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SHOOK HARDY & BACON

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FIRM NEWS

Two Shook Partners Recognized for Excellence in FDA Law

Cosmetics and Personal Care Products Co-Chairs Debra Dunne and Madeleine McDonough are among the 50 Shook, Hardy & Bacon attorneys nationwide recently selected by their peers for inclusion in the 2017 edition of *The Best Lawyers in America*. The peer-review directory is regarded as the "definitive guide to legal excellence in the United States," and Dunne and McDonough were singled out for their expertise in FDA law.

SPOTLIGHT

FDA Continues Deluge of Warning Letters to Cosmetic and Dietary Supplement Manufacturers

The U.S. Food and Drug Administration (FDA) has continued issuing warning letters to makers of cosmetics and dietary supplements alleging misbranding of their products.

This month, FDA posted 10 warning letters alleging Food, Drug and Cosmetics Act (FDCA) violations.

Several supplement manufacturers have also received warning letters alleging product misbranding.

FDA's authority to regulate cosmetic labeling is limited. Determining, however, when a product crosses the line from a cosmetic to a drug, depends on the manufacturer's intended use for the product. According to the FDCA, cosmetics are "articles intended to be rubbed, poured, sprinkled, sprayed on, introduced into, or otherwise applied to the human body…for cleansing, beautifying, promoting attractiveness, or altering the appearance." (21 U.S.C. § 321(i)) Drugs are defined as "articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease" or "articles (other than food) intended to affect the structure or any function of the body." 21 U.S.C. § 321(g)(1).

FDA examines marketing claims for the products to show that the products are intended for use as drugs, making them unapproved and "misbranded" drugs under the FDCA. In its letters, FDA has highlighted claims of age-defying properties; promotion of regeneration of tissues or collagen production; safe alternatives to surgery; minimization of the appearance of wrinkles, spots or lines; and anti-inflammatory or health-promoting properties.

Letters to dietary supplement manufacturers also allege misbranding. In a letter to New Horizon Nutraceuticals LLC, FDA pointed to One World Whey™ Protein Power Food product label claims that included stopping inflammation, stopping cell damage and testimonials about pain reduction.

FDA concluded that "[t]he product is not generally recognized as safe and effective" and is thus a new drug under FDCA. (21 U.S.C. § 321(p)). Further, FDA told New Horizon that even if the product was not an unapproved new drug, it failed to comply with dietary supplement labeling regulations. The agency also found that the company's Elite Series Premium Whey vanilla ice cream and Dioxyme BCAA 6-3-3 Blue Razz dietary supplement were misbranded under section 403 of the FDCA. (21 U.S.C. § 343)

All of the letters ask the companies to notify FDA within 15 working days of the specific steps taken to correct the violations.

LITIGATION

FTC Wins Case Involving Supplement to Reverse Graying Hair

A Wyoming federal court has ruled in favor of the Federal Trade Commission (FTC), granting summary judgment in its lawsuit against Coorga Nutraceutical Corp. *FTC v. Coorga Nutraceuticals Corp.*, No. 15-0072 (D. Wyo., order entered August 15, 2016).

In July, FTC filed a motion to prevent dismissal of its suit against Coorga and company executive Garfield Coore. In the original complaint, filed in May 2015, FTC argued that the defendants labeled, marketed and sold the dietary supplement Grey Defence®, which they promoted as able to reverse or prevent the formation of gray hair. FTC contended the company and Coore made false or unsubstantiated and scientifically unproven representations.

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

Debra Dunne
215.575.3112
ddunne@shb.com

Laurie Henry
816.559.2421
lhenry@shb.com

Madeleine McDonough
816.559.2342
202.783.8400
mmcdonough@shb.com

If you have questions about this issue of the *Bulletin* or would like to receive supporting documentation, please contact Mary Boyd at mboyd@shb.com.

FTC's complaint included pages from Coorga Nutraceuticals' website, GreyDefence.com, which contained claims such as, "Grey Defence® Reverses Greying – Detailed Observational Study Proves it!" and "Grey Defence® supplements and re-energizes the body's 'antioxidant defence system', naturally reversing grey hair."

The defendants responded to FTC's allegations with scientific articles, the patent for Grey Defence and the company's user experience survey. Their exhibit, a "Summary of Scientific Investigation Leading to the Basic Formulation of Grey Defence," contained statements by Coore that purported a scientific basis for Grey Defence's claims.

FTC's July 22 motion countered that expert evidence shows the defense's survey, patent and articles failed to provide competent and reliable scientific evidence. Additionally, FTC argued that Coore was not qualified to provide expert testimony, and the opinions he offered as part of the defendants' brief supporting summary judgment dismissal were not admissible in support of the challenged claims.

In granting FTC's motion for summary judgment, the court said, "[T]here can be little doubt Defendants made material representations. Defendants undisputedly disseminated radio, television, and internet ads through the U.S. with the express claims that Grey Defence prevents and reverses the graying of human hair and is scientifically proven to do so."

The court found FTC's expert, George Cotsarelis, qualified to provide expert opinion on whether the defendants' research sufficiently substantiated their efficacy claims. The court also found that Coore, as a defense lay witness, could not provide expert opinions in an effort to refute Cotsarelis's expert opinions, and further noted that Coore did not quality as an expert under the Federal Rules of Civil Procedure.

The court ruled that injunctive and monetary relief be awarded and directed the parties to work to reach an agreement as to the terms by September 19, 2016.

Manufacturer of Just for Men Hair Dye Seeks to Dismiss Suit

The maker of Just for Men hair dye, Combe Inc., filed a motion to dismiss a lawsuit alleging that its product is dangerous and sought to strike the class allegations. *Povich v. Combe Inc.*, No. 16-0097 (E.D. Mo., filed August 3, 2016).

The original complaint, filed in February 2016 by a Just for Men user, claimed the defendants failed to adequately warn against the negative effects and risks associated with Just for Men cosmetic hair dye. The plaintiffs claimed that the defendants knew or should have known their products have a risk of burning, scarring, allergic reactions, anaphylactic shock, skin pigmentation and other injuries. Specifically, the plaintiffs argued that Just for Men products contain p-Phenylenediamine (PPD), which the U.S. Environmental Protection Agency apparently links to acute and chronic injuries such as severe dermatitis, renal failure, acute contact dermatitis, vitiligo, convulsions and comas, and eczematoid contact dermatitis. The plaintiffs contended that Just for Men products do not properly warn customers of these risks on labeling, inserts or marketing materials.

The defendants filed replies in support of their motion to dismiss and motion to strike class allegations. In support of the motion to dismiss, the defendants argued that the plaintiff had suffered no injuries. "He purchased a product, used it as he had intended to use it, and was sufficiently satisfied that he purchased it again (and again and again). It caused him no harm," the reply argues. Without an injury, the plaintiff does not have standing, the defense argued. In their reply in support of their motion to strike class allegations, the defense stated, "Discovery is not going to change the defects that are apparent on the face of the Complaint and that make certification of the proposed class impossible here. Accepting the facts alleged by plaintiff as true, he has suffered no injury, so he has no standing and will never be an adequate class representative, irrespective of what happens in discovery." The reply also noted that the plaintiff had abandoned the personal injury claims of people that he claims suffered from physical injury, amounting to improper claims splitting.

In response, the plaintiffs' opposition to the motion to strike class allegations argued that the defense motion was "severely premature, as no discovery has been conducted" and that the plaintiffs "have appropriately alleged their class clams."

LEGISLATION, REGULATIONS AND STANDARDS

FDA Releases Draft Guidance for Dietary Supplement Industry

The U.S. Food and Drug Administration (FDA) has issued revised draft guidance intended to "help industry in evaluating whether to submit a premarket safety notification for a new dietary ingredient (NDI), or for a dietary supplement containing an NDI, and in preparing such premarket safety notifications."

The Dietary Supplement Health and Education Act (DSHEA) requires manufacturers and distributors to notify FDA 75 days in before marketing a dietary supplement containing a NDI, a term defined as an ingredient not marketed in the United States before October 15, 1994.

"This revised draft guidance is an important step forward in the agency's work to protect public health from potentially dangerous new dietary ingredients," said Steven Tave, acting director of the FDA's Office of Dietary Supplement Programs. "Notification of new dietary ingredients is the only pre-market opportunity the agency has to identify unsafe supplements before they are available to consumers. The revised draft guidance is intended to improve the quality of industry's new dietary ingredient reporting so the FDA can more effectively monitor the safety of dietary supplements."

Comments on the draft guidance are due by October 11, 2016. *See FDA News Release,* August 11, 2016; *Federal Register*, August 12, 2016.

FDA Warns of Mercury Dangers in Imported Skin Care Products

The U.S. Food and Drug Administration (FDA) recently released a consumer update cautioning against using skin creams, beauty soaps and lotions that contain mercury. According to FDA, "The products are usually marketed as skin lighteners and anti-aging treatments that remove age spots, freckles, blemishes, and wrinkles. Adolescents may use these products as acne treatments."

FDA directs consumers to review product labeling, and if mercurous chloride, calomel, mercuric, mercurio, or mercury are listed, to immediately stop using the product. Consumers are also encouraged to be wary of products without labels or with labels without ingredient listings in English.

"Even though these products are often promoted as cosmetics, they also may be unapproved new drugs under the law," said Linda Katz, director of FDA's Office of Cosmetics and Colors. FDA does not allow mercury to be used in cosmetics or drugs except under certain conditions, which these imported products do not meet. *See FDA Consumer Update*, July 26, 2016.

Trade Association Announces Launch of Dietary Supplement Warning Letter Database

The Natural Products Association (NPA), a dietary supplement industry trade association, has launched a database containing U.S. Food and Drug Administration (FDA) warning letters and information about other federal agencies' enforcement activities.

"NPA is proud to announce a database for the industry that is more than just warning letters," said NPA Chief Operating Officer Daniel Fabricant. "It differentiates itself by capturing enforcement actions from various agencies. While it is searchable in many different ways you would think a warning letter database would be, it is also being designed to search disease claims/claim categories and allow for customized reports by member end users."

The database tracks various agency enforcement actions and currently contains actions taken by the U.S. Department of Justice, U.S. Food and Drug Administration (FDA), and the Federal Trade Commission since 2008. It also contains more than 440 publically released FDA warning letters.

GLOBAL

EU Bans Methylsothiazolinone in Leave-on Cosmetic Products

The EU ban on methylsothiazolinone (MI) in leave-on Cosmetic Products was published in the *Official Journal of the European Union* in late July 2016, amending Annex V (preservatives) to Cosmetics Regulations.

The European Union notified the World Trade Organization of the pending prohibition in January, and in the spring the European Commission voted on the proposed modifications, resulting in support for the ban on MI in leave-in products and restrictions on its use in rinse-off products.

Manufacturers must remove products from the market that fail to comply with the revised regulation by February 12, 2017.

China Revises Sunscreen Rules; Investigations Reveal Cosmetic Regulation Violations

The China Food and Drug Administration (CFDA) has revised its sunscreen labeling requirements and announced that it will take action against manufacturers whose products are noncompliant.

CFDA has clarified new guidelines for the labeling of Sun Protection Factors (SPFs) such that sunscreens with SPFs between 2 and 50 must now list the actual value on their labels. UVA protection factors (PFA) classes were also changed and must correspond with UV protection values. Those with PFA 2-3 are to be labelled as PA+, 4-7 as PA++, 8 to 15 as PA+++, and 16 or higher as PA++++. Before these new guidelines, sunscreens in China were only measured as high as SPF30 and PA+++. Now, the guidelines allow for up to a SPF50, with anything higher labeled as SPF50+ and for protection values up to PA++++. Waterproof sunscreens are not allowed to have decreased SPF values of more than 50 percent. Manufacturers can now apply for a modified license if they would like to adjust claims in currently approved sunscreens. Sunscreens previously approved by CFDA, however, can use their current packaging until June 30, 2017. As of December 1, 2016, applications for licenses must comply with the new rules.

The Chinese government focuses on pre-market approval and licensing of cosmetic products. Recent post-market investigations, however, have allegedly found manufacturers of sunscreen products using higher than allowed amounts of certain ingredients. Regulations prohibit manufacturers from using more than 4 percent Ethylhexyl Salicaylate or more than 5 percent of 4-Methylbenzyldene Camphor, which are used as sun protection and UV filter. Investigations by Chinese authorities apparently revealed 84 batches of domestically produced sunscreen with ingredients in violation of licensing and labeling guidelines. These manufacturers are said to face “severe punishment” or a ban on sales.

Reportedly, CFDA has advised that products with higher than allowed amounts of those ingredients should immediately remove them from the market and that violations should be reported. *See Chemlinked*, August 11, 2016; *Cosmetics Design-Asia*, August 24, 2016.

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.

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