ISSUE 36 | NOVEMBER 20, 2014

# LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

CONTENTS



## FIRM NEWS

### Saikali to Participate in Global Cyber Security & Data Privacy Forum

Shook, Hardy & Bacon Data Security & Data Privacy Practice Co-Chair Al Saikali will join a distinguished faculty in Washington, D.C., January 15-16, 2015, for the American Conference Institute's "15th Advanced Global Legal & Compliance Forum on Cyber Security & Data Privacy and Protection." He will serve as co-moderator of the opening session, titled "Federal Regulatory, Legislative, and Enforcement Landscape: Changes on the Horizon and Integrating New and Anticipated Initiatives Into Your Privacy and Compliance Program." The session panel includes Federal Trade Commission, Department of Justice and Federal Bureau of Investigation representatives.

## INSIDE GOVERNMENT

### House Approves Senate Bill to Speed Sunscreen Ingredient Approvals

The U.S. House of Representatives has approved without modification a Senate bill (S. 2141) that would establish a process for the Food and Drug Administration's (FDA's) approval of the active ingredients in over-the-counter sunscreen products. It now awaits the president's signature. "The Sunscreen Innovation Act" would limit FDA to 300 days from the date of application to issue a proposed order reflecting its determination that an ingredient is generally recognized as safe and effective (GRASE) for use in nonprescription sunscreens. It would also require the agency to issue draft guidance within one year of enactment to explain what information and data will be needed for applicants to demonstrate that a particular ingredient meets the "safety and efficacy standard for determining whether a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients is GRASE and is not misbranded." The legislation would further require the Government Accountability Office to issue a report within three years on FDA's progress in completing the required reviews.

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*SHB 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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### Democratic Representative-Elect Pledges to Lead Fight to Ban Animal Testing

U.S. Rep.-elect Don Beyer (D-Va.) has reportedly indicated to his constituents and supporters that he, like retiring Rep. Jim Moran (D-Va.), will work to enact legislation that would prohibit testing cosmetic products on animals. In a campaign email, Beyer said, "The United States must be a world leader and not a follower" on this issue. With Republicans taking control of Congress in 2015, this type of legislation may be difficult to pass, although more than 140 cosmetic companies have endorsed a bill that Moran introduced to ban animal testing and the sale of any new cosmetics if the product or any component was developed with animal testing. Of the 55 representatives signing on as co-sponsors of the Moran bill just one was a Republican who has apparently received contributions from the Humane Society Legislative Fund. *See Salon.com*, November 15, 2014.

### FDA Sues Dietary Supplement Maker over Alleged Manufacturing Shortcomings

The U.S. Food and Drug Administration (FDA) has filed a complaint against SciLabs Nutraceuticals, Inc. and its CEO Paul Edalat, seeking to permanently enjoin them from distributing dietary supplements that are adulterated due to the alleged failure to, among other things, test product ingredients, establish product specifications, prepare batch production records, document manufacturing practices, and establish and follow written quality control procedures. *United States v. SciLabs Nutraceuticals, Inc.*, No. 14-1759 (U.S. Dist. Ct., C.D. Cal., filed November 4, 2014). These alleged shortcomings apparently came to light during January and February 2014 inspections of the company's Irvine, California, facility and follow previous deviations from good manufacturing practices documented in 2012 and 2013.

FDA seeks an order enjoining the defendants from distributing dietary supplements until it complies with the law and allowing FDA to inspect its places of business to ensure continuing compliance with the injunction's terms.

## LITIGATION AND REGULATORY ENFORCEMENT

### Partial Class Certification Granted in Homeopathic Flu Remedy Suit

A federal court in California has granted partial certification to a class of purchasers of Boiron's homeopathic flu remedies in a suit claiming that label statements about the relief of flu symptoms are false. *Lewert v. Boiron, Inc.*, No. 11-108-3 (U.S. Dist. Ct., C.D. Cal., order entered November 5, 2014). The court earlier denied class certification because the named plaintiff, who has since been voluntarily dismissed, gave inconsistent deposition testimony as to whether he had actually read the product label before purchasing it. Additional details about that ruling appear in Issue 21 of this *Report*.

The new named plaintiff alleges that he purchased Oscillo®, relying on the label statement that it treats flu-like symptoms, and stopped taking it after two doses, because it did not relieve his symptoms. He briefly researched the product's ingredients and learned that the active ingredient was "a very minute portion of a duck liver that is boiled in many hundreds of gallons of water and then extracted and done again." He claims that "this process yields a solution so dilute that it cannot possibly contain a single molecule of the incubated duck hearts and livers" and that placing this ultra-dilute solution of sugar pellets makes it a sugar pill. Any relief that could be provided, he alleges, comes "solely from a placebo effect."

The court rejected the company's claim that the class is unascertainable because (i) it maintains no records of individual purchasers and "most consumers do not keep receipts for purchases of cheap products" such as Oscillo, (ii) the court would have to determine whether a particular purchase occurred after the close of a similar class action that was settled for $5 million and whether that settlement publicity had any effect on each class member, and (iii) the proposed class is overly broad due to the inclusion of people who benefitted from the product or received a full refund and those who bought the product on a physician's recommendation rather than the company's representations. The court noted that the exact purchase date will be important to avoid requiring the defendants to pay a double satisfaction, stating, "This may be problematic for purchases allegedly made within the first month or so of the proposed class period," which follows the class period in the settled case, and further stated, "Nevertheless, this concern regarding the apportionment of damages is insufficient to defeat class certification." The court also observed that it could determine which customers had received refunds and would be ineligible to recover damages because "Boiron presumably maintains records of the individuals to whom it pays refunds."

The court briefly analyzed the Rule 23 class-certification requirements and found each one satisfied. But the court focused some attention on whether the new named plaintiff was credible and thus adequate to represent the class. Boiron had alleged that he was a manufactured plaintiff, had a relationship with an attorney who had brought other cases against the company and also had credibility problems. The court apparently required the attorney, the plaintiff's brother and plaintiff's counsel to submit declarations about their relationships and involvement in the litigation. The court had some reservations about "the bona fides" of the plaintiff's claim, since he stopped taking Oscillo® after doing online research and deciding that the product was not going to work. The court stated that "he lacks a background in pharmacology, chemistry, or a similar field which would allow him to judge Oscillo's efficacy based on its active ingredient." The court determined, however, that its suspicions were not sufficient to render the plaintiff inadequate.

The court agreed with Boiron that the class could not include purchasers of Children's Oscillo® because the named plaintiff had not purchased it, and that the definition needed additional modification to account for new packaging that Boiron used, as required by the other class-action settlement. Thus the court limited the class period to purchases made before the packaging with so-called *Gallucci* disclaimers was introduced into the stream of commerce. The class period is therefore relatively short, confined to purchases made after July 27, 2012, and up to August 31, 2013.

**Federal Magistrate Certifies Statewide Classes in "Organic" Labeling Suit**

A federal magistrate in California has certified two statewide classes of those who purchased Hain Celestial Group Inc.'s Avalon Organics and Jason personal-care product lines that were labeled organic but allegedly contained less than 70-percent organic ingredients as required by the state's Organic Products Act (COPA). *Brown v. Hain Celestial Group, Inc.*, No. 11-3082 (U.S. Dist. Ct., N.D. Cal., San Francisco Div., order entered November 14, 2014). The plaintiffs alleged violations of COPA, the Unfair Competition Law, Consumers Legal Remedies Act, and the Commercial Code's express warranties provision.

Among other matters, Hain contended that (i) the class definitions in the plaintiffs' motion for certification differed from the definitions in the first amended complaint and potentially included non-actionable products, and (ii) the class is not ascertainable because consumers must self-identify and are unlikely to have receipts. The magistrate noted that class definitions are often revised over the course of a lawsuit and said this was "not a ground on which to viably challenge the plaintiffs' motion." She did, however, discuss at some length Hain's suggestion that the Avalon Organics class definition violates "one-way intervention" because it asks the court to make a merits ruling before class certification—i.e., the class would expand or contract depending on whether post-June 2011 Avalon Organics purchasers could prove that water used to rehydrate aloe powder counts toward COPA's 70-percent threshold, a matter raised in the plaintiffs' summary-judgment motion. The magistrate agreed that "one-way intervention" is a serious issue, because a merits ruling before certification binds the named parties but not the absent putative class members who would be able to "re-litigate ostensibly decided questions. Generally speaking, this is inefficient and unfair."

The magistrate agreed with Hain that she should not rule on merits issues before a class is certified and thus denied as premature the summary-judgment motion without prejudice. Still, the magistrate observed that "within the context of ascertaining the class, the issue is not quite the one that Hain identifies. . . . Hain misapprehends the role and effect of the parties' disagreement over whether water counts toward organic content in the reformulated (after about June 2011) Avalon Organics products. That issue doesn't affect

the class definition. All purchasers are defined into the class. A key merits question for those who bought after June 2011 will then be: Does water count toward organic content? If Hain proves that water should count, then Hain will prevail over post-June 2011 buyers."

The magistrate further disagreed with Hain that the class was not ascertainable, distinguishing cases to the contrary because they were either in a different circuit or involved a multiplicity of products, a "proliferating variety" in product labels (which the plaintiffs here accounted for in their class definitions) or potential damages that were "wildly disproportionate to any adverse effects class members suffered." The magistrate assessed the Rule 23(a) prerequisites and the Rule 23(b)(3) predominance and superiority requirements and found them all met. The magistrate also rejected Hain's objections to plaintiffs' damages models and found them consistent with *Comcast*. Having certified two damages classes, the magistrate declined the alternative injunction-only class requested under Rule 23(b)(2).

### FTC Finalizes $1.5 Million Settlement with Caffeine-Infused Clothing Makers

The U.S. Federal Trade Commission, in a 5-0 vote, has approve two final orders settling claims that Norm Thompson Outfitters, Inc. and Wacoal America, Inc. misled consumers by promoting their caffeine-infused undergarments as able to reshape the wearer's body and reduce cellulite. The final orders require the companies to pay $230,000 and $1.3 million, respectively, that FTC will use to provide refunds to consumers. Information about the consent agreements appears in Issues 33 and 34 of this Report. *See FTC News Release*, November 10, 2014.

### Nature Made Glucosamine Challengers Tentatively Certified as Class

In a tentative ruling, a California federal court has reportedly certified a class of purchasers of Nature Made TripleFlex glucosamine supplements; they allege that the product fails to provide advertised joint-health benefits. *Barrera v. Pharmavite LLC*, No. 11-4153 (U.S. Dist. Ct., C.D. Cal., tentative ruling given November 6, 2014). The court found "some classwide basis of proof" despite being "dubious about some of the merits of plaintiffs' case." The judge also invited the parties to confer and stipulate whether she should be removed from the case because she had seen moderate improvement after taking a different glucosamine supplement at the recommendation of her doctor for some joint inflammation in her hand. *See Law360*, November 6, 2014.

### Putative Class Challenges Vital Pharma's Energy Enhancement Claims

A Massachusetts resident has filed a putative statewide class action against a Florida company that makes an energy drink, Redline® Xtreme Energy Drink, which is allegedly marketed as a dietary supplement, claiming that it misleads

the public into believing that the product is "university proven with statistically competent, reliable and scientific evidence to safely and effectively increase, energy, mental focus, and reaction time," when it is actually "associated with adverse health effects" and is otherwise inadequately labeled. *Mark v. Vital Pharm., Inc.*, No. 14-14148 (U.S. Dist. Ct., D. Mass., filed November 12, 2014).

The plaintiff alleges that she "purchased the Product to obtain energy, for an improvement in reaction time, and an increase in mental focus," but it "caused her to suffer adverse health effects, including dizziness, jitteriness, and heart palpitations." Still, she seeks economic damages only, claiming that the product was worthless or that she and class members paid a price premium for it. The complaint mentions specific ingredients, such as anhydrous caffeine, evodiamine, tyrosine, yerba mate extract, green tea extract, 5-HTP, vinpocetine, and yohimbine, described as "notable for the adverse effects they cause to humans and go well beyond the Product's goal of energy enhancement." The plaintiff contends that the product "misleadingly represents that it is no stronger than less than two cups of coffee."

Alleging violation of Massachusetts unfair competition law, breach of express warranty and implied warranty of merchantability, and unjust enrichment, the plaintiff seeks declaratory and injunctive relief, including corrective advertising; actual, consequential and special damages; attorney's fees; and costs.

**Putative Class Action Alleges That Supplements Contain Anabolic Steroids**

A consumer has filed a putative class action in a Florida federal court alleging that three products manufactured by Purity First and Mira Health were falsely advertised because they contain undisclosed and "extremely harmful" anabolic steroids. *Morales v. Purity First Health Prods., Inc.*, No. 14-587 (U.S. Dist. Ct., N.D. Fla., filed November 3, 2014). According to the complaint, several Healthy Life Chemistry supplements contain Dimethazine and Dimethyltestosterone as well as Methasterone, which the Drug Enforcement Administration has apparently classified as a Schedule III controlled substance. These steroids, the plaintiff argues, can cause a variety of side effects, including kidney failure, increased risk of stroke and heart attack, unusual hair growth, and short stature in children.

The complaint cites the U.S. Food and Drug Administration's 2013 consumer warning, which stated that the agency had received 29 adverse incident reports related to Healthy Life Chemistry B-50, Multi-Mineral and Vitamin C. Purity Life and Mira Health later initiated a nationwide recall of specific product lots. The plaintiff alleges deceptive and unfair trade practices, false advertising, breach of express and implied warranties, negligence, and unjust enrichment, and seeks class certification, a declaratory judgment, an injunction, damages, and a corrective advertising campaign.

## INTERNATIONAL DEVELOPMENTS

### EU Project Poised to Develop Cosmetic Packaging with Nanoparticles

A 24-month project, dubbed "Nanopack," financed by the Valencian Institute of Business Competitiveness, is reportedly working to develop the first prototypes of packaging for cosmetics using nanomaterials. Packaging research institutes the Technological Institute of Plastic and AINA Technological Centre will collaborate on the research and development project, which offers the promise of adding the nanoparticles to biopolymers from renewable resources to give the plastics desirable properties, such as a higher gas barrier and improved mechanical and thermal properties relating to design, weight, strength, and durability. *See Packaging Europe News*, November 12, 2014.

### French NanoProduct Registry Triples

With formulators and distributors adding to their notifications, the number of declarations included in the French nanomaterials register apparently tripled during its second year of implementation. In its first year, the register included 3,409 declarations; this year, it includes 10,417. Cosmetics and personal-care products account for 23 percent of the chemical declarations made in 2014, while perfumes and related products account for .5 percent of these declarations.

### Turkish Cosmetics Company Criticized for Use of Terrorist's Image in Advertising

According to a news source, Turkish cosmetics company Epila has been criticized for using an image of Khalid Sheikh Mohammed, former al-Qaeda leader and "principal architect" of the September 11 attacks, in an advertisement for a hair-removal product that apparently reads, "Waiting won't get rid of that hair!" Critical articles appeared internationally in British, Russian, Spanish, and American media, although many adopted an amused tone. Epila reportedly told English-language Turkish newspaper the *Hürriyet Daily News*, "We didn't know that he was a terrorist. This image is in popular use in Turkish memes on the Internet. The guy is quite hairy, so we thought his body was a good fit for our ad. We didn't want to imply anything political. We didn't know that it could become an international story. I repeat: We featured him for his hair, not terrorism." *See vox.com*, November 1, 2014.

## EMERGING TRENDS

### Trade Group Creates Online Tool for Dietary Supplement Industry

Industry trade association Council for Responsible Nutrition has created a free searchable online database of U.S. Food and Drug Administration (FDA) warning letters sent to dietary supplement companies. The goal is to enable

the industry to improve its regulatory compliance. Council President and CEO Steve Mister said, "Our goal is to help companies in the supplement industry better understand the types of transgressions that will trigger a Warning Letter from FDA, so that all companies can learn from others' mistakes and identify priorities in FDA enforcement, thereby raising the level of compliance with the law." The database currently contains some 300 letters issued from January 2008 through August 2014 involving purported violations of dietary supplement good manufacturing practices; illegal marketing of supplements containing undisclosed pharmaceutical ingredients; or impermissible claims to prevent, treat, cure, or mitigate a disease. *See Council for Responsible Nutrition News Release*, November 13, 2014.

## SCIENTIFIC/TECHNICAL DEVELOPMENTS

### Cosmetics, Personal Care Products Purportedly Linked to Kids' Allergies

A small study of households in India has purportedly associated higher levels of indoor pollutants, including household products, such as cosmetics and personal-care products that emit volatile organic compounds, with increased levels of asthma and hay fever. Titled "The Association of Household Air Pollution with Allergic Respiratory Diseases in Children," the study was presented during the November 6-10, 2014, American College of Allergy, Asthma and Immunology's (ACAAI's) annual scientific meeting in Atlanta. Researchers reportedly measured the indoor air in 70 households where no children had asthma or hay fever symptoms and the indoor air in 70 households that had at least one child with one of those conditions. *See ACAAI News Release*, November 7, 2014.