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LEGISLATION, REGULATIONS & STANDARDS

FDA Issues Draft Guidance for Homeopathic Drug Products

The U.S. Food and Drug Administration (FDA) has issued draft guidance, "Drug Products Labeled as Homeopathic," that would prioritize enforcement and regulatory actions to homeopathic products in several categories: (i) products with reported safety concerns; (ii) products that may contain ingredients associated with potentially significant safety concerns, such as pathogens, controlled substances or those with known toxicity; (iii) products administrated in a way other than oral or topical; (iv) products for prevention or treatment of serious or life-threatening diseases; (v) products for vulnerable populations, such as the elderly or immunocompromised; and (vi) products deemed adulterated under the federal Food, Drug, and Cosmetic Act. Public comments will be accepted until March 20, 2018.

“In many cases, people may be placing their trust and money in therapies that may bring little to no benefit to combating serious ailments, or worse—that may cause significant and even irreparable harm because the products are poorly manufactured, or contain active ingredients that aren’t adequately tested or disclosed to patients,” said FDA Commissioner Scott Gottlieb. “Our approach to regulating homeopathic drugs must evolve to reflect the current complexity of the market, by taking a more risk-based approach to enforcement. We respect that some individuals may want to use alternative treatments, but the FDA has a responsibility to protect the public from products that may not deliver any benefits and have the potential to cause harm.”

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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Rep. Calls for Rodan + Fields Investigation for Misleading Benzophenone Marketing

Rep. Frank Pallone Jr. (D-N.J.) has urged the U.S. Food and Drug Administration (FDA) to investigate Rodan + Fields after the cosmetics company allegedly used false and misleading marketing to deflect consumer inquiries about benzophenone, an ingredient that the California Environmental Protection Agency and World Health Organization's International Agency for Research on Cancer have identified as a carcinogen and potential endocrine disruptor. In letters to FDA and Rodan + Fields, Pallone said that the company's website contained links to more information "about the FDA's position" on the chemical. One linked to California's Safe Drinking Water and Toxic Enforcement Act website, but the other, Pallone said, directed consumers to a site "fully funded by the cosmetics industry itself and which outlines the industry's self-assessment on the safety and use of benzophenone." Pallone noted that the hyperlink has since been updated to link to FDA but does not guide consumers to any information about the agency's position.

FDA Issues Warning Letters to Young Health Products, Optimum Bioenergy and Maine Natural Health

The U.S. Food and Drug Administration (FDA) has issued warning letters to the owners of Young Health Products LLC, Optimum Bioenergy International and Maine Natural Health Inc., notifying the companies of violations of the Federal Food, Drug and Cosmetic Act (FDCA) and the Current Good Manufacturing Practice (CGMP) regulations.

FDA reviewed the website of Young Health Products and determined that the claims the company makes for Lugol's Solution 2%, Liquid Vitamin D3, Probimune, Flax Seed & Omega 3-6-9 Fish Oil, Balance Drops, Whey Protein and Fruit of the Spirit establish the products as drugs intended to treat a variety of diseases, including diabetes, high blood pressure, pain, inflammation and allergies. In addition, the company claims that its Flax Seed product can "help nourish the body when attacked by conditions" including cancer, Alzheimer's, autism and asthma.

After inspecting Optimum Bioenergy International's manufacturing facility in California, FDA warned the company

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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.

that violations of agency regulations caused its dietary supplement products to be adulterated. Among the alleged violations were: (i) failure to establish procedures for quality control; (ii) failure to establish product specifications; (iii) failure to establish procedures for cleaning or pest control; and (iv) storage of components and finished products in tents outside the facility near potential sources of contamination.

FDA also warned the owner of Maine Natural Health that after a plant inspection and a review of its product labeling, multiple alleged violations of CGMP regulations and labeling requirements resulted in findings that the company was selling unapproved new drugs, adulterated and misbranded dietary supplements.

Claire's Pulls Cosmetics Products After Asbestos Allegedly Found

Claire's Stores Inc. has pulled from shelves several makeup products targeted at children after a CNN affiliate reported that a laboratory found asbestos in 24 talc-based items, including eye shadows and powder compacts. The company's initial tests reportedly showed no asbestos in the products, and it announced that it had confirmed the talc was obtained from a certified asbestos-free European supplier. Additional testing reportedly found the products are "asbestos free, completely safe and meet all government requirements." The North Carolina lab that apparently found the asbestos told *CNN* that Claire's had not tested the exact products that had tested positive because they remained at the lab.

Ad Board Reviews Claims for Memory Problems, Weight Loss and Teeth-Whitening

The National Advertising Division (NAD) has recommended that Cebria, the maker of Senior Moment Advance Memory Enhancing dietary supplements, discontinue claims that the product will alleviate memory problems or enhance memory function. Before the review, Cebria asked NAD to close the matter because the Federal Trade Commission previously reviewed the challenged claims and closed the investigation without taking action against the company. Cebria submitted evidence supporting its claims about the active ingredient but not the product as a whole, and NAD determined that the evidence was "not a good fit for the advertiser’s strong, unqualified claims.” NAD previously

recommended that Cebria discontinue or modify "clinically proven" claims for Procera AVH supplements, although the advertiser had conducted a "peer-reviewed, double-blind, randomized, placebo-controlled clinical trial" on the supplement.

The Electronic Retailing Self-Regulation Program (ERSP) reviewed online advertising for Mayfair's Garcinia Cambogia Allure weight-loss product. After reviewing outlines and summaries of studies, ERSP determined Mayfair's claims were not supported by the evidence provided. Mayfair has notified ERSP that it will no longer sell Garcinia Cambogia Allure or any other garcinia cambogia supplement. ERSP also reviewed Stain-Away LLC's Power Swabs marketing claims and determined that Stain-Away supported its claims that the product whitens teeth by an average of six shades in seven days and that users will see visible results within five minutes of use.

LITIGATION

Court Trims Class Claims from NBTY Labeling Action

An Illinois federal court has dismissed nationwide class claims alleging NBTY Inc. misrepresents the health benefits of glutamine in its marketing for Body Fortress 100% Pure Glutamine Powder. *DeBernardis v. NBTY Inc.*, No. 17-6125 (N.D. Ill., entered January 18, 2018). The court determined the issue of personal jurisdiction with regard to the U.S. Supreme Court's 2017 decision in *Bristol-Myers Squibb v. Superior Court of California, San Francisco County*, which confirmed that courts have limited jurisdiction over non-resident defendants.

The Illinois court concluded that "it is more likely than not based on the Supreme Court's comments about federalism that the courts will apply *Bristol-Myers Squibb* to outlaw nationwide class actions in a for[u]m, such as in this case, where there is no general jurisdiction over the Defendants." Accordingly, the court dismissed putative class claims extending outside of Illinois. Further, the plaintiff failed to allege a potential future injury, the court held, so he lacked standing to seek an injunction.

FTC and Supplement Maker Settle Claims on Products Targeting Cancer Patients

CellMark Biopharma LLC has agreed to stop making false, misleading or unsubstantiated claims about CellAssure and Cognify, supplements marketed to cancer patients. *Fed. Trade*

Comm'n v. CellMark Biopharma LLC, No. 18-14 (M.D. Fla., entered January 11, 2018). The Federal Trade Commission's complaint alleged that CellMark advertised its products as able to treat or mitigate cachexia, cognitive dysfunction, cancer and the effects of cancer treatment. CellMark is barred from making any representation about any product marketed to treat any disease without substantiating scientific evidence. The company is also enjoined from "disclosing, using or benefitting from" any personal customer data obtained before the entry of the consent order. According to the order, CellMark CEO Derek Vest entered federal prison in August 2017 to serve an 18-month sentence in an unrelated case involving the marketing of dietary supplements.

Court Denies Hain Celestial's Motion to Dismiss "Natural" Deodorant Class Action

A California federal court has denied Hain Celestial Group's motion to dismiss a putative class action alleging that its Jason deodorant products are advertised and labeled as "natural" despite containing tocopheryl acetate, glycerin and ethylhexylglycerin. *Pecanha v. The Hain Celestial Grp.*, No. 17-4517 (N.D. Cal., entered January 24, 2018). Additional details about the matter appear in Issue 53 of this *Bulletin*.

The court first refused to dismiss the complaint's fraud, breach of warranty and unjust enrichment claims, finding they involved questions of fact that could not be resolved at this stage of litigation. The court also refused to grant a stay, finding no evidence that the U.S. Food and Drug Administration is defining "natural" in cosmetics. In addition, the court rejected Hain's argument that its subsidiary manufactured, sold and marketed Jason products and that the plaintiffs had alleged no wrongdoing by Hain itself.

Plaintiff Alleges Whole Foods Vitamin B12 Supplements Have Too Much Vitamin B12

A California plaintiff has filed a putative class action alleging that some of Whole Foods Market's liquid vitamin B12 supplements contain amounts of the vitamin in "significant excess" of the 500 to 1,000 micrograms advertised on the product labels. *Palmer v. Whole Foods Market IP, L.P.*, No. BC690514 (Cal. Super. Ct., Los Angeles Cty., filed January 18, 2018). The plaintiff alleges that the products he purchased—Liquid Vitamin B12, Super B12 B

Complex and Liquid Energy Shot—as well as similar B vitamin products made with cyanocobalamin contain amounts of the vitamin in excess of the amount a reasonable consumer would expect. The plaintiff speculates that because cyanocobalamin is less stable than other forms of the vitamin, Whole Foods may have added the excess to ensure that consumers received the vitamin even as the product degraded after opening or that the excess is "indicative of a lack of quality control." The complaint also alleges that the labeling is false and misleading even if it complies with the requirements of the Federal Food, Drug and Cosmetic Act, which allegedly "does not provide a shield from liability."

Plaintiff Alleges Protein Supplement Container Is More Than Half Slack Fill

A plaintiff has filed a putative class action alleging Coexist Nutrition's 14.82-ounce containers of 22 Days Nutrition Plant Power Protein Supplement contain as much as 56 percent slack fill. *Ross v. Coexist Nutrition, LLC*, No. 18-0587 (S.D.N.Y., filed January 23, 2018). The plaintiff asserts that Coexist cannot argue that the slack fill is functional because a smaller container of another Coexist product, 22 Days Organic Plant Protein Powder, contains 46 percent slack fill. Claiming deceptive and unfair trade practices, false advertising and common law fraud, the plaintiff seeks injunctive relief, class certification, restitution, disgorgement, reimbursement, damages and attorney's fees.

Peter Thomas Roth Eye Serum Caused Permanent Injury, Lawsuit Alleges

A plaintiff has filed a lawsuit alleging Peter Thomas Roth Labs' eye serum, which he purchased through co-defendant Sephora, caused permanent injuries to his face. *Grullon v. Peter Thomas Roth Labs LLC*, No. 150399/2018 (N.Y. Super. Ct., filed January 15, 2018). The complaint alleges that the plaintiff used Peter Thomas Roth Laser Free Eye Serum according to instructions, but after three uses, red and painful bumps developed where the product was applied. The plaintiff further alleges that one of the bumps developed a hole which remains unhealed. Claiming that both companies knew the serum was "defective and dangerous" and that both defendants are "guilty of malice, oppression and fraud," the plaintiff seeks $500,000 in damages from each defendant for injury, physical and mental pain, anguish and distress.

Banana Boat Lawsuits Allege Label Misrepresentation

A consumer has filed a putative class action alleging Edgewell Personal Care's Banana Boat line of sunscreens is not "natural" as marketed because the products contain synthetic and artificial ingredients. *Hernandez v. Edgewell Personal Care, LLC*, No. 18-128 (C.D. Cal., filed January 21, 2018). The plaintiff asserts that Natural Reflect, Natural Reflect Baby and Natural Reflect Kids contain several artificial ingredients, including glyceryl stearate, tocopheryl acetate, dimethicone and phenoxyethanol.

In another Edgewell lawsuit, a consumer has alleged that Banana Boat Kids products were labeled as SPF 50 but offered SPF 8 protection. The case has been referred for settlement mediation. *In re Edgewell Personal Care Co. Litig.*, No. 16-3371 (E.D.N.Y., entered January 23, 2018).