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SHOOK HARDY & BACON

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FIRM NEWS

Shook Lawyers Secure Dismissal of Two Suits Against Baby Powder Manufacturer

A Superior Court of New Jersey judge has dismissed two cases against Johnson & Johnson after a two-week hearing to determine the sufficiency of the scientific evidence. *Carl v. Johnson & Johnson,* No. 6546-14; *Balderrama v. Johnson & Johnson,* No. 6540-14 (N.J. Super. Ct., Atlantic Cty., order entered Sept. 2, 2016).

The court ruled that the plaintiffs' causation experts failed to support the claim that Johnson's Baby Powder caused ovarian cancer.

Shook's Johnson & Johnson team includes Gene Williams, Hunter Ahern, Mark Hegarty, Kat Frazier and Scott James.

SPOTLIGHT

FDA Bans 19 Ingredients from Antibacterial Wash Products

The U.S. Food and Drug Administration (FDA) has issued a final rule prohibiting the marketing of over-the-counter consumer antiseptic wash products that contain certain ingredients. Nineteen banned ingredients are specified in the final rule, including triclosan and triclocarbon, the most commonly used ingredients in antiseptic wash products.

In 2013, FDA proposed a rule requiring manufacturers to prove that the ingredients were safe for long-term daily use and more effective at preventing illness and infections than soap and water. FDA found that insufficient data was submitted to support a finding that the ingredients are Generally Recognized as Safe and Effective.

"Consumers may think antibacterial washes are more effective at preventing the spread of germs, but we have no scientific evidence that they are any better than plain soap and water," said Janet Woodcock, director of FDA's Center for Drug Evaluation and Research. "In fact,

some data suggests that antibacterial ingredients may do more harm than good over the long-term."

The agency is still considering prohibiting the use of banzalkonium chloride, benzethonium chloride and chloroxylenol (PCMX). Manufacturers have one year to submit new safety and effectiveness information to FDA before a decision is made.

The recent ban applies to products intended for rinsing off with water. Of note, the rule does not apply to consumer hand sanitizers and wipes or antibacterial products employed in health care-related settings. Manufacturers of products with one or more of the 19 banned ingredients have until September 6, 2017, to remove their products from the market. *See FDA Press Release*, Sept. 2, 2016.

LITIGATION

First Circuit Revives Vitamin E Class Action Against CVS

The First Circuit recently overturned a district court ruling dismissing a class action against CVS Caremark Corp. *Kaufman v. CVS Caremark Corp.*, 16-1199 (1st Cir., order entered September 6, 2016).

The original complaint, filed in May 2014, claimed that CVS markets, sells and distributes vitamin E products that they represent as supporting "heart health." The plaintiff alleged the retailer's "heart health" and "supports heart health" statements were false, misleading and reasonably likely to deceive the public.

The district court ruled that the suit was preempted by the Food, Drug, and Cosmetic Act (FDCA), dismissing the complaint. The three-judge panel for the First Circuit disagreed. While finding that CVS would be protected by the safe harbor of FDCA if its label met the requirements of section 343(r), the panel ultimately decided that Kaufman adequately pled that the labeling does not meet the statutory requirements.

NutraClick and FTC Reach Agreement on Membership Complaint

The Federal Trade Commission (FTC) recently brought a complaint against NutraClick, LLC under the Federal Trade Commission Act and Section 5 of the Restore Online Shoppers' Confidence Act. *FTC v. NutraClick, LLC*, No. 16-6819 (C.D. Cal., filed September 12, 2016).

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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FTC alleged the company failed to clearly disclose that consumers who ordered sample products from NutraClick's website would automatically be enrolled in a membership program for nutritional supplements and beauty products, costing between $29.99 and $79.99 per month. FTC said complaints had been filed by at least 70,000 people and that the company made tens of millions of dollars from the membership charges.

NutraClick and FTC have now reached an agreement which includes a change to NutraClick's billing practices. Among other things, the stipulated order prohibits the misrepresentation of costs. NutraClick will not be allowed to obtain customers' billing information until charges have been disclosed and in cases where the cost will increase over time, consumers must be informed upfront. If charges will automatically recur until cancellation, the company must also disclose that information. The range of costs and deadlines for cancellation must also be communicated before the company obtains customers' billing information. NutraClick must also pay FTC $350,000.

LEGISLATION, REGULATIONS AND STANDARDS

Federal Lawmakers Aim to Bolster FDA's Authority over Cosmetic Products

In response to criticisms of regulatory gaps for cosmetics and personal care products, congressional lawmakers have drafted proposed legislation aimed at strengthening the Food and Drug Administration's (FDA's) authority. Sponsors Rep. Frank Pallone, Jr (D-N.J.) and Rep. Leonard Lance (R-N.J.) announced the legislation at a mid-September 2016 news conference that included the mother of a child whose story of hair loss after using Wen® Cleansing Conditioner was featured in an August *New York Times* article.

"Millions of Americans assume the cosmetics they use each day are safe, however the reality is that cosmetics are one of the least regulated consumer products on the market today," Pallone said.

A draft summary of the proposal highlights giving FDA the authority to collect and review cosmetic ingredient data to determine if ingredients are safe for cosmetic use.

Cosmetic manufacturers, processors, packers and holders would be required to register their facilities with FDA. Mandatory reporting of adverse events by cosmetic manufacturers as well as warnings on cosmetic products are also part of the proposal.

A week after Pallone and Lance's proposal was announced, the Senate Health, Education, Labor and Pensions Committee held a hearing on the Personal Care Products Safety Act (S.B. 1014). Introduced by Sen. Dianne Feinstein (D - Calif.) in April 2015, the proposed law would amend the Federal Food, Drug, and Cosmetic Act to require, in part, registration of facilities, submission of cosmetic ingredient statements and facility registration fees. It also would give FDA the authority to prohibit cosmetic product distribution upon determination of reasonable probability that a product causes serious adverse health problems as well as mandate development and implementation of national cosmetic manufacturing standards.

Cosmetic Companies Continue to Receive FDA Warning Letters

The U.S. Food and Drug Administration (FDA) sent seven warning letters to cosmetics companies in September 2016, continuing the agency's trend of clamping down on what it contends are unapproved drug claims for cosmetic and personal care products.

A letter to Zo Skin Health Group, LLC targeted three products, including the company's Ossential® Growth Factor Serum Plus, Ossential® Daily Power Defense and Ossential® C-Bright Serum 10% Vitamin C. FDA highlighted website claims such as "Helps stimulate cell renewal" and "Helps prevent new pigment from forming," which the agency said establishes the products as drugs under the Federal Food, Drug, and Cosmetic Act.

Another company that received a letter, Tata's Natural Alchemy, LLC, sells products online that include Boosted Contouring Eye Mask & Rejuvenating Serum, with the claim, "2 hours: RELAX MUSCLE, 95% of wrinkle-causing muscle contractions decrease." FDA's letter highlighted several other products on the company's website, including a Concentrated Brightening Serum with the claim, "A blend of targeted technology…to fighting every stage of the hyperpigmentation process, by helping to inhibit the passage of melanin to the surface…" and "24 hours: REDUCE MELANIN Test studies show a reduction in the skin's melanin content by 36%*."

Healing-Scents, which sells oils and herbs (among other products), also received a warning letter. FDA pointed to claims about Neem Seed Oil on the company's website such as "Neem produces pain-relieving, anti-inflammatory and fever reducing compounds that can aid in the healing of cuts, burns, sprains, earaches, and headaches, as well as fevers." The letter also noted claims about the company's Heart Herb that FDA cited as evidence that the product is intended to be used as a drug. For example, "Use of this blend may help prevent and/or reduce the symptoms of many heart disease related conditions, including atherosclerosis, angina, neuritis, neuralgia, rheumatism, liver problems, arteriosclerosis, prevent coronary heart disease, congestive heart disease…"

Nineteen warning letters for cosmetic and personal care product claims have been posted since June of this year.

GLOBAL

High Court Upholds EU Ban on Animal Testing to Prove Safety of Cosmetics

The High Court of Justice (England and Wales) has upheld an EU ban on the sale of cosmetics products tested on animals. The ban has been in place since 2009, but in 2014 the European Federation for Cosmetic Ingredients (EFfCI) brought a case to the high court asking for judicial review to determine the scope of the prohibition.

EFfCI claimed the prohibition applied only when the testing was done to meet the requirements of the EU law, Article 18(1)(b) of Regulation (EC) no. 1223/2009. Thus, if the test was performed either outside the EU or to meet the regulatory or legislative requirements of another country, the sale of such products would not be prohibited under EFfCI's interpretation.

In March 2016, the Advocate General delivered an advisory ruling recommending the EFfCI's argument be rejected. The court agreed with the Advocate General and found that manufacturers cannot use animal testing data to support the safety of cosmetics products. The location of where the data is generated does not affect the ban. The court noted that an objective of the regulation at issue is to establish that as a condition for selling in the EU market, a cosmetic product must ensure "a high level of protection of human health, whilst ensuring the well-being of

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.

animals by prohibiting animal testing" and that the "regulation must be understood to make that access conditional upon compliance with the prohibition of animal testing."

The decision does not result in a blanket ban on any cosmetic testing on animals—it affects situations where the animal testing data is relied on to prove the safety of a product so that it can be marketed in the EU. If the product is tested on animals to provide safety data under other countries' requirements, those products can still be sold in the EU if the EU's safety requirements are met by other data not stemming from the animal testing.