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LEGISLATION, REGULATIONS & STANDARDS

FDA Study Finds Sunscreen is Absorbed into Bloodstream

JAMA has published a study conducted by researchers at the U.S. Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) purportedly finding that sunscreen ingredients are absorbed into the bloodstream when the product is used as directed. The study authors argue that the active ingredients of sunscreen—avobenzone, oxybenzone, octocrylene and ecamsule—should undergo a nonclinical toxicology assessment. "The fact that an ingredient is absorbed through the skin and into the body does not mean the ingredient is unsafe," CDER Director Janet Woodcock and researcher Theresa Michele wrote in an FDA Perspectives column. "Rather, this finding calls for further testing to determine the safety of that ingredient for repeated use. Such testing is part of the standard pre-market safety evaluation of most chronically administered drugs with appreciable systemic absorption." CDER and the researchers continue to recommend that "the public should continue to use sunscreen with other sun protective measures."

The study received some criticism, including that it was not conducted outdoors "where the UV radiation would likely break down some of the active ingredients," according to the chief executive of Cancer Council Australia. Another critic noted that the study protocol included the use of sunscreen four times daily and argued that consumers are unlikely to apply sunscreen with that level of frequency.

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FDA Issues Warning on Vinpocetine's Effects on Reproductive Health

The U.S. Food and Drug Administration (FDA) has issued a statement warning about "safety concerns regarding an ingredient called vinpocetine that is found in dietary supplements, specifically concerns about the use of this ingredient by women of childbearing age." The ingredient apparently "may cause a miscarriage or harm fetal development," according to the statement. The agency cited a draft technical report by the National Toxicology Program to support its announcement.

"These findings are particularly concerning since products containing vinpocetine are widely available for use by women of childbearing age," the agency stated. "That's why today we're advising pregnant women and women who could become pregnant not to take vinpocetine. We are also advising firms marketing dietary supplements containing vinpocetine to evaluate their product labeling to ensure that it provides safety warnings against use by pregnant women and women who could become pregnant."

NAD Recommends Ad Changes, ASA Dismisses Complaint

The National Advertising Division (NAD) has recommended that multiple dietary supplement companies change their marketing materials to reflect available substantiating studies. EnergyBits Inc. was advised to discontinue claims that its spirulina algae supplement could "improve mental focus," "reduce brain fog," "improve skin, hair, nails, bones, and eye health," and "improve mood," but the company indicated that it will appeal the ruling. NAD also recommended that Eli Nutrition amend its claims that TummyZen can provide "total heartburn relief," finding that "this claim conveys a message that the product provides more benefits than is provided by occasional heartburn relief remedies, and that the communicated claim was not properly supported."

NAD also inquired into substantiation for advertising claims about Vayarin, a supplement marketed as helping with ADHD in children, but the manufacturer, VAYA Pharma Inc., informed the ad board that the product has been discontinued and the company has closed.

The U.K. Advertising Standards Authority (ASA) considered a complaint about Beiersdorf UK Ltd.'s Nivea Q10 cream asserting that a television commercial promising that the product "reduces the appearance of fine lines and wrinkles" with "10 times more

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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.

creatine" misleadingly implied that the product could provide results comparable to a cosmetic procedure. ASA found that the ad showed a woman choosing the Nivea product after considering a cosmetic procedure and facial exercises but determined that "consumers would interpret the ad as presenting different anti-ageing options but would understand that each of those options would produce different results on the skin." The agency did not uphold the complaint.

FDA Releases Dietary Supplement Ingredient Advisory List

The U.S. Food and Drug Administration (FDA) has created a Dietary Supplement Ingredient Advisory List, a "rapid-response tool meant to quickly alert the public when the FDA identifies ingredients that do not appear to be lawfully marketed in dietary supplements." The Constituent Update notes that ingredients are added to the list "based on a preliminary assessment by the FDA" and the list "enables the FDA to communicate with the public while it completes a final determination regarding these ingredients." The list contains four entries: andarine, higenamine, hordenine and 1,4 dimethylamylamine.

Agenda Announced for FDA Public Meeting on ICCR

The U.S. Food and Drug Administration (FDA) has released the agenda for its June 5, 2019, meeting to prepare for the International Cooperation on Cosmetics Regulation (ICCR) meeting July 9-11. The public meeting will feature comments from the Personal Care Products Council, National Center for Health Research, American Cosmetics Manufacturers Association and Humane Society of the United States.

LITIGATION

CVS Glucosamine Lawsuit Dismissed

A California federal court has dismissed a putative class action alleging that CVS Health Corp.'s glucosamine supplements are ineffective at supporting joint health, finding the allegations preempted under the Nutrition Labeling and Education Act (NLEA). *Kroessler v. CVS Health Corp.*, No. 19-0277 (S.D. Cal., entered May 16, 2019).

The court dismissed the plaintiff's allegations brought under California's consumer-protection statutes, finding that the NLEA preempted them because CVS did not make improper structure/function claims by presenting its glucosamine as "support[ing] flexibility & range of motion." The court distinguished the marketing representations from those that "purport to 'reduce' or 'improve' anything" or specifically target "joint pain."

The plaintiff also argued that studies showed glucosamine to have little effect on joint health, but the court noted that those studies did not disprove the studies the defendants could cite to support their marketing representations. "Furthermore, California law does not allow private plaintiffs to demand substantiation for advertising claims," the court held, dismissing the allegations.

Hi-Tech Pharmaceuticals Sues FDA for DMHA Actions

Following the announcement of nine U.S. Food and Drug Administration (FDA) warning letters sent to companies that sell dietary supplements with 1,5-Dimethylhexylamine (DMHA), Hi-Tech Pharmaceuticals has filed a lawsuit against the agency seeking declaratory and injunctive relief "forbidding" FDA "from claiming in any court that DMHA containing products are adulterated or misbranded." *Hi-Tech Pharm. v. Sharpless*, No. 19-1268 (D.D.C., filed May 1, 2019). Hi-Tech alleges that FDA "has long chaffed at the statutory/regulatory structure for dietary supplements" and "has embarked on a campaign to drive certain dietary ingredients/supplements from the marketplace by simply declaring, without evidence or rule making, that certain dietary ingredients/supplements are not in fact dietary ingredients but rather unapproved food additives, deemed adulterated by statute." The company alleges FDA has acted arbitrarily and capriciously in an attempt to remove DMHA from the market.

"Unlike many prior warning letters, the DMHA warning letter makes no specific claim that the ingredient is unsafe and describes no potential adverse consequences from consuming the ingredient," Hi-Tech argues. "There is no allegation that DMHA is synthetically produced. There is no citation to any scientific study or literature. There is no allegation that Hi-Tech (or other companies) have made inappropriate or unsubstantiated claims regarding DMHA. In other words, the FDA has taken the unprecedented position that its assertion, without more, that an ingredient was not in the food supply before the effective date of [the Dietary Supplement Health and Education Act] (October 15, 1994) is enough in and of itself to deem a product/ingredient

unlawful and/or adulterated."

Court Denies Motion to Dismiss Nivea Lotion Lawsuit

A court has denied Beiersdorf Inc.'s motion to dismiss a lawsuit alleging that its Nivea Skin Firming Hydration Body Lotion is a drug under U.S. Food and Drug Administration (FDA) regulations. *Franz v. Beiersdorf Inc.*, No. 14-2241 (S.D. Cal., entered May 20, 2019). The plaintiff argued that the lotion was a drug—"articles (other than food) intended to affect the structure or any function of the body of man or other animals"—rather than a cosmetic because it was marketed as providing "skin firming hydration" that "improves skin's firmness in as little as 2 weeks" and is "proven to firm and tighten skin's surface."

Both parties argued that FDA opinions supported their arguments; the plaintiff asserted that FDA warned companies for similar "firming" and "tightening" claims, while the defendant argued that guidance titled "Wrinkle Treatments and Other Anti-Aging Products" allows manufacturers to market cosmetic products as anti-aging if they claim the product can "make lines and wrinkles less noticeable, simply by moisturizing the skin."

"But FDA guidance, as helpful as it may be, doesn't necessarily determine what is and isn't a drug under the [Federal Food, Drug, and Cosmetic Act (FDCA)]," the court stated. "The Court, is, of course, bound by the language of the FDCA. It is likewise bound by the FDA's promulgated regulations to the extent those regulations are permissible constructions of the FDCA. [] But the parties have not identified a provision of the FDCA or any applicable agency regulation [] that would exclude a product that 'affects the structure or function of the body' from the definition of 'drug' simply because it does so through moisturization."

"Accepting as true the allegations in the complaint, which the Court is required to do at this stage, [the plaintiff] has stated a *plausible* claim that the lotion is a drug and that it was sold unlawfully," the court held. "This is a limited holding. The Court is not deciding that the lotion *is* a drug. That's a factual question not suitable for resolution at this stage of the litigation. It is simply determining that [the plaintiff's] claims clear the relatively low bar of plausibility."

L'Oréal Hit With Keratin Suit, Appeals Olaplex Decision

L'Oréal USA Inc. allegedly misleads consumers into believing its hair products "actually contain keratin and will confer the claimed benefits of keratin to the consumer," according to a putative class action. *Devane v. L'Oréal USA Inc.*, No. 19-4362 (S.D.N.Y., filed May 14, 2019). The plaintiff asserts that she purchased EverSleek KeratinCaring shampoo and conditioner on the belief that they would provide keratin for her hair, but she later learned that the products do not contain keratin. She seeks to represent a class of plaintiffs alleging violations of Florida and New York consumer-protection statutes.

L'Oréal has also filed an appeal of a Delaware federal court's grant of a preliminary injunction requiring the company to stop selling bond-building hair products in its Matrix, Redken and L'Oréal Professionnel lines that allegedly infringe Liqwd Inc. and Olaplex LLC's patent on a bond-building hair care technology. *Liqwd Inc. v. L'Oréal USA Inc.*, No. 17-0014 (D. Del., notice of appeal filed May 24, 2019). The court adopted a magistrate judge's recommendation to grant the preliminary injunction in April 2019, finding evidence of actual monetary and reputational harm and a reasonable likelihood of success on the merits.

GNC Supplements Misbranded as Drugs, Consumers Allege

Three consumers have filed a putative class action alleging that GNC Holdings Inc.'s dietary supplements lack the required disclosures about U.S. Food and Drug Administration (FDA) evaluation "on all panels with structure/function claims" and that the product labels that do feature disclosures lack "the prominence required." *Arora v. GNC Holdings Inc.*, No. 19-2414 (N.D. Cal., filed May 3, 2019).

The complaint asserts that GNC store-brand supplement labels lack the required FDA disclosure: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." The plaintiffs cite an FDA Final Rule on dietary supplement labeling to argue that the disclosure must appear on each panel prominently; "[t]o be prominent, the disclaimer may not be crowded with non-required, or voluntary, information or imagery and additionally must use bolded font *at least* 1/16th of an inch in size," according to the complaint. "Failure to abide by the disclaimer requirements renders non-compliant supplements misbranded, unapproved, and unlawful drugs under federal law."

The complaint includes images of multiple GNC supplement labels to argue that the "omission of mandatory disclaimers from Supplement panels is systemic" and contrasts the images with

photos of Target store-brand supplements that feature the disclaimer. For alleged violations of California and New York consumer-protection statutes as well as unjust enrichment, the plaintiffs seek class certification, damages, injunctive relief and attorney's fees.

Brooke Shields Sues Charlotte Tilbury for "Brooke S" Eyebrow Pencil

Charlotte Tilbury Beauty allegedly infringes Brooke Shields' right to publicity by selling an eyebrow pencil called "Brooke S," Shields asserts in a complaint filed against the beauty company and a number of cosmetics retailers. *Shields v. Beautylish Inc.*, No. 19-16029 (Cal. Super. Ct., C. Dist., filed May 8, 2019). The company sells a "Three-Way Shape, Lift & Shade Tool" with shade variations featuring female names, and Shields argues that the shade "recommended for those with dark blonde to medium brown hair" is named after her without her permission.

"Tilbury neither sought nor secured permission from Shields to use Shields's name in connection with the advertising and marketing of the Product," the complaint asserts. "Shields is known for her bold eyebrows which have been a trademark of her look and a target for endorsements and collaborations since the 1980s. The product named for Shields falsely suggests it is endorsed by Shields and undoubtedly attracts consumers hoping to emulate her signature look." The complaint also alleges that Shields has "invested time and resources investigating and developing potential opportunities to create her own cosmetics line with an emphasis on eyebrow-enhancing products" and that the use of her name for "Brooke S" "unlawfully interferes with Shields's ability to market a cosmetics line created and/or properly endorsed by Shields."

MEDIA

The Guardian "Toxic America" Series Includes Cosmetic, Fragrance Reports

The Guardian has released "Toxic America," a "major series to investigate the risks of contamination in our food, water, and cosmetics." Articles in the series include:

- an examination of the ingredients in cosmetics, noting that health experts have looked to the ingredients in cosmetics as a possible explanation for rising or maintained cancer, infertility and allergy rates;

- a comparison of U.S. and EU cosmetics laws arguing that the United States has “a strong favouritism towards companies and manufacturers, to the extent that public health and the environment is being harmed”; and

- a report on ingredients in fragrances asserting that “fragrance chemicals” could be “shaping serious disease trends.”