ISSUE 65 | 2022 IN REVIEW

LEGISLATION, REGULATIONS & STANDARDS

Congress Gives FDA Oversight Over Cosmetics, Punts on Dietary Supplement Reforms

In a year-end $1.7 trillion spending package in late December, Congress voted to increase FDA's oversight of cosmetics and their ingredients. A portion of the bill titled the Modernization of Cosmetics Regulation Act requires cosmetic manufacturers to register each of their facilities within one year.

Companies are also required by the new law to give FDA information including a list of ingredients in their products, including fragrances, and update that information on an annual basis. The law also gives FDA the authority to issue mandatory product recalls.

The Personal Care Products Council applauded the legislation's passage. In a statement, the group said the legislation creates a comprehensive and uniform national framework for cosmetics regulation.

“This truly historic moment took over a decade, bringing together a diverse group of stakeholders to support a contemporary approach to cosmetics oversight and further strengthen consumer trust in the products they use every day,” PCPC President and CEO Lezlee Westine said, thanking the bill's sponsors from both sides of the aisle. “This landmark legislation would not have been possible without their leadership and commitment.”

In the same spending bill, Congressional leaders were unable to pass regulatory reform involving FDA’s oversight of dietary

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supplements. Two former FDA commissioners called on Congress to pass such legislation, along with the MCRA, in an October article in *JAMA Forum*.

An earlier provision relating to dietary supplements would have required all dietary supplement manufacturers to notify FDA when a product is introduced or modified, as well as disclose the composition of ingredients and factors, such as the product's intended dosage and serving size.

Three States Ban PFAS in Cosmetics

A year after a study found high levels of per- and polyfluoroalkyl substances (PFAS) in several popular cosmetics products, legislators in several states proposed bills seeking to ban the substances from cosmetics sold in their respective states.

Colorado became the first state in the country to explicitly ban PFAS in cosmetics after Gov. Jared Polis signed H.B. 22-1345 in June. The ban takes effect in 2024.

Maryland joined Colorado the same month, with Gov. Larry Hogan letting HB 643 become law without his signature. The Maryland law, which takes effect in January 2025, prohibits the sale of products with more than trace amounts of two phthalates, formaldehyde and more than 20 other substances.

California became the third state to adopt similar legislation. In September, California Gov. Gavin Newsom signed AB 2711 into law. The law prohibits the manufacture, sale and delivery of cosmetic products that contain PFAS. It takes effect January 1, 2025.

States Consider Restricting Weight Loss Supplement Sales to Minors

In 2022, legislators in New York, California and New Jersey took actions to restrict the sales of weight loss supplements to minors.

In March, both chambers of the New York State Legislature approved a bill prohibiting the sale of over-the-counter diet pills or supplements for weight loss or muscle building to minors without a prescription. Gov. Kathy Hochul vetoed the measure in December.

In August, the California state legislature approved a bill prohibiting retailers in the state from selling certain weight-loss dietary supplements without a prescription or ID to minors. The bill would have also required the California Department of Public

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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.

Health (CDPH) to establish a list of dietary supplements that would be subject to the bill.

The following month, Gov. Gavin Newsom vetoed the bill, saying in a veto message that while the bill addresses an important public health issue, dietary supplements for weight loss are not considered drugs and the measure would require CDPH to take actions beyond the scope of its capabilities. He directed CDPH to form a work group to study the issue.

In December, legislators on New Jersey's state senate committee advanced a similar bill, S2387, after holding a hearing on it. As of the year's end, the bill remained pending.

New York, Louisiana Ban Sales of Cosmetics Tested on Animals

The list of states banning the sale of cosmetics tested on animals grew by two in 2022: Louisiana and New York became the ninth and tenth states, respectively, to pass such legislation.

In June, Louisiana Gov. John Bel Edwards signed Act 712 into law. The bill makes it illegal to sell new cosmetics that have been tested on animals, unless the tests were done under certain exemptions. It took effect in August.

In December, New York Gov. Kathy Hochul signed into law the New York Cruelty Free Cosmetics Act, which prohibits the manufacture and sale of cosmetics in the state that have been tested on animals. The law takes effect in January 2023.

California Lawmakers Ban "Pink Tax"

Looking to end the so-called Pink Tax, the practice of placing higher prices on goods marketed to women, California Gov. Gavin Newsom signed a law prohibiting the practice.

In September, Newsom signed AB 1287 into law. The law builds on 1990s-era legislation prohibiting charging women higher prices for similar services. It prohibits charging higher prices for substantially similar goods.

The law applies to businesses acting in California that sell goods that are used, bought or rendered primarily for personal, family or household purposes. The law does not provide a private right of action or class action relief—instead, its enforcement mechanism is through the state's attorney general.

FDA Bans Sale of NMN as a Dietary Supplement

The U.S. Food and Drug Administration (FDA) in October notified prospective suppliers that anti-aging ingredient beta-nicotinamide mononucleotide (NMN) cannot be sold as a dietary supplement in the United States.

In letters to prospective suppliers in October and November, FDA said NMN cannot be sold as a dietary supplement because the agency has authorized it for investigation as a new drug.

The Council for Responsible Nutrition panned the move, saying FDA had previously acknowledged a New Dietary Ingredient Notification for NMN without objection and had not previously raised any concerns about NMN's use in dietary supplements.

In a statement, CRN President and CEO Steve Mister said FDA's actions "demonstrate a disregard for consumers who benefit from the innovation and investments of dietary supplement companies."

"These decisions to broadly invoke drug preclusion to protect the profits and monopolies of drug companies do not serve a public safety objective," he said. "FDA's reasoning and its refusal to provide a date certain when the authorization as a drug occurred just further raise concerns that it is protecting pharma's interests over consumer welfare."

FDA Says It Will Exercise Enforcement Discretion on NAC

The U.S. Food and Drug Administration (FDA) in August announced the issuance of final guidance on its policy regarding products labeled as dietary supplements that contain N-acetyl-L-cysteine (NAC).

In March, FDA denied a request in two citizen petitions from the Council for Responsible Nutrition (CRN) and Natural Products Association (NPA), asking it to determine that products containing NAC are not excluded from the definition of a dietary supplement under the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA also said that it had not yet reached a final decision on the NPA petition's request to initiate rulemaking to permit the use of NAC in or as a dietary supplement.

FDA said that while its full safety review remains ongoing, its initial review has not revealed safety concerns. The agency said it intends to exercise enforcement discretion with respect to the sale

and distribution of certain products that contain NAC and are labeled as dietary supplements.

The enforcement discretion policy applies to products that would be lawfully marketed dietary supplements if NAC were not excluded from the definition of "dietary supplement" and that do not otherwise violate the FD&C Act.

FDA Drops Objections to Certain Magnesium Claims

In January, FDA announced in a letter of enforcement discretion that it does not intend to object to the use of certain qualified health claims regarding the consumption of magnesium and a reduced risk of high blood pressure (hypertension), so long as claims are worded in such a way as to avoid misleading consumers and other factors for the use of the claim are met.

FDA responded to a health claim petition submitted on behalf of the Center for Magnesium Education and Research, LLC, which requested the agency authorize a health claim about the relationship between consuming magnesium and a reduced risk of high blood pressure.

After reviewing the petition and evidence, FDA concluded that the totality of the scientific evidence supports a qualified health claim on the relationship between magnesium and a reduced risk of high blood pressure in conventional foods and dietary supplements.

Companies Put on Notice for New Dietary Ingredients, Cardiovascular Claims

Several dietary supplement companies came under the U.S. Food and Drug Administration's (FDA's) scrutiny in 2022 for ingredients that affect the cardiovascular system and for product claims that their supplements cure, treat, mitigate or prevent cardiovascular disease.

In May, FDA sent warning letters to 10 companies for selling adulterated dietary supplements, including some that contained new dietary ingredients (NDIs) for which FDA has not received required premarket NDI notifications and some that contained unsafe food additives.

Some of the dietary supplements contained higenamine, an ingredient over which FDA has previously expressed concern for its effects on the cardiovascular system.

In November, FDA issued warning letters to seven companies it says illegally sold dietary supplements claiming to cure, treat, mitigate or prevent cardiovascular disease or related conditions.

FDA issued warning letters to Essential Elements (Scale Media Inc.); Calroy Health Sciences LLC; Iwi; BergaMet North America LLC; Healthy Trends Worldwide LLC (Golden After 50); Chambers' Apothecary; and Anabolic Laboratories, LLC for violating the Federal Food, Drug, and Cosmetic Act.

Supplement Manufacturers Remain Under Scrutiny for COVID Claims

As the COVID-19 pandemic entered its third year, federal regulators continued to scrutinize dietary supplement manufacturers' claims that their products treated or cured COVID-19 and its related symptoms.

In November, the Federal Trade Commission (FTC) filed a complaint against the California-based Precision Patient Outcomes, Inc. and its CEO, Margrett Priest Lewis, for marketing an over-the-counter dietary supplement that just contained vitamins, zinc and a flavonoid as a COVID-19 treatment. FTC sought to permanently block the company and its CEO from using deceptive treatment or prevention claims.

HOT TOPICS

FDA Enforcement of CBD Heats Up

The U.S. Food and Drug Administration (FDA) has increased its scrutiny on cannabidiol (CBD) products, including a surge in warning letters sent to companies manufacturing or marketing CBD products. In November, the agency issued a Constituent Update about five letters it sent to companies "selling CBD containing products that people may confuse for traditional foods or beverages which may result in unintentional consumption or overconsumption of CBD."

The same month, FDA also published an interview with two agency experts about concerns associated with ingestion of CBD. "While we continue exploring policy solutions to address the large, violative market of CBD products, we will continue to monitor the marketplace and take action, as needed, against companies that pose the greatest risk of harm to the public," the experts stated.

FTC to Update Green Guides, Seeks Comments

In December, the Federal Trade Commission (FTC) announced it is seeking public comment on potential updates and changes to the Green Guides for the Use of Environmental Claims. Companies refer to the Green Guides to avoid making environmental marketing claims that are unfair or deceptive under federal law.

FTC is specifically seeking comments on claims involving carbon offsets and climate change; the use of the terms "recyclable" and "recycled content"; and the need for additional guidance regarding claims such as "compostable," "degradable," "ozone-friendly," "organic" and "sustainable."

As consumers become more environmentally conscious and seek out products accordingly, awareness of changes to the Green Guides will be crucial for cosmetics and personal care product manufacturers.

CDC Study Shows Rise in Pediatric Melatonin Ingestions

A study published in the U.S. Centers for Disease Control and Prevention's *Morbidity and Mortality Weekly Report* publication in May found that from 2012 to 2021, there was a 530% increase in the number of pediatric ingestions of melatonin reported annually to poison control centers. Most ingestions were unintentional exposures, with the largest annual increase occurring from 2019 to 2020. The study's authors attributed the increase to the pandemic, when overall use of melatonin increased and more children were at home.

The vast majority of cases reviewed resulted in no symptoms or minor symptoms. The study identified 4,555 cases that resulted in more serious outcomes, including five children who were hospitalized and required mechanical ventilation, and two young children who died at home after ingesting melatonin. The authors of the study suggested dietary supplement manufacturers consider child-resistant packaging for melatonin products and encouraged doctors to warn patients about the risks of children ingesting melatonin.

In August, a California consumer filed a proposed class action against Zarbee's Inc., alleging the company's children's melatonin product contained substantially more melatonin than advertised.

It appears likely that dietary supplement manufacturers will continue to see scrutiny of their melatonin products into 2023.

LITIGATION

Adulterated, Misbranded Dietary Supplements Prompt FDA Consent Decree

An Arizona dietary supplement maker accused of allowing its products to become adulterated and selling misbranded products has entered into a consent decree with the U.S. Food and Drug Administration (FDA). *U.S. v. Global Vitality, Inc.*, No. 22-1744 (D. Ariz., filed October 12, 2022).

FDA filed the consent decree and complaint against Global Vitality, which does business as Enzyme Process International. According to the complaint, during an inspection of the company's Arizona plant in 2021, FDA investigators documented significant deviations from current good manufacturing processes for dietary supplements, including a failure to maintain and clean equipment, utensils and all food-contact surfaces.

FDA also found problems with product labeling, calling the labeling on the company's Enzyme Process-branded shark cartilage product "false and misleading" because it states that the product contains shark cartilage that is freeze-dried, concentrated and bottled without added ingredients, but the product also contains magnesium stearate in addition to shark cartilage.

Under the consent decree, Global Vitality is required to retain independent experts to perform a comprehensive inspection of the facility, review the company's dietary supplement labeling, conduct audit inspections of the facility and certify that the company has brought its operations into compliance.

Virtual Try-On Technology Prompts BIPA Suits

Increasingly, cosmetics and other personal care products manufacturers are using facial scan technology to help consumers try on their products virtually and engage with their brands. In 2022, consumers have filed proposed class actions against cosmetics companies for how they handle the data collected by such technology. Consumers have brought suits against

companies including Estée Lauder and Wella under the Illinois Biometric Information Privacy Act (BIPA).

An Illinois federal judge ruled in November that Estée Lauder cannot fully avoid proposed class action claims brought against it by an Illinois consumer. *Kukovec v. Estée Lauder Cos., Inc.*, No. 22-1988 (N.D. Ill., entered November 7, 2022).

The plaintiff alleged the company unlawfully collects and uses biometric facial geometry from the photos consumers upload to virtually try on products. The plaintiff is seeking class certification for consumers who used the technology for Estée Lauder products under the Too Faced, Smashbox and MAC brands. The court denied the company's motion to dismiss.

In December, an Illinois consumer sued cosmetics manufacturer Wella under similar claims. *Shores v. Wella Operations US LLC*, No. 22-7152 (N.D. Ill., filed December 20, 2022). The plaintiff alleged that Wella violated BIPA by failing to obtain consent from users who used the company's try-on tool to virtually try on the brand's hair dye.

Lawsuits Put Spotlight on Cosmetics' Ingredients, Additives

Makeup companies in 2022 faced a number of claims alleging the use of unsafe additives and ingredients.

One area of litigation involved PFAS in cosmetics. In August, plaintiffs in California, New York, New Jersey, Michigan, North Carolina and Iowa joined in a consolidated lawsuit against L'Oréal USA Inc., alleging the company intentionally fails to disclose to consumers that its popular waterproof mascara products contain harmful PFAS.

In September, a California consumer filed a putative class action alleging that the eye makeup manufactured and sold by ColourPop Cosmetics LLC contains "color additives and ingredients that are dangerous when used on the immediate eye area." *Wilson v. ColourPop Cosmetics LLC*, No. 22-5198 (N.D. Cal., filed September 12, 2022). The products at issue include eyeshadow palettes and eyeliner products.

The plaintiff argues that more than 10 of the color additives used by ColourPop are designated by the U.S. Food and Drug Administration as "unsuitable and unapproved for cosmetic use in the eye area." She further asserts that the disclaimer language on ColourPop's website does not mitigate the harm.

The following month, Environmental Health Advocates, Inc. (EHA) sued Urban Decay in California state court for selling eyeshadow palettes containing titanium dioxide with airborne, unbound particles of respirable size, alleging the cosmetics company violated California's Proposition 65. *Environmental Health Advocates Inc. v. Urban Decay Cosmetics LLC*, No. T22-1772 (Alameda Super. Ct., filed October 7, 2022). EHA alleged the company knows its products contain titanium dioxide, yet knowingly and willfully exposes consumers to a known carcinogen.

Consumer Suits Target 'Natural' Claims

Another source of litigation for both personal care products and supplements stemmed from marketing of the products as "natural."

An Illinois woman filed a proposed class action against cosmetics manufacturer Dr. Squatch, alleging the company's labeling on its Men's Natural Shampoo misleads consumers into believing it is natural when it contains synthetic ingredients. *Fleming v. Dr. Squatch, LLC*, No. 22-4842 (N.D. Ill., filed September 8, 2022). The plaintiff alleged that the shampoo is misleading because while it is labeled as "natural," it contains several synthetic ingredients, including glycerin, citric acid, fragrance and decyl glucoside.

In another lawsuit, a plaintiff alleged that Drip Drop Hydration Inc. misleads consumers about the nature of the ingredients that flavor its rehydration drink mixes. *Helems v. Drip Drop Hydration Inc.*, No. 22-1419 (S.D. Cal., filed September 20, 2022). The complaint included pictures of the front of the product packaging that show fruit in a glass of water and asserts that the depictions "emphasize the purported natural flavors of the Products."

"By using depictions of fruits on the packages, Drip Drop signals to consumers, and consumers reasonably understand Drip Drop to be claiming, that the Products are flavored only by the depicted fruits. These claims made on the labels and associated marketing materials of the Products are false. The Products are artificially flavored," the complaint argues. The plaintiff alleges that the flavoring comes from malic acid. "DL malic acid is not a 'natural flavor' as this term is defined by federal and state regulations and is not derived from a fruit or vegetable or any other natural source," the plaintiff asserted.

Collagen Anti-Aging Claims Come Under Scrutiny in Consumer Suits

Skincare products' claims of anti-aging properties came under scrutiny by consumers in 2022.

A federal court in New York denied L'Oréal USA Inc.'s bid to throw out a proposed class action claiming it misleads consumers about the anti-aging properties of its topical products containing collagen. *Lopez v. L'Oréal USA, Inc.*, No. 21-7300 (S.D.N.Y., entered September 27, 2022).

The plaintiffs allege that the company marketed certain topical products as anti-aging because they contained collagen, despite knowing that the collagen in the products could not sufficiently penetrate the skin to produce the purported anti-aging effects.

In the opinion, the court found that the narrow question was whether a reasonable consumer would believe that the term "collagen" on the label referred to collagen molecules that provide cosmetic benefits. The court held that the plaintiff has plausibly alleged that the term "collagen" is associated with the skin-related benefits of the collagen molecule.

In another suit in federal court in New York, a judge threw out a consumer's claims against Algenist that mirrored the claims against L'Oréal. *Nguyen v. Algenist LLC*, No. 22-00013 (S.D.N.Y., November 28, 2022).

The plaintiff alleged Algenist falsely advertised its vegan collagen-based products as having anti-aging properties, when collagen topically applied to the skin is too big to be absorbed by it. The court granted Algenist's motion to dismiss, finding the plaintiff failed to state a claim for deceptive practices, false advertising or breach of express warranty.

8th Cir. Affirms Ruling for Memory Drug Maker

A memory supplement manufacturer secured a win in a federal appeals court in 2022, blocking a consumer from proceeding on her claims that the company violated Missouri state law by failing to disclose the retraction of clinical studies it used to tout the benefits of its product. *Vitello v. Natrol, LLC*, No. 21-3150 (8th Cir., entered October 6, 2022).

The plaintiff purchased Natrol, LLC's Cognium supplement after seeing it advertised as improving memory and concentration. At the time of her purchase, the product's box contained language

claiming that in nine clinical studies in adults, seniors and children, participants showed statistically significant improvements in memory and cognition.

After taking the product and seeing no noticeable improvements, she filed a proposed class action, alleging that prior to her purchases, two of the clinical studies indicated on the packaging had been retracted for data manipulation and fraud/fabrication and Natrol failed to update its packaging or inform consumers of the retractions. She claimed she would not have purchased the product and sustained the loss had Natrol disclosed the information.

The district court granted Natrol's motion for summary judgment after ruling that the plaintiff failed to establish an ascertainable loss. On appeal, the 8th Circuit panel agreed.

Suit Asserts Beverages Misled Consumers on Usable Protein

As so-called functional beverages soar in popularity, companies that blend supplements with beverages should keep an eye on another area likely to grow: litigation surrounding health claims. One suit that exemplifies this potential trend is a proposed class action against REBBL, alleging the company's Plant Based Elixir beverage packaging misleads consumers as to the product's usable protein content. *Roffman v. REBBL, Inc.*, No. 22-5290 (N.D. Cal., filed September 16, 2022).

The plaintiff in the case, a California woman, alleged that REBBL prominently displays on the front of its beverages that they contain 16 grams of protein. She asserted that REBBL failed to follow U.S. Food and Drug Administration requirements that food manufacturers calculate the corrected amount of protein per serving based on the quality of the product's protein.