ISSUE 66 | APRIL 2023

LEGISLATION, REGULATIONS & STANDARDS

Proposed FDA Restructuring Would Move Cosmetics under Office of Chief Scientist

A proposed U.S. Food and Drug Administration (FDA) restructuring plan seeks to move cosmetics regulation and color certification out of the Center for Food Safety and Applied Nutrition and into the Office of Chief Scientist (OCS).

In late February, FDA Commissioner Robert Califf announced the agency's plans to restructure its Human Foods Program and Office of Regulatory Affairs. The agency is also using the proposed reorganization to prepare for the late-2023 implementation of the Modernization of Cosmetics Regulation Act by moving cosmetics under OCS oversight.

"This proposed move will better align the expertise of the agency's cosmetics subject matter experts with the Chief Scientist who is focused on research, science, and innovation that underpins the agency's regulatory mission, and recognize the evolution and innovation in this product space," he said in a news release. "Further, this shift will leverage the FDA's areas of expertise across the agency as it works to implement the Modernization of Cosmetics Regulation Act of 2022."

The FDA is seeking to finalize its restructuring proposal in fall 2023.

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 to Host Listening Session with Cosmetics Manufacturers

The U.S. Food and Drug Administration (FDA) has announced that it will host a virtual public meeting, “Good Manufacturing Practices for Cosmetic Products Listening Session,” for cosmetics manufacturers. The event will take place from 10 a.m. to 1 p.m. ET on June 1, 2023. The purpose of the event is to consult cosmetics manufacturers, including smaller businesses and contract manufacturers, consumer organizations and other experts to inform FDA's efforts to develop regulations establishing good manufacturing practices for facilities that manufacture or process cosmetic products distributed in the United States.

Specifics on the meeting, including information on how to register, will be made available through a *Federal Register* notice and posted to FDA's meeting page.

California Assembly Advances Bill Banning 26 Chemicals from Cosmetics

The California Assembly has voted to advance a bill banning the sale of cosmetics products containing 26 chemicals. On March 23, 2023, the Assembly approved AB 496, which seeks to ban a list of chemicals that includes borate compounds, lily aldehyde, cyclotetrasiloxane, trichloroacetic acid, styrene and certain colors. The bill passed with 62 yeses, zero noes and eight votes not recorded. The bill now advances to the Senate.

The bill was introduced in February by Assemblymember Laura Friedman. In a statement announcing the bill, Friedman said personal care products and cosmetics should be non-toxic for everyone.

“If you consider that the European Union prohibits over 1600 chemicals in such products, a ban in California on these noxious carcinogens and endocrine disrupters is long overdue,” she said. “AB 496 continues our progress toward cleaner, healthier, and environmentally-safer products.”

The bill follows the Toxic-Free Cosmetics Act, which was signed into law in 2020 and prohibited 24 ingredients beginning in 2025, and 2022 legislation banning the sale of cosmetics with added per- and polyfluorinated substances (PFAS). The new law would take effect January 1, 2027.

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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.

FDA Releases Dietary Supplement Ingredient Directory

The U.S. Food and Drug Administration (FDA) has introduced a dietary supplement ingredient directory to help manufacturers, retailers and consumers quickly access the latest information on dietary supplement ingredients. The directory includes links to FDA actions and communications regarding particular dietary ingredients and other ingredients used in products marketed as dietary supplements. FDA said it will periodically update the directory. The directory is not intended to be a comprehensive list of all ingredients, and may not include all actions the agency has taken regarding a specific ingredient. The agency is welcoming feedback and information regarding ingredients. Users may submit information via FDA's Office of Dietary Supplement Programs.

FTC Accuses Supplement Maker of Online Review Hijacking

The Federal Trade Commission (FTC) has, for the first time, taken action against a dietary supplement manufacturer the agency alleges abused a feature of Amazon.com to deceive consumers into thinking its newly introduced supplements had more product ratings and reviews, higher average ratings and "#1 Best Seller" and "Amazon's Choice" badges.

On February 16, FTC announced it had issued a complaint against the Bountiful Co., which sells supplements under the Nature's Bounty and Sundown brands. The agency said the case is its first enforcement action challenging "review hijacking," when a marketer steals or repurposes reviews of another product. FTC alleges that Bountiful engaged in review hijacking by merging its new products with different well-established products that had more ratings, reviews and badges.

"Boosting your products by hijacking another product's ratings or reviews is a relatively new tactic, but is still plain old false advertising," Samuel Levine, director of FTC's Bureau of Consumer Protection, said in a statement. "The Bountiful Company is paying back $600,000 for manipulating product pages and deceiving consumers."

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. The action follows an announcement from FTC in October 2022 that it was exploring rulemaking to crack down on fake reviews and

deceptive endorsements.

Washington Legislature Passes Toxic-Free Cosmetics Act

Both chambers of the Washington state legislature have given their approval to a bill to ban formaldehyde, per- and polyfluorinated substances (PFAS), lead and other chemicals in cosmetics. On April 8, the Washington Senate voted 28-20 to approve the Toxic-Free Cosmetics Act (HB 1047), just over a month after the House approved the bill 55-41. The bill will return to the House for a concurrence vote. Rep. Sharlett Mena introduced the bill in January. Mena said in a statement that the bill "will simply prevent toxics from going into cosmetics."

"We're talking about forever chemicals like PFAS, we're talking about lead, we're talking about formaldehyde. Essentially we are talking about things that there is no safe amount to be putting on your face, or in your body, or in the environment," she said.

In early 2023, the state House Environment and Energy Committee heard the findings of a legislature-commissioned Washington State Department of Ecology report. The report found high levels of formaldehyde in cosmetics and personal care products marketed to people of color.

The bill marks the second attempt to pass the Toxic-Free Cosmetics Act. Lawmakers approved a version of a 2022 bill that stripped out a ban on certain chemicals in cosmetics, allowing only for regulations of PFAS.

FDA Ends Voluntary Cosmetic Registration Program

The U.S. Food and Drug Administration (FDA) announced March 27 that it has stopped accepting and processing submissions to the Voluntary Cosmetic Registration Program (VCRP) as the agency plans to develop a program for submission of the facility registrations and product listings required by the Modernization of Cosmetics Regulation Act of 2022 (MoCRA).

The VCRP was a reporting system used by manufacturers, packers and distributors of cosmetic products that are in commercial distribution in the United States. It was established in 1972 as a way for the agency to obtain information about cosmetic products and their ingredients, their frequency of use and businesses engaged in their manufacture and distribution.

FDA is creating a new system to handle the large number of submissions resulting from the requirement under MoCRA that certain companies register their facilities and list their products. "We request that cosmetics companies wait to register with FDA until we announce the availability of the new system," the agency said in a constituent update. "Information in the VCRP will not be transferred to the program being developed for facility registrations and product listings mandated by MoCRA."

State Lawmakers Consider Bills Banning Weight Loss Supplement Sales to Minors

Lawmakers in New York and Maryland are considering legislation that would prohibit the sale of weight loss supplements to minors, while lawmakers in Colorado have struck language that would have restricted minors' access to such products.

In Maryland, a bipartisan group of state lawmakers have introduced HB 634, which would require customers purchasing weight loss supplements to provide proof that they are 18 or older to complete their purchases, as well as require Maryland retailers to restrict access to weight loss supplements. The dietary supplements subject to the law, which excludes dietary fiber products, are defined as products labeled, marketed or otherwise represented for the purpose of achieving weight loss or building muscle. Additionally, the bill would require the Maryland Department of Health to develop a notice with information about the potential health risks of diet pills and authorize the department to establish limitations on which diet pills are subject to the act. HB 634 was introduced on February 3, and the House Economic Matters Committee held a hearing on the bill March 1.

In New York, lawmakers are considering SB 5823B, which was introduced March 17. State Sen. Shelley Mayer sponsored the bill, which is identical to the one passed by the Assembly in 2022 and vetoed by Gov. Kathy Hochul in January.

Meanwhile, dietary supplement groups are claiming victory in Colorado. 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."

According to the Natural Products Association (NPA), Majority Leader Dominick Moreno amended the bill and removed the

language “after extensive collaboration between the NPA, Natural Grocers and Majority Leader.” The NPA called the amendment a "big victory for consumer access in Colorado."

“We wish more state lawmakers in other capitals would exercise the same approach to science, reason, and common sense,” said Kyle Turk, director of government affairs for the NPA. “Far too often, legislators simply ignore science, data and the consequences of poorly-designed legislation that ends up hurting consumers, but this was not one of those instances.”

FTC Warns Companies about Substantiating Product Claims

The Federal Trade Commission (FTC) has sent 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.

Companies are required under FTC regulations to back up claims about what their products can do with reliable evidence, according to an agency news release. A company’s claims about the health or safety benefits of a product must be based on scientific evidence.

“The requirement for advertisers to have adequate support for their advertising claims at the time they’re made is a bedrock principle of FTC law,” Sam Levine, director of FTC’s Bureau of Consumer Protection, said. “The prospect of steep civil penalties will help ensure that advertisers don’t play fast and loose with the truth.”

By sending the letters, FTC is warning companies they could incur significant civil penalties—up to $50,120 per violation—by failing to adequately substantiate their product claims.

Idaho Senate Rejects Bill Seeking to Limit Federal Dietary Supplement Regulatory Changes

The Idaho State Senate has 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, with 17 lawmakers voting for and 18 against. The vote followed strong support in the House, where it passed 51-13, with six lawmakers absent.

The bill states that the production, marketing, distribution, sale and use of dietary supplements shall be legal in the state in compliance with the applicable federal law and regulations as of July 1, 2022, "notwithstanding any amendment, repeal, or addition made to federal law or regulations applicable to dietary supplements subsequent to July 1, 2022." Rep. Jaclyn Gallagher, the bill's sponsor, told Natural Products Insider that federal legislation advanced in 2022 that would have provided greater oversight over dietary supplements, including requiring a mandatory product listing, inspired the bill.

Dietary Supplement Groups Call on FDA to Reverse NMN Decision

Two dietary supplement industry groups have filed a citizen petition urging the U.S. Food and Drug Administration (FDA) to reverse its position that the anti-aging ingredient beta-nicotinamide mononucleotide (NMN) cannot be sold as a dietary supplement in the United States. In the petition, the Natural Products Association and Alliance for Natural Health USA called on the FDA commissioner to determine that NMN is not excluded from the definition of a dietary supplement or commit to exercise enforcement discretion in connection with the marketing and selling of NMN in or as a dietary supplement.

The petition follows FDA's letters to prospective suppliers in October and November 2022 in which it said NMN cannot be sold as a dietary supplement because the agency has authorized it for investigation as a new drug. The letters prompted Amazon to notify sellers in February that they could no longer sell dietary supplements containing NMN on its platform.

LITIGATION

Proposed Class Action Alleges Sleep Aid Falsely Marketed as "All Natural"

A New York consumer has filed a proposed class action against Global Product Management, Inc., and Dish Direct, Inc., alleging their Alteril-branded sleep aid products are falsely marketed as "Natural" or "All Natural" when the products contain non-natural, synthetic ingredients. *Timmerman v. Global Product Mgmt. Inc.*, No. 23-01078 (E.D.N.Y., filed February 9, 2023). The Alteril products at issue in the suit are Alteril All Natural Sleep Aid Tablets, Alteril Natural Sleep Aid Tablets, Alteril Fast Acting

Softgels Natural Sleep Aid and Alteril PM with Turmeric Natural Sleep Aid.

The plaintiff alleges that consumers relied on the defendants' representations that their products are "Natural" or "All Natural" when purchasing them. The complaint asserts that sorbitol, gelatin and riboflavin are synthetic and argues that while the ingredients are listed on product packaging, consumers lack the ability to independently verify whether they are natural or synthetic.

The plaintiff is alleging violations of Sections 349 and 350 of the New York General Business Law and breach of express warranty and seeks class certification, injunctive relief, damages, costs and attorney's fees.

Pure Body Naturals Sued for Misleading "Natural" Product Claims

The maker of Pure Body Naturals personal care products is facing claims that its product packaging misleads consumers into thinking their products are "pure" and "natural." *Klar v. Sendayco*, No. 23-00823 (E.D.N.Y., filed February 3, 2023). A New York consumer filed a proposed class action against Sendayco, LLC, which does business as Pure Body Naturals. The suit includes two dozen products from the brand, including serums, face masks, moisturizers, scrubs and shampoos.

The plaintiff alleges that the defendant manufactures, sells and distributes the products using a marketing and advertising campaign "centered around claims that appeal to health-conscious consumers," including that its products are "Pure," "100% Natural," "Natural" and "100% Pure."

"However, Defendant's advertising and marketing campaign is false, deceptive, and misleading because the Products contain non-natural, synthetic ingredients," the plaintiff alleged in the complaint, asserting that ingredients such as glycerin, citric acid and alcohol are synthetic.

For alleged violations of Sections 349 and 350 of the New York General Business Law and breach of express warranty, the plaintiff is seeking class certification, injunctive relief, damages, costs and attorney's fees.

Suits Allege Compression Garments' CoQ10 Claims Misled Consumers

Consumers in two states have filed putative class actions against the maker of Copper Fit ICE-branded compression garments, alleging the company falsely claims in its marketing that its CoQ10-infused garments provide health benefits to wearers. *Morehouse v. Ideavillage Prods. Corp.*, No. 23-0298 (S.D.Cal., filed February 15, 2023); *Gray v. Ideavillage Prods. Corp.*, No. 23-1233 (E.D.N.Y., filed February 15, 2023).

The plaintiffs in each suit say they purchased the products—a plantar fasciitis ankle sleeve and knee sleeve, respectively—believing the company's claims that the CoQ10 infused in the fabric is released and absorbed into the human body when moving while using the product, and the absorbed CoQ10 would provide health benefits, including increased energy.

The plaintiffs asserted, however, that the CoQ10 infused in the fabric is "useless" and they "received no such benefits." They said that had they known the infused CoQ10 is not absorbed into the body, and, even if absorbed in some amount, provides no benefits, they would not have purchased the product.

The plaintiffs are alleging violations of New York and California consumer law and unjust enrichment, and they seek class certification, declaratory judgment, damages, injunctive relief and costs and expenses including reasonable attorney's fees.

COVID-19 Claims Result in Civil Penalties, Permanent Injunction Against doTERRA Distributers

Three distributers for the multi-level marketing company doTERRA International, LLC, have agreed to pay $15,000 civil penalties to resolve allegations that they made deceptive COVID-19 claims while marketing essential oils and nutritional supplements.

The U.S. Department of Justice and the Federal Trade Commission announced the entry of stipulated orders for civil penalty judgments against the three, as well as permanent injunctive relief. The government alleged that the defendants represented in public webinars in January 2022 that their products prevent, reduce the risk or severity of, or cure COVID-19 and long-haul COVID-19 and counteract purported negative effects of COVID-19 vaccinations. The government alleged that no published report of any well-controlled human clinical study substantiates the defendants' COVID-19-related claims.

The stipulated orders prevent each defendant from making COVID-19 prevention, treatment or cure claims for any product or

service, except for claims specifically approved by FDA. “The Department of Justice remains vigilant in its efforts to stem the deceptive promotion of supposed COVID-19 treatments that have no proven benefits in combatting the disease,” Principal Deputy Assistant Attorney General Brian M. Boynton, head of the Justice Department’s Civil Division, said in a statement. “We will continue working with our law enforcement and agency partners to stop those who seek financial gain by peddling unproven cures for COVID-19.”

Judge Dismisses ‘L’Oréal Paris’ Labeling Suit

A federal court in New York has dismissed a proposed class action claiming L’Oréal's product labels misled consumers into thinking the products were made in France. *Eshelby v. L’Oréal USA, Inc.*, No. 22-1396 (S.D.N.Y., filed March 27, 2023). The plaintiff sued after purchasing L’Oréal haircare products with labeling that prominently displays “Paris” on the front of the packaging and contains French-language text. She asserted that she relied on the front of the packaging and believed the products were made in France, and she would not have bought the products at their current price point if she had known they were not manufactured in France.

L’Oréal sought dismissal of the suit, alleging the plaintiff has not plausibly pleaded that reasonable consumers are likely to be misled by L’Oréal's product packaging. The court agreed, finding that a mere reference to Paris is not sufficient to deceive a reasonable consumer regarding the manufacturing location of a product. Additionally, the court noted that the plaintiff acknowledged that “Paris” is part of the brand name, “L’Oréal Paris.”

“The company was founded in Paris, and its global headquarters is still located in Paris,” the court said. “The word 'Paris' always appears in stylized text underneath the word ‘L’Oréal,’ in the same font and color as the word ‘L’Oréal,’ such that a reasonable consumer would understand that ‘Paris’ is part of the brand name ‘L’Oréal Paris.’”

The court dismissed the plaintiff's claims of breach of express warranty, negligent representation and unjust enrichment; her claims on behalf of the putative class; and her claims for injunctive relief. The court also denied her request for leave to amend the complaint.

The choice of a lawyer is an important decision and should not be based solely upon advertisements.