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DIETARY SUPPLEMENT & COSMETICS LEGAL BULLETIN

ISSUE 47 | JANUARY 2017

SHOOK HARDY & BACON

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SPOTLIGHT

FDA Makes Dietary Supplement and Cosmetic Adverse Event Data Publicly Available

In December, the U.S. Food and Drug Administration (FDA) announced that it will make publicly available certain data received through the Center for Food Safety and Applied Nutrition's Adverse Event Reporting System (CAERS), including adverse event information pertaining to cosmetics and dietary supplements.

The currently available data includes consumers' and practitioners' reports as well as mandatory industry reports compiled from January 2004 to March 2016. Voluntary industry report data will become available in February 2017. FDA has also indicated that it will issue quarterly reports beginning in February 2017.

LITIGATION

FDA Sued for Inaction on Citizen Petition Regarding Dangers of Formaldehyde in Salon Products

Environmental Working Group (EWG) and Women's Voices for the Earth (WVE) have filed a lawsuit against the U.S. Food and Drug Administration (FDA) alleging that FDA has failed to protect hair salon workers and consumers from the health effects of hair products containing formaldehyde. *Envtl. Working Grp. v. FDA*, 16-2435 (D.D.C., filed December 13, 2016).

The plaintiffs argue that FDA failed to respond to EWG's April 2011 citizen petition alleging that formaldehyde-releasing chemicals, including hair straighteners that contain the ingredient, pose a clear health hazard to consumers. The complaint states that ample scientific evidence demonstrates the risk of formaldehyde exposure and cites adverse event reports from users of Keratin Hair-Straighteners.

According to the complaint, FDA sent a warning letter to a manufacturer of keratin hair straightening products in August 2011. The letter alleged that the product was adulterated and misbranded because the labeling indicated the product was "Formaldehyde Free," despite containing methylene glycol, which releases formaldehyde when the product is used under the conditions described in the product's labeling. EWG and WVE argue that FDA responded to EWG's petition in September 2011 saying that competing priorities had prevented action on the petition and refused to provide a detailed report on its status after an inquiry in July 2012. The groups' complaint requests that the court set a deadline for FDA to respond to the citizen petition.

FTC Files Suit against Jellyfish Supplement Marketers

The Federal Trade Commission (FTC) and New York State Attorney General Eric Schneiderman have filed suit against the marketers of Prevagen, a dietary supplement with a protein derived from jellyfish, alleging the marketers' claims that Prevagen improves memory and cognition are false and unsubstantiated. *FTC v. Quincy Bioscience Holding Co., Inc.*, 17-0124 (S.D.N.Y., filed January 9, 2017).

The marketers of Prevagen attracted national attention with advertising campaigns promoting the supplement through television and satellite radio, websites, newspapers and magazines, social media and an infomercial, the "Better Memory Show." In 2015, the defendants ran a campaign—the "Better Memory Tour"—in which representatives of the company visited health food expos and centers across the country in the "Prevagen Express" bus.

The complaint lists four claims against the marketers: two from FTC alleging false or unsubstantiated efficacy claims and false proof claims and two from the state of New York for repeated fraudulent acts as well as deceptive practices and false advertising. The alleged violations stem from the defendants' representations that the supplement improves memory within 90 days, reduces memory problems associated with aging and provides other cognitive benefits such as healthy brain function, a sharper mind and clearer thinking.

FTC's arguments focus on the defendants' advertising claiming to have a clinical basis for the marketed effects of the supplement. According to the complaint, the defendants conducted a double-blind, placebo-controlled

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clinical study in which the researchers gave 218 subjects either 10 milligrams of the supplement or a placebo and then ran participants through nine cognitive tests, which failed to show a statistically significant improvement in the subjects' memory. The researchers then conducted more than 30 post hoc analyses of the results, looking at data based on variations of smaller subgroups for the different cognitive tasks in the study, and managed to show a few positive findings. FTC argues that these results are not reliable evidence of a positive treatment effect and thus should not form a basis for clinical claims.

The plaintiffs ask the court for an injunction preventing further violations and for redress of consumer injuries with restitution, refunds and rescission of contracts. The state of New York also requests civil penalties of up to $5,000 per violation of its executive laws.

REGULATION

Granting PCPC Petition, FDA Releases Draft Guidance on Lead Levels in Cosmetics

The U.S. Food and Drug Administration (FDA) has announced the release of its draft guidance, "Lead in Cosmetic Lip Products and Externally Applied Cosmetics: Recommended Maximum Level Guidance for Industry." The draft guidance recommends a maximum level of 10 parts per million (ppm) for lead in cosmetic lip products and externally applied cosmetics. The Personal Care Products Council (PCPC) submitted a citizen petition in June 2011 requesting that FDA issue such guidance. FDA announced that it would grant the petition "[a]fter completing testing of cosmetics products and exposure analysis" and that "[t]his guidance will educate new manufacturers who wish to enter the market and encourage current manufacturers to continue to follow or improve on voluntary good manufacturing practices that limit trace amounts of lead as an impurity." Public comments will be accepted on the draft guidance until February 21, 2017.

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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.

GLOBAL

India Issues Health Supplement Regulations

The Food Safety and Standards Authority of India (FSSAI) recently issued regulations for functional foods and health supplements. The rules allow supplements to be used for the purposes of supplementing the diets of individuals over the age of five. The regulation requires that supplements must not contain food products covered elsewhere in the regulations and prohibits the quantity of nutrients from exceeding the daily allowances specified by the Indian Council of Medical Research or, where no standards are specified by the Council, the Codex Alimentarius Commission. Labeling and advertisements of the supplements are not allowed to claim that the product prevents, treats or cures a human disease. The regulations also contain rules for what the supplements can contain as well as guidelines for the packaging and labeling of the products.