health, he argues, and without its heart benefits, the product is allegedly worthless. "What reasonable person wants to pay for and ingest supplements that do not work?" the complaint asks. "Plaintiff and each class member paid for Products that are, in truth, worthless." The plaintiff alleges violations of New York's consumer-protection statute and the Magnuson-Moss Warranty Act as well as breach of warranties and misrepresentation, and he seeks class certification, damages, restitution, rescission, injunctive relief and attorney's fees.

Aquaphor Maker Sued for 'No Preservatives' Claim

Beiersdorf Inc. has been targeted with a putative class action challenging Aquaphor Lip Repair's "no preservatives" label based on the product's sodium ascorbyl phosphate content. *Watts v. Beiersdorf Inc.*, No. 24-0527 (E.D.N.Y., filed January 24, 2024). The plaintiff alleges that the sodium ascorbyl phosphate listed as an ingredient contains ascorbic acid, a preservative, contradicting the label's "no preservatives" representation. "Sodium ascorbyl phosphate is frequently used in cosmetic and skin care products because it is a gentler on the skin and better suited for use in these products than pure ascorbic acid," the plaintiff argues. "However, it still retains the same properties as ascorbic acid, albeit at a lower strength." For alleged violations of New York General Business Law, breach of express warranty and unjust enrichment, the plaintiff seeks class certification, declaratory judgment, damages, prejudgment interest, restitution, injunctive relief and attorney's fees.

Consumer Alleges Supergoop Sunscreen Provides Less Protection than Advertised

A consumer has alleged in a proposed class action that Supergoop's Unseen Sunscreen SPF 40 products provide less protection than displayed on the product's Principal Display Panels. *Dunning v. Supergoop, LLC*, No. 23-11242 (S.D.N.Y., filed December 28, 2023). The plaintiff asserts that SPF testing of

Supergoop products showed that Unseen Face Sunscreen is actually SPF 23 while Unseen Body Sunscreen is SPF 20. “Defendant knew or should have known that the Products contain a materially lower SPF protection than the advertised SPF 40 stated on the Products’ labels because they were required to perform testing in accordance with FDA regulations to determine the Products’ SPF Label Values,” the plaintiff argues. She alleges violations of New York's General Business Law, breach of express warranty and unjust enrichment and seeks class certification, injunctive relief, damages, interest and attorney's fees.