Shook, Hardy & Bacon L.L.P.

ISSUE 18 | JANUARY 24, 2014

# LEGAL TRENDS REPORT

COSMETICS • COSMECEUTICALS • DIETARY SUPPLEMENTS • NUTRACEUTICALS

CONTENTS



## INSIDE GOVERNMENT

### FDA Announces New Adverse Event Reporting Portal for Dietary Supplements

The U.S. Food and Drug Administration (FDA) has announced that "in the interest of efficiency and as a convenience to dietary supplement manufacturers, packers and distributors, as well as the public at large," it will now accept voluntary and mandatory dietary supplement adverse event reports via its new online portal. The agency notes that with more than 85,000 dietary supplements on the market and no product-specific registration requirement, adverse event reporting is "invaluable" in identifying harmful products and "critically important" in protecting consumers' health and safety. Under the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Public Law 109-462), the dietary supplement maker, packer and distributor whose name appears on the label of a dietary supplement marketed in the United States must report to FDA information about any serious adverse events received regarding its dietary supplement products when used in the United States.

For mandatory reporters, other than a new electronic alternative to the MedWatch 3500A paper form, the announcement does not change existing reporting requirements, and the agency will continue to accept paper 3500A and 3500 forms. Noting that anyone can submit a voluntary dietary supplement adverse event report (3500 form), FDA encourages physicians, in particular, to file voluntary reports when their patients have experienced adverse events associated with dietary supplements. FDA has sent letters to all dietary supplement manufacturers, packers and distributors encouraging them "to use the new capability and detailing its benefits." *See FDA News Release*, January 13, 2014.

### FDA Guidance Differentiates Liquid Dietary Supplements from Beverages

The U.S. Food and Drug Administration (FDA) has issued two final guidance documents for industry on distinguishing liquid dietary supplements from beverages. Titled "Distinguishing Liquid Dietary Supplements From Beverages" and "Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements," the documents update 2009 draft

*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.*

*For additional information on SHB's Health, Wellness & Personal Care Products capabilities, please contact*

***Debra Dunne***
*215-278-2555*
*ddunne@shb.com*

***Laurie Henry***
*816-559-2421*
*lhenry@shb.com*

***Madeleine McDonough***
*816-559-2342*
*mmcdonough@shb.com*

*If you have questions about this issue of the Update, or would like to receive supporting documentation, please contact Mary Boyd (mboyd@shb.com) or Dale Walker (dwalker@shb.com); 816-474-6550.*

guidance intended "to help dietary supplement and beverage manufacturers determine whether a liquid food product is properly classified as a dietary supplement or as a beverage, and to remind the industry of legal requirements regarding the substances that may be added to either type of product."

In "Distinguishing Liquid Dietary Supplements from Beverages," FDA describes the factors characterizing liquid products deemed dietary supplements and those characterizing beverages deemed conventional foods. These include product claims, names, packaging, serving size, recommended daily intake, conditions of use, and product composition, as well as statements or graphic representations in labeling, advertising and other marketing practices, including promotional Websites and social media. For example, use of the terms "beverage," "drink," "water," or "soda" in the marketing or the product name would render the product a conventional food. Representation as a conventional beverage can also be implied by the size, shape, color, and design of the container or other packaging.

"Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements," reminds industry about the different regulatory requirements under the Federal Food, Drug, and Cosmetic Act for ingredients used in these two types of products. For beverages, ingredients must be either GRAS (generally recognized as safe) or approved as food additives. For dietary supplements, any substance considered a new dietary ingredient (NDI) must have a pre-market NDI notification to FDA; non-dietary ingredients such as binders would need either food additive approval or GRAS status for their intended use. The agency noted that some of the novel substances added to conventional foods, including beverages, "may cause the food to be adulterated because these added substances may not be GRAS for their intended use and are not being used in accordance with a food additive regulation."

### California Unveils Cosmetics Database

The California Department of Public Health (CDPH) has **unveiled** its Safe Cosmetics Program Product Database, a searchable Website to help consumers determine whether the cosmetic products they are using contain ingredients known to cause cancer or reproductive harm. Reportedly the first state-run public resource of its kind, the database was created to make information collected under the California Safe Cosmetics Act (CSCA) of 2005 publically available. CSCA requires each cosmetics company to report to the program if (i) its products are sold in California; (ii) the company has more than $1 million a year in aggregate cosmetic sales; and (iii) its products contain a chemical ingredient found to cause cancer, birth defects or other reproductive damage.

"Inclusion in this website means a product contains a chemical that has been identified as a known or suspected carcinogen or reproductive toxin by one of the authoritative bodies named in the Safe Cosmetics Act such as the International Agency for Research on Cancer or the National Toxicology Program," said CDPH Director Ron Chapman. "It does not mean that the cosmetic product itself has been shown to cause cancer, but since most products are not extensively tested for safety, providing information on chemical components will allow consumers to make more informed choices."

Advocacy groups, including the Campaign for Safe Cosmetics, applaud the database and say that it reveals a snapshot of "a Wild West industry where cosmetics companies can and are using a shocking array of unsafe and cancer-causing chemicals in seemingly innocent products." According to Campaign for Safe Cosmetics Co-founder Janet Nudelman, "California's database is one more tool for consumers to use to make safer choices about cosmetics. It will also keep the pressure on companies to reformulate products to remove chemicals linked to adverse health effects."

Some 475 companies have submitted information on roughly 30,000 products so far, and chemicals in the database include phthalates, mercury and mercury compounds, toluene and formaldehyde, and other known toxicants. The Website also includes information to educate users as to how exposure to chemicals can affect their health and what is known about specific chemicals. *See CDPH News Release*, January 10, 2014; *SFGate.com*, January 13, 2014.

## LITIGATION AND REGULATORY ENFORCEMENT

### L'Oréal & eBay Settle Dispute over Counterfeit Sales

Without disclosing the terms of their agreement, cosmetics maker L'Oréal and auction company eBay have settled a long-running legal dispute involving the online sale of unauthorized or counterfeit L'Oréal products. The cosmetics company sued eBay in five European countries in 2007. According to a joint statement issued on January 15, 2014, details, "including financial terms in favour of L'Oréal, are confidential." They refer to a European Court of Justice decision from 2011, finding that online retailers such as eBay could be held liable if users sell counterfeit goods on their Websites, and state, "The Parties believe that cooperation, rather than litigation, is the way forward to fight against counterfeiting." The EU court ruling was made in the context of trademark infringement claims filed by L'Oréal. At issue were products such as testers that are not intended for sale, as well as goods bearing the cosmetic company's trademarks intended for sale elsewhere, or perfumes and cosmetics sold on eBay without packaging. *See The Wall Street Journal* and *Law360*, January 15, 2014.

### Resolution Reached in Counterfeit Cosmetics Claims in Australia

According to a news source, Australia's Federal Court has approved a settlement that will require Target Australia to pay Estée Lauder $1 million and state in a corrective advertising campaign that the retailer was unable to prove that the M.A.C. line of cosmetic products it was forced to remove from store shelves was not fake. Details about the case and a previously unsuccessful effort to resolve the cosmetic company's allegations appear in Issue 5 of this *Report*. A Target spokesperson reiterated that the company did not admit guilt or liability, saying "The testing required to prove if the products were authentic would have been both costly and time-consuming, and so we have taken the commercially prudent decision to settle." The corrective ads will run on the front page of Target's catalogue and for 30 days on its Website, Facebook page and in-store signage. *See The Australian*, December 20, 2013; *CosmeticsDesign-asia.com*, January 16, 2014.

### Court Allows Amendment of False Efficacy Allegations Against Vitamin Shoppe

While a federal court in New Jersey determined Article III standing in the plaintiff's favor, it has dismissed, without prejudice, putative class claims that the Vitamin Shoppe's labeling and advertising of a dietary supplement product—"True Athlete Training Formula"—violate state consumer-fraud laws. *Hodges v. Vitamin Shoppe, Inc.*, No. 13-3381 (U.S. Dist. Ct., D.N.J., decided January 15, 2014).

The defendant apparently argued that the plaintiff cannot establish that he sustained an injury-in-fact based on the mere purchase of a product, contending that the complaint fails to allege that he ingested the supplement or, when using it, was "disappointed by its underperformance and/or failure to provide the promised enhancement to his exercise routine." Because "[t]his is not a personal injury action," the court found that the alleged economic loss was sufficient to establish Article III standing.

The court agreed with the defendant that the complaint failed to adequately plead consumer fraud, stating, "The principal deficiency in Plaintiff's claim lies in the Complaint's lack of factual allegations specifying how or why the statements made on the Product label and on Vitamin Shoppe's website were false or deceptive. The Complaint fails to state with plausibility, much less particularity, that the statements violate the Consumer Fraud Act." The court further observed, "The Complaint recites various scientific studies concerning the efficacy of the active ingredients to perform various functions in the body. However, their findings, as described by the Complaint, are by and large inapposite to the crucial assertion that Vitamin Shoppe's representations about the Product's benefits are false." As well, the court found that the basis for the plaintiff's allegations that the product representations are false "requires a leap from the existing scientific research" and "this leap is made through nothing but speculation."

The court further rejected the plaintiff's "prior substantiation theory," that is, the "allegations of falsity are rooted in the lack of prior substantiation that the benefits are possible at the Product's dosage of active ingredients." According to the court, this is not a viable theory under New Jersey law. The court outlined the types of allegations that the plaintiff must make in an amended complaint to cure his pleading deficiencies as to the consumer fraud, express warranty, implied warranty, and unjust enrichment claims.

### Indictment Returned Against Former Va. Governor

The U.S. attorney for the Eastern District of Virginia has reportedly charged former governor Robert McDonnell and his wife for illegally accepting more than $135,000 in gifts and loans from the former CEO of Star Scientific, which recently received a warning from the U.S. Food and Drug Administration over therapeutic claims for its Antabloc dietary supplement. Additional information about the warning appears in Issue 17 of this *Report*.

According to a news source, McDonnell repaid more than $120,000 to former CEO Jonnie Williams, but characterized the gifts and loans as legal. He has vowed to fight what he calls "false allegations" of wire fraud, conspiracy and obtaining property under the auspices of his official duties. *See USA Today*, January 21, 2014.

## EMERGING TRENDS

### L'Oréal's Garnier and Revlon Withdraw from Chinese Beauty Market

Citing a slowing market, beauty giant L'Oréal reportedly plans to withdraw its Garnier line of beauty products from China to concentrate on marketing its L'Oréal Paris and Maybelline New York lines, which apparently perform more strongly there. The action follows rival Revlon's recent announcement that it plans to pull out of the Chinese market altogether.

Noting the period a few years ago when China was experiencing double-digit annual GDP growth and consumers were clamoring for foreign cosmetic and beauty products, some industry experts claim that firms selling such items may have set overly ambitious sales targets. Now that China resembles a more typical emerging market—still with much potential for growth, experts note, it is less certain that every foreign product entering it will experience favorable sales. Sales of beauty products reportedly grew by only 10 percent last year, down from 15 percent two years earlier.

Other contributors to China's slowing market for foreign beauty products reportedly include (i) heavy online discounting of brands that are "supposed to be" expensive; (ii) more sophisticated consumers unwilling to pay a premium for anything but the very best brands; (iii) rising costs for the "beauty assistants" and other saleswomen used to market such products; (iv) complex

marketing and logistics in such a large and diverse country; and (v) the increasing popularity of products made by Chinese cosmetics manufacturers. Insiders also point out that China's legal requirement that all cosmetics be tested on animals adds to Western firms' costs and often creates public-relations challenges. *See JingDaily.com*, January 9, 2014; *The Economist,* January 11, 2014.

### British Scientists Develop Alternative Toxicity Test for Mascara

Scientists at the University of Liverpool in England have developed a new toxicity test for mascara that uses protozoa, or single-celled organisms, claiming that the test has "great potential" to become a cheaper, more reliable alternative to animal testing. Although the protozoa have a similar metabolism to animals, they are not apparently classified as animals.

The scientists tested six different brands of mascara by painting samples onto glass slides and placing the slides into experimental chambers along with two types of protozoa and their food. The two protozoa species were chosen because of their genetic similarities to humans, historic use as model organisms and large size, which made it easier to monitor their growth. Noting a significant difference between the mascara brands—some killed the protozoa, some slowed the growth rate and others did not harm them at all—project supervisor David Montagnes observed, "if there was a slight toxicity of the mascara, the [protozoa] grew up slower than if there was no toxicity."

According to Montagnes, this method could potentially be used to test cosmetics other than mascara, including lipstick and perfume. "It could be used on all kinds of cosmetics that are potentially toxic. The basic premise could be applied all over the place, to anything you could paint onto a [glass slide]," he said. *See University of Liverpool News Release* and *CBC News.com*, January 3, 2014.

## INTERNATIONAL DEVELOPMENTS

### Philippines Bans Lead in Cosmetics

The Philippines' Department of Environment and Natural Resources (DENR) has issued an **order**, effective January 7, 2014, that prohibits the use of lead in cosmetics and other products. Although environmental groups who have long campaigned against the country's use of heavy metals in consumer products reportedly welcome the ban, they have voiced concern about the government's ability to enforce it, citing previous unsuccessful attempts to enforce bans on cyanide, asbestos and mercury.

Among other things, the order aims to (i) "increase awareness about the toxicity of lead and lead compounds and the availability of technically superior and safer alternatives" and (ii) "develop the framework for proper implementation of appropriate prevention-based programs to reduce and eliminate risks from

the use of lead." Import, manufacturing, distribution, or recycling firm executives who violate the order face imprisonment of up to six months under the country's toxic substances law, the ministry reportedly said. *See YahooNewsSingapore.com*, January 10, 2014; *ChemLinked.com*, January 20, 2014.

### Taiwan Changes Cosmetics Regulations

The Taiwan Food and Drug Administration (TFDA) has reportedly announced a public consultation on a revised list of coloring agents allowed in cosmetic products. The draft list includes 93 substances—20 fewer than the current list—divided into the following four classes, instead of the current two classes, based on the scope of their application: (i) "permitted in all cosmetic products"; (ii) permitted in all cosmetic products except those intended for application near the eyes, such as eye make-up and eye make-up remover; (iii) "permitted only in cosmetic products intended not to come into contact with the mucous membranes"; and (iv) "permitted only in cosmetic products intended to come into contact only briefly with the skin." If a colorant is not listed, it must be registered with TFDA before use, and foreign companies do not need to register products if they can prove with official documentation that a colorant has been approved in the European Union, United States and Japan.

On a related note, TFDA has reportedly amended its "Provision of Maximum Levels of Residual Heavy Metals (lead and arsenic) from Impurities in Cosmetics," effective January 8, 2014. The existing provision from TFDA's Notice No. 0940306865 in 2005 prohibits the use of lead, arsenic and their compounds in any cosmetic products. The amended standard further specifies that the residue concentrations of lead and arsenic, "produced as byproducts of irreplaceable raw materials required during production or any other technically unavoidable factors during the manufacturing process," shall be limited to a maximum of 10 ppm (parts per million) and 3 ppm, respectively. *See ChemLinked.com*, January 10 and 15, 2014.

## SCIENTIFIC/TECHNICAL DEVELOPMENTS

### Vitamin D Linked to Improved Cognition and Mood in Parkinson's Disease Patients

A recent study examining the relationship between vitamin D and neuropsychiatric function in people with Parkinson's disease (PD) reportedly suggests that increased levels of vitamin D may reduce the risk of developing cognitive impairments and depression in patients who suffer from the disease. Amie Peterson, et al., "Memory, Mood, and Vitamin D in Persons with Parkinson's Disease," *Journal of Parkinson's Disease*, December 9, 2013. Conducted by scientists from the Oregon Health and Sciences University, the study involved a cross-sectional analysis of 286 patients with PD and found that higher plasma vitamin D levels were associated with lower symptom severity, better cognition and less depression in the entire

group. Researchers also found that the relationships were even stronger in those who did not have dementia, which is experienced by approximately 30 percent of PD patients.

For the analysis, which was an add-on study to an ongoing longitudinal study of neuropsychiatric function in people with PD, patients were tested for measures of global cognitive function, verbal memory, semantic verbal fluency, executive function, and depression. The researchers also measured their vitamin D levels the same day. Of the group, 225 patients suffered from symptoms of dementia, while 61 did not. For all patients, those who had higher levels of vitamin D were better able to recall names and experienced a shorter delay in remembering items on a verbal learning test, the researchers observed. When divided into two groups, however, dementia and non-dementia, they noted that higher levels of vitamin D only appeared to improve fluency and verbal learning for Parkinson's patients who were free of dementia.

Commenting on the findings, lead study author Amie Peterson said, "The fact that the relationship between vitamin D concentration and cognitive performance seemed more robust in the non-demented subset suggests that earlier intervention before dementia is present may be more effective." The researchers also noted that (i) higher levels of vitamin D appeared to improve symptoms of depression in subjects who were free of dementia; (ii) higher vitamin D levels had no impact on depression for participants with dementia; and (iii) for the group as a whole, vitamin D levels made no difference on disease severity. Although the findings indicate a connection between vitamin D levels and cognition and mood, the authors remark that a cross-sectional study cannot determine causation. The study did not consider whether patients were taking vitamin D supplements. *See IOS Press*, January 17, 2014.

OFFICE LOCATIONS

**Geneva, Switzerland**
+41-22-787-2000
**Houston, Texas**
+1-713-227-8008
**Irvine, California**
+1-949-475-1500
**Kansas City, Missouri**
+1-816-474-6550
**London, England**
+44-207-332-4500
**Miami, Florida**
+1-305-358-5171
**Philadelphia, Pennsylvania**
+1-215-278-2555
**San Francisco, California**
+1-415-544-1900
**Seattle, Washington**
+1-425-765-0650
**Tampa, Florida**
+1-813-202-7100
**Washington, D.C.**
+1-202-783-8400