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LEGISLATION, REGULATIONS & STANDARDS

FDA Issues Guidance on Concentrated Caffeine

The U.S. Food and Drug Administration (FDA) has released guidance clarifying that "dietary supplements containing pure or highly concentrated caffeine in powder or liquid forms are considered unlawful when sold in bulk quantities directly to consumers." The guidance specifically acknowledges powdered caffeine that requires unusually small, precise measurements—such as 1/64 teaspoon—to obtain the correct serving size. Further, "reasonably foreseeable measurement errors, such as packing the powder too tightly or use of a 'heaping scoop' instead of a 'level scoop,' can increase the amount of caffeine in a single dose by more than 200%, resulting in the ingestion of a toxic quantity of caffeine."

"Despite multiple actions against these products in the past, we've seen a continued trend of products containing highly concentrated or pure caffeine being marketed directly to consumers as dietary supplements and sold in bulk quantities, with up to thousands of recommended servings per container. We know these products are sometimes being used in potentially dangerous ways. For example, teenagers, for a perceived energy kick, sometimes mix dangerously high amounts of super-concentrated caffeine into workout cocktails. The amounts used can too easily become deceptively high because of the super-concentrated forms and bulk packaging in which the caffeine is being sold," FDA Commissioner Scott Gottlieb said in a press release. "We're making clear for industry that these highly concentrated forms of caffeine that are being sold in bulk packages are generally illegal

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.

For additional information about Shook's capabilities, please contact

Laurie Henry
816.559.2421
lhenry@shb.com

under current law. We'll act to remove these dangerous bulk products from the market."

FDA Shuts Down Distributors of Dietary Supplements

Federal courts in New York and Florida have approved consent decrees that will bar two companies from selling dietary supplements until they comply with manufacturing regulations and other requirements under the Food, Drug and Cosmetic Act.

A New York federal court has entered a consent decree prohibiting manufacturer and distributor Riddhi USA Inc. and owner Mohd Alam from selling adulterated and misbranded dietary supplements. The violations included failure to establish product specifications, inadequate master manufacturing and batch production records, lack of quality control procedures and lack of process for product complaints. In addition, the U.S. Food and Drug Administration (FDA) determined that product labeling failed to declare ingredients, allergens and Riddhi's place of business. Additional details appear in Issue 54 of this *Bulletin*.

A Florida court has entered a consent decree between the United States and MyNicNaxs LLC, its owner Chevonne Torres and company officer Michael Banner. According to the complaint, FDA tests showed that the company's products contained undisclosed drugs such as sildenafil, sibutramine and phenolphthalein.

Salmonella Risk Spurs Mandatory Recall of Kratom

The U.S. Food and Drug Administration (FDA) has announced a mandatory recall of products containing kratom produced by Triangle Pharmanaturals LLC following the company's failure to cooperate with the FDA's request to conduct a voluntary recall. "This action is based on the imminent health risk posed by the contamination of this product with *salmonella*, and the refusal of this company to voluntarily act to protect its customers and issue a recall, despite our repeated requests and actions," FDA Commissioner Scott Gottlieb said in a press release.

Additional details on actions by FDA and the Centers for Disease Control and Prevention pertaining to kratom and *Salmonella* appear in Issue 56 of this *Bulletin*.

Jennise Stubbs
713.227.8008
jstubbs@shb.com

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 Warns of Drug Claims, Misbranded and Adulterated Supplements

The U.S. Food and Drug Administration (FDA) has issued warning letters to three manufacturers of dietary supplement products related to unapproved new drugs, misbranded drugs and food, and adulterated and misbranded dietary supplements. FDA warned Amerigo Labs that website claims for PowerUp and PowerDown supplements establish that the products are drugs. Among other comments, FDA noted that the product labels lack nutrition information and a domestic address and phone number for adverse event reporting.

After inspecting its manufacturing facility and reviewing its catalog, FDA warned South Texas Botanicals that at least 15 of its products are unapproved new drugs and noted that the agency had previously warned the company about misbranding violations. The agency further warned that the products are adulterated and misbranded dietary supplements. FDA also reviewed product labels and a catalog after an inspection of Ozark Country Herbs and commented that the company's claims and testimonials establish that more than 40 products are unapproved new drugs, adulterated or misbranded dietary supplements.

Ad Boards Issue Rulings on Ads for Cosmetics and Supplements

The National Advertising Board (NAD) has referred three advertising claims to the Federal Trade Commission after companies failed to provide substantiation. NAD announced that FemaLife Nutrition LLC failed to file a substantive written response or provide evidence in support of its claims for its Super Flora Probiotic dietary supplement. Similarly, NAD referred Perfect Prime, maker of Perfect Prime Anti-Aging Serum, and The Silver Edge, maker of Micro-Particle Colloidal Silver Generator, to FTC after the companies failed to participate in the self-regulatory process. The board also recommended that Evolution Nutraceuticals discontinue health claims for its Cardio Miracle dietary supplement, including a claim that the product could prevent or reverse heart attack or stroke, because of insufficient supporting evidence.

NAD also recommended that Too Faced Cosmetics discontinue its claim that its Better Than Sex mascara increases eyelash volume by 1,944 percent. NAD found that Too Faced did not demonstrate that the “after” images on its product packaging were “not

retouched or enhanced in any way" and that the laboratory results provided were irrelevant. In addition, NAD ruled that Too Faced's consumer-perception surveys did not support "a precise quantified volume increase or specific images that purportedly show such an increase." Additional details appear in Issue 54 of this *Bulletin*.

The U.K. Advertising Standards Authority (ASA) upheld a complaint that HotHouse Partnerships' advertisements claiming St. Moriz self-tanner to be the nation's "No. 1" tanner brand were misleading. ASA reviewed the advertiser's summary of sales data collected by an independent research agency, which compared the company's sales to competitor sales. ASA ruled that either the summary duplicated the advertiser's sales data or data for St. Moriz was compiled in a manner different from that of competitors, "render[ing] the data unreliable." ASA determined that the advertisements could not appear again in their current form.

Virginia Bans Animal Testing

Virginia has passed a law prohibiting manufacturers from testing products on animals unless no other test method is available. The bill exempts testing "for the purposes of medical research" and imposes the civil penalty of $5,000 for violations. The law echoes similar statutes passed by California, New York and New Jersey.

FDA Invites Public Input on International Cooperation on Cosmetics Regulation Positions

The U.S. Food and Drug Administration (FDA) has announced a public meeting on "various topics pertaining to the regulation of cosmetics" that may prepare the agency for an International Cooperation on Cosmetics Regulation meeting to be held July 10 to 12, 2018, in Japan. The notice indicated that FDA will announce an agenda for the public meeting by May 31, 2018.

LITIGATION

Advocacy Groups Cannot Compel FDA to Review Formaldehyde in Hair Products

A federal court has granted the U.S. Food and Drug Administration's (FDA) motion to dismiss two advocacy groups' complaint urging FDA to consider banning the use of formaldehyde in hair-straightening products. *Envtl. Working Grp. v. FDA*, No. 16-2435 (D.D.C., entered March 19, 2018).

Environmental Working Group and Women's Voices for the Earth (WVE) filed the complaint after FDA announced it was unable to reach a decision on a 2011 citizen petition. The court found that neither plaintiff could establish organizational standing because neither could demonstrate that FDA's conduct impaired the groups' ability to provide services. Although both groups alleged they had expended "substantial time and economic resources" to focus FDA's attention on regulation of the products, the court held that investment of time and resources in lobbying and educational efforts is "exactly what these organizations always do" and that the groups offered "no evidence that the FDA's alleged inaction required them to spend anything beyond their typical annual expenditures." The court noted that "injuries to an organization's government lobbying and issue advocacy programs cannot be used to manufacture standing, because that would allow lobbyists on either side of virtually any issue to take the Government to court."

WVE also attempted to establish associational standing by listing three members who allegedly suffered injuries from exposure to formaldehyde. The court rejected the argument, noting that a plaintiff seeking injunctive relief cannot establish standing based only on past harm. "Confronted with only past injuries to WVE's members, no allegations that these members or others are likely to use or be exposed to formaldehyde-releasing hair straighteners in the future, and evidence from WVE itself indicating that alternative products are available on the market," the court held that it "cannot conclude that future injuries constitute a 'real and immediate threat' to WVE's members."

Ninth Circuit Partially Reverses PharmaCare Summary Judgment

The Ninth Circuit has affirmed in part and reversed in part a grant of summary judgment in a putative class action alleging PharmaCare US Inc. falsely advertised its sexual-enhancement product IntenseX. *Sandoval v. Pharmacare US Inc.*, No. 16-56301 (9th Cir., entered April 5, 2018). The appeals court affirmed the summary judgment orders denying class certification, limiting the use of expert rebuttal reports, and dismissing advertising and warranty claims based on the IntenseX website. To sustain a false advertising claim under California law, the court held, a plaintiff

must show actual reliance on the allegedly false statements. Here, one plaintiff testified that the website had no effect on his decision to purchase the product, and the second failed to submit sufficient evidence that he relied on the website claims before his first purchase.

The court reversed summary judgment for the plaintiffs' label-based claims, finding the statements on the label "sufficiently specific and concrete such that a reasonable consumer could construe it as an affirmation of fact or promise and not just the seller's opinion." In addition, the court reversed summary judgment on the plaintiffs' claim based on California's Unfair Competition Law. The court found that a product marketed as a dietary supplement will be regulated as a drug if the company represents it as providing results only possible with drugs, and the district court had noted that some of the website representations may rise to that level.

Court Dismisses False Advertising Suit Against Maker of AdvoCare Spark

A California federal court has dismissed with prejudice a putative class action alleging that AdvoCare International L.P. falsely advertised its 24-Day Challenge bundle of supplement and nutrition products. *Tubbs v. Advocare Int'l L.P.*, No. 17-4454 (C.D. Cal., entered March 21, 2018). The plaintiffs alleged that the products failed to deliver their promised benefits, including assistance with "weight management, energy, overall body composition [and] overall wellness." Because the plaintiffs were barred from a lack-of-substantiation claim by statute, they must demonstrate that the advertising was false through personal experience or "persuasive studies," the court held. The proffered studies failed to persuade the court because they failed to address the plaintiffs' circumstances or primarily relied on secondary sources that had not examined AdvoCare's products. In addition, the court noted, details relating to the plaintiffs' personal experiences were unconnected to "specific products, specific supporting studies, or specific advertisements" and were thus speculative.

Consumer Alleges Derma-E Products Are Not "Natural"

Derma-E skincare products, marketed as "natural," allegedly contain synthetic ingredients, according to a putative class action complaint. *Meyers v. Stearn's Products Inc.*, No. 18-0557 (S.D.

Cal., filed March 15, 2018). The complaint asserts that products in the Derma-E line contain a variety of synthetic materials, including dimethicone, xanthan gum, zinc oxide, titanium dioxide and glycolic acid. “Surveys and other market research, including expert testimony Plaintiff intends to introduce, will demonstrate that the term ‘natural’ is misleading to a reasonable consumer because the reasonable consumer believes that the term ‘natural,’ when used to describe goods such as the Products, means that the goods are free of synthetic ingredients,” the plaintiff alleges. “By way of example, according to a consumer survey, ‘[e]ighty-six percent of consumers expect a ‘natural’ label to mean processed foods do not contain any artificial ingredients.’” Alleging fraud and violations of California’s consumer-protection statutes, the plaintiff seeks class certification, damages and attorney’s fees.

Plaintiffs Lack Standing Without Economic Injury, Court Holds

A Florida federal court has dismissed a putative class action alleging IQ Formulations LLC’s Synedrex and Metabolic Nutrition E.S.P. are adulterated with illegal stimulant methylpentane citrate, an alternative term for 1,3-dimethylbutylamine (DMBA). *DeBernardis v. IQ Formulations LLC*, No. 17-21562 (S.D. Fla., entered March 29, 2018). The court ruled that the plaintiff did not have standing to sue, finding that the plaintiffs did not allege that the products failed to perform as advertised or caused adverse health effects. Finding no adequate allegation of economic injury, the court dismissed the case.

Supplement Co. Manager Pleads Guilty to Mail Fraud

The U.S. Department of Justice has announced that a woman who worked as a supply-chain manager for two Chinese ingredient producers has pleaded guilty to charges that she agreed to help sell illegal stimulants in the United States. Amy Gao also reportedly admitted to making false statements to the U.S. Food and Drug Administration’s (FDA's) import division.

“U.S. consumers trust that their dietary supplements are safe and contain appropriate labeling. When unscrupulous producers add undeclared or misidentified ingredients to dietary supplements, there is no assurance that the product is safe for consumption,” Catherine Hermsen of FDA’s Office of Criminal Investigations said in a press release. “The FDA will continue to pursue and

bring to justice those who participate in fraudulently marketing dietary supplements to the detriment of public health."

Court Dismisses Most Claims Against Workout Supplement Maker

A federal court has dismissed most claims in a putative class action against PhD Fitness LLC but allowed claims for fraudulent inducement and unjust enrichment to proceed. *Sandviks v. PhD Fitness LLC*, No. 17-0744 (D.S.C., entered March 20, 2018). The plaintiff alleged that PhD's workout supplements, including Pre-JYM and Post-JYM, are not properly dosed, have no scientific backing and have "been found to be completely ineffective." The court dismissed claims for breach of express and implied warranties because the plaintiff failed to provide timely notice of the alleged breach to the seller as required by South Carolina law. The court also dismissed claims for negligent and intentional misrepresentation because the plaintiff's losses were purely economic; although the plaintiff asserted an "industry standards exception" to the economic loss doctrine, the court found that the exception has previously been rejected by South Carolina courts.

Rodan & Fields Fails to Disclose Lash Boost Harms, Lawsuit Alleges

Four consumers have filed a putative class action alleging Rodan & Fields' Enhancements Lash Boost eye serum causes side effects the company fails to disclose to purchasers. *Lewis v. Rodan & Fields LLC*, No. 18-2248 (N.D. Cal., Oakland Div., filed April 13, 2018). The serum contains isopropyl cloprostenate, part of a class of ingredients used in the management of glaucoma, the complaint asserts. The class—prostaglandin analogs—has allegedly been linked to several adverse eye reactions, including corneal inflammation, eyelid drooping, skin darkening, eye pain and increased pigmentation of the iris. The complaint cites a 2011 U.S. Food and Drug Administration (FDA) warning letter to a manufacturer selling an eye serum with a prostaglandin analog, asserting that the letter indicated the products "are not safe for use except under the supervision of a practitioner licensed by law to administer them." The plaintiffs seek class certification, damages and attorney's fees for alleged violations of California and New York consumer-protection statutes as well as fraud and negligent misrepresentation.

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

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