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DIETARY SUPPLEMENT & COSMETICS LEGAL BULLETIN

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SHOOK HARDY & BACON

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FIRM NEWS

Shook Attorneys Discuss Ideas for Companies to Rebut False Labeling Claims

As dietary supplement and nutraceutical companies face a growing wave of purported class actions by plaintiffs claiming that product test results allegedly show fraudulently labeled goods, Shook attorneys are writing and speaking about ways companies can address these claims, which are often brought under state fraud or consumer protection laws.

Partner **Jim Muehlberger** and associate **Jeff Lingwall** explain in ***Law360*** how companies can analyze plaintiffs' "tests" to determine if the procedures and samples used align with U.S. Food and Drug Administration (FDA) requirements or if the plaintiffs are attempting to apply stricter liability under state law than is required under federal law.

They also provide guidance for companies on how to avoid liability based on allegedly independent product testing.

Partner **Laurie Henry**, who serves as vice chair of the Food, Cosmetics, and Nutraceuticals Committee of the ABA Section of Science & Technology Law, spoke on consumer class actions at the American Conference Institute's Legal, Regulatory & Compliance Forum on Cosmetics in early March 2015 and discussed ways in which companies can minimize their risk of becoming targets for these lawsuits.

SPOTLIGHT

Mobile Apps Offer Opportunity, Challenges for Health & Beauty Field

As devices plug more people into the "Internet of Things," there is a growing overlap between the world of smartphones, tablets and software, and the world of dietary supplements, cosmetics and nutraceuticals. Regulatory agencies are also becoming more involved in the mobile and online space. The Food and Drug Administration's (FDA's) recently

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released draft guidance document for general wellness products, which adds to the agency's previously finalized guidance on mobile medical apps, and the Federal Trade Commission's (FTC's) recent enforcement actions could direct the development of health and beauty mobile apps.

FDA has issued a **guidance document** governing mobile apps that it will regulate as medical devices. Most apps for dietary supplements, cosmetics and nutraceuticals, however, are likely to fall into the "general wellness" category. According to the draft guidance, FDA does not intend to regulate low-risk general wellness devices. The agency defines "low-risk" products as those that are non-invasive, do not involve a technology or intervention that poses a risk to user safety if it is uncontrolled (e.g. lasers), and do not raise novel questions of usability or biocompatibility. "General wellness" products fall into two categories: (1) They can be intended for use to sustain or encourage a general state of health without referencing specific diseases or conditions; and (2) They can be intended for use as a way to promote, track or encourage choices that may help people live well or reduce the risk of certain chronic diseases or conditions. The **draft guidance document** for general wellness products is currently available for public comment until April 20, 2015.

In the mobile app field, FTC has focused on two primary areas: data privacy and deceptive marketing claims. FTC has sent warning letters to app makers for **collecting data in violation of the Children's Online Privacy Protection Act** and for **failing to disclose types of private data that apps collect**.

In the past, app makers who claimed that their apps could detect skin cancer were **charged with deceptive marketing practices** and forced to give up their profits to settle FTC's claims, as were app makers who **claimed that their product could treat acne**.

As an example of a mobile app in this space, the National Institutes of Health (NIH) has created a **My Dietary Supplements** app to help consumers keep track of vitamins, minerals, herbs, and any other dietary supplements they take. It contains information from product labels, including directions, health claims and warnings. Because the NIH app is low-risk and intended to help consumers track their general wellness, it would not be regulated by FDA, but the FTC may be interested in how the NIH stores consumers' information and the privacy disclosures that are made when consumers download the app.

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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Companies have new opportunities to reach clients, market their products and grow their businesses through mobile apps, but this evolving landscape comes with possible legal and regulatory risks. Being aware of regulatory concerns will ensure that mobile apps in the health and beauty space help grow businesses without triggering legal or regulatory minefields.

LITIGATION

New Wave of Labeling Lawsuits Develop from N.Y. Attorney General's Supplement Investigation

Lawsuits have now been filed in Arkansas and California against four national retailers following New York Attorney General Eric Schneiderman's allegations that the retailers' dietary supplements failed to contain labeled botanicals such as ginseng, Echinacea and St. John's wort. Schneiderman's investigation reportedly found that the majority of supplements tested did not contain the labeled herbs or were contaminated. These class action lawsuits similarly allege that the supplements failed to contain the ingredients they claimed and contained other materials not disclosed. At least one of the retailers has challenged the results of the attorney general's investigation and noted that its products were made and tested according to Food and Drug Administration regulations.

District Court of Oregon Enters Injunction Against Maxam Nutraceutics

The U.S. District Court for the District of Oregon recently issued a permanent injunction against James G. Cole Inc., manufacturer of products under the name "Maxam Nutraceutics," to prevent the distribution of unapproved and misbranded drugs and adulterated dietary supplements. The Department of Justice filed a complaint, at the request of the Food and Drug Administration (FDA), alleging that the company was manufacturing dietary supplements under conditions that were inadequate to ensure the quality of the products and that the products were unapproved and misbranded. The court's decision was based in part on the company's claims that its products could treat autism, Alzheimer's, HIV, and fibromyalgia, among other diseases. The court also found that the company's products were misbranded because they failed to bear adequate directions for use and were adulterated because they were not produced in compliance with federal good manufacturing practice regulations.

Expert Testimony in Fixodent® MDL Deemed Unreliable and Dismissed

The U.S. district judge presiding over the Fixodent® MDL in the Southern District of Florida has for the second time held that the plaintiffs failed to produce sufficient proof that the denture cream can cause a neurological condition known as copper deficiency myeloneuropathy, or CDM. The plaintiffs claim that the zinc contained in Fixodent® increases the risk of copper deficiency that results in neurological problems. Although plaintiffs' experts relied on a number of scientific studies that they claimed provided sufficient connection between higher levels of zinc in Fixodent® and increased risks of neurological problems for a reasonable jury to find causation, Judge Cecilia Altonaga disagreed, concluding that the expert testimony "relies on factually inaccurate data and unsupported assumptions, and generally lacks the sound scientific basis and intellectual rigor required by *Daubert*. These experts' opinions also leave significant gaps in plaintiffs' general causation theory."

Boiron® Homeopathic Remedy Settlement Upheld by Ninth Circuit

The Ninth Circuit Court of Appeals has upheld a Boiron® homeopathic remedy class action settlement after disagreeing with an objector who had argued that the 2012 deal was the result of collusion. The objector argued that the class action settlement was neither fair, reasonable nor adequate, and that the $5-million false advertising settlement amounted to less than 1 percent of Boiron's retail sales. The court found that U.S. District Judge John Houston did not abuse his discretion by approving the class action settlement, which resolved allegations that Boiron made false claims about the effectiveness of its homeopathic treatments in treating the flu, arthritis, joint pain, cough, insomnia and other conditions. Boiron denied the allegations but agreed to settle the lawsuit to avoid the cost of further litigation.

LEGISLATION, REGULATIONS AND STANDARDS

New York Attorney General Proposes Ban on Plastic Microbeads in Cosmetic Products

The proposed **Microbead-Free Waters Act** in the New York Assembly would prohibit the production, manufacture, distribution and sale in New York of any beauty product, cosmetic or other personal care product

containing plastic particles less than 5 millimeters in size. The Act notes that microbeads, which have been reported in New York waters, can persist in the environment and be mistaken as food by small fish and wildlife. New York Attorney General Eric Schneiderman previously issued a report documenting the potential environmental impact of microbeads when discharged into New York's wastewater stream. Microbeads are commonly found in more than 100 products, including facial scrubs, soaps, shampoo and toothpaste, where they work as abrasives.

FDA Steps Up Issuance of Warning Letters to Cosmetic and Dietary Supplement Companies

The Food and Drug Administration (FDA) has issued a number of warning letters to cosmetic and dietary supplement companies over the last several months. A February 12, 2015, warning letter to L'Oreal states that Rosalic AR Intense and Mela-D Pigment Control appear to be promoted for uses that caused the products to be classified as drugs. The letter cites examples from L'Oreal's website, including language such as "reduces visible redness and sensations of discomfort" for the Rosalic AR Intense product and "concentrated dark spot correcting serum" for Mela-D Pigment Control. The warning letter also states that the Rosalic AR Intense product is offered for conditions that are not amenable to self-diagnosis and treatment by consumers who are not medical professionals, making the directions for use unusable for laypeople.

On January 20, FDA issued a warning letter to Chaga Mountain, Inc. for its mushroom tea bags, mushroom tincture/extract, powered loose teas, skin cream and lip balm, finding that the company's advertisements caused the products to be classified as drugs. Chaga Mountain's website made various claims about its products, including representing that products were anti-cancer agents; antiviral, antimicrobial, antifungal, and/or anti-inflammatory; and may be used as treatment for arthritis, influenza, erectile dysfunction, Crohn's disease, ADHD, hepatitis and several other diseases. The warning letter also notes that the tincture/extract, tea bags and loose teas were adulterated and not prepared under conditions that meet current good manufacturing practice requirements for dietary supplements. Finally, the warning letter states that the tincture/extract product was misbranded as a dietary supplement because it failed to bear nutritional information as required.

On January 9, FDA issued a warning letter to Derma Pen, LLC about its micro-needle skin dermabrasion device, Dermapen®, finding the device to be a Class I medical device, misbranded and adulterated because it lacked premarket approval or approval for an investigational device exemption. Dermapen® consists of needles controlled by a motor to penetrate the skin while the user moves it across the skin surface. Currently, the safe ranges of needle lengths, penetration depths and speeds of the device are unknown, creating concern that the device could damage vessels and nerves. FDA requested the company immediately cease commercial distribution of the Dermapen Auto-Microneedle Therapy System. FDA also warned about promotional materials calling products "cosmeceuticals," as this category is not recognized by FDA.

FTC Refunds Consumers for Deceptive Marketing Practices

The Federal Trade Commission (FTC) has begun sending refund checks totaling more than $426,000 to consumers who lost money buying "Body Slimming" creams that were deceptively marketed by L'Occitane, Inc. The refunds come from money collected in a January 2014 settlement order with the company, and the amount of each consumer's refund varies based on the amount of product purchased. L'Occitane has also agreed to stop making deceptive claims that Almond Beautiful Shape and Almond Shaping Delight skin creams have body-slimming capabilities and are clinically proven.

FTC is also mailing refund checks totaling about $955,000 to consumers who purchased AdvaCAL® calcium products. Lane Labs advertised AdvaCAL® as a "superior" calcium supplement, claiming that it was the only calcium supplement that could increase bone density and was on par or superior to prescription drugs for treating osteoporosis. The refunds come from funds collected after two federal court rulings finding the company's claims to be unsubstantiated and false.

GLOBAL TRENDS

FTC Settles with Hispanic Global Way, Inc. for $50 Million

The Federal Trade Commission (FTC) recently settled with Hispanic Global Way, Inc., over allegations that it was targeting Spanish-speaking consumers, sending defective or incorrect products, and refusing to

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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.

Shook is widely recognized as a premier litigation firm in the United States and abroad. The firm's clients include large multinational companies in the tobacco, pharmaceutical, medical device, automotive, chemical, food and beverage, cosmetics, oil and gas, telecommunications, agricultural, and retail industries.

refund consumers' money when they complained. The company has agreed to discontinue telemarketing and selling weight-loss products.

According to the FTC complaint, Hispanic Global Way used Spanish-language TV ads and Peruvian call centers to sell its products. They shipped incomplete orders and wrong or defective products. When consumers called to complain, the telemarketers reportedly ignored or insulted the callers, told them they could not return or exchange products, or that they would have to pay an exchange fee ranging from $20 to $299. Under the settlement order, the company must provide refunds or exchanges, free of charge, for incorrect or non-working products sold in the future. Hispanic Global Way is also barred from making material misrepresentations about goods and services and must disclose, before making a sale, any restriction or condition on a refund, cancellation, repurchase or exchange. The settlement order imposes a $50-million judgment that will be suspended upon surrender of all of the defendants' significant assets.

SCIENTIFIC/TECHNOLOGICAL DEVELOPMENTS

Recent Study Indicates Smartphone App Can Influence Sun-Safety Behavior

According to a recent study published in *JAMA Dermatology*, a smartphone mobile app providing personal advice can help reduce unprotected sun exposure. David B. Buller, et al., "Evaluation of Immediate and 12-Week Effects of a Smartphone Sun-Safety Mobile Application: A Randomized Clinical Trial," *JAMA Dermatology*, January 28, 2015.

Using the app, the researchers collected data from 202 adults about their sun exposure during a three-month period. The app allows participants to share insights on sun-safety practices and pushes out notifications reminding users to apply sunscreen or to get out of the sun. The researchers found that the participants reported more shade use, but less sunscreen use, and that there was no significant difference in sunburns. While use of the app was less than expected, it did apparently provide some improved sun protection. The authors also found that use of the mobile app was greater than in a previous trial and was associated with greater sun protection, especially among women.