ISSUE 54 | MARCH 06, 2024

LEGISLATION, REGULATIONS & STANDARDS

Sen. Hatch Introduces New Bill Regulating Cosmetic Safety

Sen. Orrin Hatch (R-Utah) has introduced legislation aiming to modernize cosmetics regulation, proposing amendments to the Federal Food, Drug and Cosmetic Act that would add measures to regulate ingredients, monitor adverse reactions and establish best practices for manufacturing. The bill would also preempt state actions on cosmetic ingredients after the U.S. Food and Drug Administration (FDA) identifies a chemical for review.

The bill would require manufacturers and distributors to report adverse events to FDA, which is currently voluntary, and register all domestic and foreign manufacturers or distributors of cosmetic products. The legislation would also give FDA authority to suspend registration for companies selling products that have a "reasonable probability" of causing serious adverse health consequences.

Hatch's bill would allow FDA to permit third parties to assess and review ingredient safety; the Personal Care Products Safety Act, as proposed by Sen. Dianne Feinstein (D-Calif.), would require FDA to conduct its own safety reviews. Hatch's bill would be funded by congressional appropriation, while Feinstein's would be funded by user fees collected from cosmetic manufacturers. The bills cover similar subjects as the Cosmetic Modernization Amendments of 2017 introduced by Rep. Pete Sessions (R-Texas).

Laurie Henry
816.559.2421
lhenry@shb.com

ITC Declines to Investigate Omega-3 Supplements

The U.S. International Trade Commission (ITC) has reportedly declined to investigate a complaint filed by Amarin Pharma Inc. that alleged 18 companies falsely categorize unapproved new drugs containing omega-3 acids as dietary supplements. The complaint alleged that false labeling allows the companies to avoid clinical trials and approval protocols. ITC held that Amarin's complaint alleged violations under the Lanham Act and the Federal Food, Drug and Cosmetic Act, but the U.S. Food and Drug Administration is the proper authority to address the alleged violations.

Jennise Stubbs
713.227.8008
jstubbs@shb.com

FDA Letters Include Warning to SARMs Makers

The U.S. Food and Drug Administration (FDA) issued several warning letters to the makers of dietary supplements containing selective androgen receptor modulators (SARMs), which have been linked to liver toxicity and increased risk of heart attack and stroke. Infantry Labs LLC was warned that its distribution of the products The Officer and The Lieutenant violates the Federal Food, Drug and Cosmetic Act; Ironmag Labs was warned of similar violations regarding its Super DMZ 4.0, while Panther Sports Nutrition was warned about Ostarine MK2866 and LGD Max.

FDA also warned Biomin Industries about unapproved new drug violations as well as manufacturing and misbranding violations for multiple products, including Antibiotc for its similarity to the antibiotic drug category.

In another warning letter, FDA asserted that Create-a-Pack Foods Inc. had multiple manufacturing-practices violations, resulting in findings that its dietary supplements were adulterated and misbranded, primarily due to the failure to qualify ingredient suppliers.

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.

Schmidt's and Too Faced Plan Appeal of NAD Rulings

Schmidt's Deodorant Company and Too Faced Cosmetics LLC reportedly plan to appeal the National Advertising Division's (NAD's) adverse findings. NAD recommended that Schmidt's discontinue claims after finding that product testing did not

support the proposition that its deodorant "absorbs wetness or helps absorb wetness" despite not containing aluminum salts, found in antiperspirants. NAD also recommended that Too Faced Cosmetics discontinue ad claims that its mascaras provide "1,944% More Volume," noting it was "troubled" by the company's test methodology. In addition, NAD found that the company could not support the performance message in before-and-after pictures of consumers using the mascaras. Both companies may appeal to the National Advertising Review Board.

FDA Seeks Public Comment on Substantiation Requirements

The U.S. Food and Drug Administration (FDA) is seeking public comment on the dietary supplement claims substantiation requirements in the Food, Drug and Cosmetic Act. FDA invites comments on the following topics: (i) whether the collection of information is necessary for the performance of FDA's functions, including whether the information has "practical utility"; (ii) the accuracy of FDA's estimate of the burden of collecting the information; (iii) ways to improve the "quality, utility and clarity" of the information; and (iv) ways to "minimize the burden" of collection through automation or other information technology. Comments will be accepted through January 5, 2018.

Balance of Nature Ad Claims Referred to FTC

The National Advertising Division (NAD) has referred advertising claims made by Balance of Nature Inc. to the Federal Trade Commission (FTC) after the company failed to respond to a NAD inquiry. The Center for Responsible Nutrition challenged ads for the company's dietary supplements, which included testimonials that their products prevent pneumonia and mitigate symptoms of multiple sclerosis as well as implied claims that the products can prevent cancer.

FDA Issues Advisory On Kratom

The U.S. Food and Drug Administration has issued a health advisory for kratom, a botanical substance used in unapproved drugs and dietary supplements marketed to treat pain, anxiety, depression and other health issues. According to the agency, "kratom has similar effects to narcotics like opioids, and carries

similar risks of abuse, addiction and in some cases, death." The advisory also states that some consumers may believe that they can use kratom to treat opioid withdrawal symptoms, but FDA has found "no reliable evidence to support the use of kratom as a treatment for opioid use disorder."

GLOBAL

EU Proposes Restrictions on Tattoo Ink

The European Chemicals Agency (ECHA) has proposed new restrictions on nearly 4,000 substances used in tattoo inks and permanent cosmetics intended to limit long-term exposure to potentially hazardous substances. ECHA's report states that adverse effects are commonly "allergic in nature," but tattoo pigment deposits have been found in lymph nodes and the liver, raising concerns about lifelong exposure to the chemicals used in colorings. The report also states that tattoo inks have been found to contain heavy metals, phenols and formaldehyde and that systemic cancers or reproductive impact "cannot be ruled out."

ASA Upholds Ad Complaints, Including Misleading Snapchat Post

The U.K. Advertising Standards Authority (ASA) has upheld several advertising complaints.

ASA upheld complaints against Cambridge Nutraceuticals Ltd. and Healthspan Ltd. for advertising claims that the turmeric in their products supported healthy joints and helped maintain flexibility. Both companies relied on a pending European Food Safety Authority assessment of turmeric, which contained a negative opinion on such health claims. ASA also faulted Healthspan for not clarifying that vitamin C provided the advertised health benefits of its product Opti-Turmeric.

A complaint against New Nordic Ltd.'s magazine ads for Blue Berry Eyebright Plus and MelissaDream was also upheld. While some benefit claims for the products' ingredients are authorized, ASA noted, New Nordic's claims were exaggerated beyond the approved claims.

ASA also upheld challenges to ads for Innovaderma U.K. Ltd.'s Skinny Tan self-tanner, concluding that the company could not substantiate its claim that it was the bestselling tanner in the country. Further, the product's website stated, "No one should be

putting chemical DHAs on their skin," which ASA found likely to mislead consumers.

The agency also found that a Snapchat post by the celebrity spokesperson for Diamond Whites failed to disclose the commercial relationship. The company agreed to add the hashtag "#ad" to such posts in the future.

LITIGATION

Elaborate Cosmetics Packaging "Commonplace and Even Expected" by Consumers, Court Finds

Peter Thomas Roth Labs has won dismissal of a putative class action alleging the company deceptively packaged its Rose Stem Cell Bio-Repair Precious Cream in a box with a false top and bottom, hiding the product's actual size. *Gonzales v. Peter Thomas Roth Labs, LLC,* No. 17-1393 (C.D. Cal., entered November 17, 2017). The court found that the box accurately disclosed the net weight of the jar inside the box, including a "product actual size" notice with an arrow directed to the photo of the product. "In the context of the 'high-end cosmetics market,' 'elaborate packaging . . . is commonplace and even expected'" by a significant portion of the targeted consumers, the court held, dismissing the case. Additional details about the complaint appear in Issue 52 of this *Bulletin*.

Some Putative Class Action Claims Dismissed in Nature's Way Suit

An Illinois federal court has dismissed some allegations in a complaint brought against Nature's Way Products, leaving only the named plaintiff's claims for products she purchased. *McDonnell v. Nature's Way Prods. LLC*, No. 16-5011 (N.D. Ill., entered October 26, 2017.) The plaintiff alleged she relied on Nature's Way's representations that its vitamins were made in the United States and was deceived because some ingredients are manufactured outside of the country. The court found that the plaintiff had adequately pleaded economic injury, but the complaint contained no allegations connecting Nature's Way's activities in Illinois related to the products she did not purchase or to purchasers of the company's products outside of Illinois. Accordingly, the court dismissed for lack of personal jurisdiction all claims brought on behalf of non-Illinois residents as well as claims related to unpurchased products.

Ulta, Sexy Hair Concepts Lose Motion to Dismiss Sulfate-Free Shampoo Action

A Massachusetts federal court has denied a motion to dismiss a putative class action alleging that Healthy Sexy Hair Sulfate-Free Soy Moisturizing Shampoo was deceptively labeled because the product contains sulfates. *Crane v. Sexy Hair Concepts, LLC*, No. 17-10300 (D. Mass., entered October 10, 2017). The plaintiff alleged that she bought a bottle of shampoo prominently labeled as sulfate- and salt-free, but the small print on the back label showed that the shampoo contained sulfates and salts. The court was persuaded that a reasonable consumer could be "deceived by a large, unqualified, front-of-bottle representation" and that the plaintiff's allegation that she paid a premium price for the shampoo was a plausible economic injury.

FTC Announces Settlements with Supplement Makers

The Federal Trade Commission (FTC) has announced a $179-million settlement of charges against three individuals and 19 companies alleging they sold more than 40 weight-loss, muscle-building and wrinkle-reduction products using unsubstantiated health claims, "fake magazine and news sites, bogus celebrity endorsements and phony consumer testimonials." *FTC v. Tarr Inc.*, No. 17-2024 (S.D. Cal., entered November 14, 2017.) The settlement also includes a stipulation that the defendants will no longer use "negative-option" features to sell dietary supplements, cosmetics, foods or drugs, sell products on a trial or sample basis or sell "add-ons" when consumers purchase other products.

FTC also announced that a federal court has found several defendants, including Hi-Tech Pharmaceuticals and its Chief Executive Officer Jared Wheat, in contempt of court orders related to the sale of weight-loss supplements. *FTC v. Nat'l Urological Grp.*, No. 04-3294 (N.D. Ga., entered October 31, 2017). The court previously imposed more than $40 million in sanctions against the defendants. After protracted litigation over injunctions, two appeals and a bench trial, the court held that the defendants showed "an intentional defiance of the court's injunctions" and "repeatedly provided inaccurate and incomplete information in compliance reports submitted to the FTC." The court concluded that consumer redress in the amount of gross receipts for four of the products was appropriate, imposing a

sanction of $40,120,950. Additional information appears in Issues 30 and 32 of this *Bulletin*.

FTC and Maine announced a settlement with Health Research Laboratories LLC (HRL), ending a case alleging the company misleadingly marketed its BioTherapex and NeuroPlus supplements as targeting arthritis, reversing memory loss, causing weight loss and preventing the onset of Alzheimer's disease and dementia. *FTC v. Health Research Labs. LLC*, No. 17-0467 (D. Maine, proposed final judgment filed November 30, 2017). HRL apparently included fictitious medical doctors and consumer testimonials in its marketing and misrepresented the terms of a "risk free" trial period. Under the settlement agreement, HRL cannot make "any of the seven 'gut check' weight-loss claims that the FTC has publicly advised are always false with respect to any dietary supplement, over-the-counter drug, or any product rubbed into or worn on the skin," according to FTC's November 30, 2017, press release. The order imposes a judgment of $3.7 million that will be suspended upon payment of $800,000.

FTC's consumer-facing blog concurrently cited the settlement in its warning against "amazing health claims," such as pills that claim to "reverse signs of aging" or offer "rapid results."

DOJ Files Adulteration and Misbranding Complaint Against Riddhi USA

The U.S. Department of Justice (DOJ) has filed a civil complaint alleging Riddhi USA, Inc. distributed adulterated and misbranded dietary supplements. *U.S. v. Riddhi USA, Inc.*, No. 17-6154 (E.D.N.Y., filed October 23, 2017). The complaint alleges that U.S. Food and Drug Administration inspectors observed numerous regulatory violations during facility visits in 2015, 2016 and 2017. Riddhi and its owner allegedly failed to (i) establish product specifications for identity, purity, strength and composition of their supplements; (ii) conduct tests to verify the identity of ingredients; and (iii) establish and follow quality control procedures. The complaint also asserts that the company's product labeling fails to declare the place of business of the manufacturer, the product ingredients and the presence of soy.

California Plaintiffs Allege Two Supplement Companies Operate Pyramid Schemes

Two lawsuits filed in California federal court allege that vendors of dietary supplements are operating pyramid schemes. *Wu v. Jeunesse, LLC*, No. 17-7475 (C.D. Cal., filed October 12, 2017). In one case, four consumers allege that Jeunesse's "advanced interactive e-commerce model" is a pyramid scheme. The plaintiffs allege that the company's directors and marketing plans favor "recruitment over product sales" and do not require any product distributor to make any product sales to consumers "outside the distribution channel." They also assert that new distributors and putative subclass members were required to pay for materials, products and events produced by the company and were misled as to earning potential.

In the other matter, a California plaintiff alleges that supplement maker Kyäni Inc. recruited product distributors who paid up to $1,300 to participate in its sales program, which the plaintiff describes as a pyramid scheme. *Guo v. Kyäni, Inc.*, No. 17-8257 (C.D. Cal., filed November 13, 2017). The plaintiff also alleged that distributors were misled as to earning potential and told to avoid potential recruits who asked "too many questions" or who wanted detailed information about the program.

Putative Class Action Alleges Olivina Men Ingredients Are Not "Naturally Pure"

Olivina Napa Valley, maker of Olivina Men bath and body products advertised as "Naturally Pure," faces a putative class action alleging that the company's products contain synthetic ingredients such as glycerin and citric acid. *Evans v. Olivina Napa Valley LLC*, No. 17-6450 (E.D.N.Y., filed November 6, 2017). The complaint asserts that under 2013 draft guidance issued by the U.S. Food and Drug Administration, a substance is natural if: (i) it is a naturally occurring mineral or biological matter; (ii) it has not undergone a chemical change; or (iii) its chemical change is part of a naturally occurring biological process. The plaintiff alleges that an "average consumer" would not know the ingredients listed on the product labels were synthetic and that he would not have paid a premium price had he known the products were not "natural." Claiming breach of warranties and breach of the Magnuson-Moss Warranty Act, the plaintiff seeks class certification, injunctive relief, damages and attorney's fees.

Suit Alleges Whole Foods Products Mislabeled as Hypoallergenic

Two plaintiffs have filed a putative class action alleging Whole Foods Market Inc. labels some of its bath and body products as hypoallergenic despite containing “skin sensitizers” or “allergens” as well as chemicals allegedly known to be carcinogens, mutagens and reproductive toxins. *Kellman v. Whole Foods Mkt. Inc.*, No. 17-6584 (N.D. Cal., filed November 14, 2017). Among the ingredients cited in the complaint are citric acid, spearmint leaf oil and sodium bicarbonate (baking soda). Alleging breach of express warranty, unjust enrichment and unfair and deceptive acts and practices, the plaintiffs seek class certification, accounting, restitution, disgorgement, damages and attorney’s fees.

California Plaintiff Alleges Sephora Lipstick Tester Caused Herpes Diagnosis

A California woman has reportedly filed a lawsuit against Sephora USA alleging that she contracted oral herpes after using a lipstick sample tester at a Los Angeles store. The plaintiff argues that the store encourages consumers to use tester products and fails to warn about the risks associated with using communal makeup. She reportedly seeks $25,000 in damages for negligence and emotional distress for the "incurable lifelong affliction." *See USA Today*, November 1, 2017.

SCIENTIFIC / TECHNICAL ITEMS

Study Finds Triclosan Buildup in Toothbrushes

University of Massachusetts Amherst researchers have reportedly found that triclosan can accumulate in toothbrush bristles and can be released in the mouth at “unregulated doses." J. Han, et al., “Nylon Bristles and Elastomers Retain Centigram Levels of Triclosan and Other Chemicals from Toothpastes: Accumulation and Uncontrolled Releases,” *Environmental Science and Technology*, October 25, 2017. The researchers designed an automated brushing simulator to emulate recommended brushing habits—twice a day for two minutes—over three months. More than one-third of the 22 brushes tested reportedly showed an accumulation from 7 to 12.5 full doses, with added "polishing cups" and "cheek and tongue cleaners" showing additional accumulation. The study also noted that toothbrushes with triclosan buildup disposed in landfills may contribute to environmental exposure to the chemical.

The choice of a lawyer is an important decision and should not be based solely upon advertisements.