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LEGISLATION, REGULATIONS & STANDARDS

FDA Warns About Color Additives, Manufacturing Practices

The U.S. Food and Drug Administration (FDA) has warned three dietary-supplement manufacturers about their marketing and production practices. KPC Products Inc. received a warning about its failure "to establish component specifications that are necessary to ensure that specifications for the purity, strength, and composition of dietary supplements manufactured using the components are met." The company previously took corrective action, but FDA determined that the response was insufficient. FDA also warned KPC that it failed to use the standardized common names for several of its ingredients, including the use of "scute" for Chinese skullcap and "red peony' for Chinese peony.

Niche Pharmaceuticals received a warning letter asserting that the company produces dietary supplements adulterated with an unapproved color additive, D&C Yellow No. 10. FDA also informed Niche that its product is an unapproved new drug based on several marketing statements, including a claim that "a highly absorbable magnesium supplement such as magnesium lactate is a health strategy to prevent metabolic syndrome."

FDA warned Aegle Nutrition LLC that its production facility violates the agency's Acidified Foods regulation and Current Good Manufacturing Practice regulation. Aegle allegedly failed to establish specifications for the purity, strength and composition of its supplements and failed to provide FDA with "information as to the scheduled processes including conditions for heat processing and control of pH, salt, sugar, and preservative level, and source

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and date of the establishment of the process, for each acidified food in each container size."

Ad Board Recommends Changes to Tru Derma, TriDrive Marketing

The National Advertising Division (NAD) has recommended that VH Nutrition LLC and Tru Derma LLC discontinue marketing claims challenged in proceedings before the board. VH Nutrition submitted evidence to NAD about the efficacy of individual ingredients in TriDrive but was unable to provide independent testing for the supplement as a whole. NAD's decision found that it is "well-established that when there is substantiation only for the efficacy of ingredients in a product, but not for the product itself, any claims must be clearly expressed as ingredient claims." VH Nutrition responded that it "disagrees with some of NAD's determinations; however, for business purposes, TriDrive is no longer being sold."

NAD also informed Tru Derma that it failed to provide testing to support its assertions about its supplement's purported weight-loss effects. Further, "Tru Derma could not support qualified claims related to the weight-loss benefits of individual ingredients," the board found, but the company did provide "a reasonable basis for qualified, narrowly tailored claims about the safety and efficacy of the specific cissus quadrangularis and irvingia gabonensis ingredients used in its product." Accordingly, NAD recommended that Tru Derma change the weight-loss claims in its marketing.

GLOBAL

Canada to Ban Cosmetics Testing on Animals

The Senate of Canada has passed a bill that would ban animal testing for cosmetics in the country and prohibit the use of animal testing as evidence to establish the safety of a cosmetic. If passed by the House of Commons, the bill would amend the Food and Drugs Act to provide that "No person shall conduct or cause cosmetic animal testing to be conducted in Canada." The provisions would take effect four years after the ban's effective date.

A columnist for the *Toronto Star* argued that a vote in the House of Commons for "this very moderate bill" might not succeed because (i) the Trudeau government has indicated that it would

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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.

prefer to reassess animal-cruelty laws as a whole; (ii) the bill is incremental in nature and possibly not "worth pursuing"; and (iii) 99 percent of cosmetics sold in Canada are free of animal testing, potentially creating the perception that the legislation is unnecessary.

EU Issues Opinions on Hair Dye, Vetiver Oil and Nail Polish Ingredients

Following its plenary meeting June 21-22, 2018, the EU Scientific Committee on Consumer Safety issued opinions on multiple personal care products ingredients.

- HEMA and Di-HEMA Trimethylhexyl Dicarbamate: when applied topically as part of UV-cured artificial nail modeling systems, the monomers "are not likely to pose a risk of sensitisation, provided that their use is restricted to the nail plate only and contact with the adjacent skin is avoided."
- Vetiver Oil: when used as a fragrance ingredient, Acetylated Vetiver Oil is safe at low concentrations as used in cosmetics products.
- Hair Dye 1,2,4-trihydroxybenzene: the ingredient is not safe "due to potential genotoxicity when used as an auto-oxidative hair dye in permanent hair dye formulations."

LITIGATION

AuraVie Sellers Barred From Continuing Marketing and Billing Practices

The U.S. Federal Trade Commission (FTC) has obtained a permanent injunction preventing a group of marketers from selling AuraVie, Dellure, LéOR Skincare and Miracle Face Kit products with "risk-free" trials, resolving charges initially filed in 2015. *FTC v. Bunzai Media Grp. Inc.*, No. 15-4527 (C.D. Cal., W. Div., entered June 27, 2018). FTC alleged that Bunzai Media Group Inc. and other defendants enticed consumers into enrolling in "risk-free trials" but continued to charge their credit cards up to $97.88 per month. The court barred the defendants from using deceptive marketing tactics, including "failing to disclose clearly and conspicuously material terms of offers" and "failing to obtain a consumer's express informed consent before submitting billing information for payment." The court also ordered the defendants to pay $320,665.89 but suspended the judgment based on inability to pay.

Consumers Allege L'Oréal Packaging Fails to Dispense Products

Four consumers have filed a potential class action arguing that L'Oréal USA Inc.'s cosmetics are sold in bottles with pump dispensers incapable of dispensing the full contents of the products within. *Critcher v. L'Oréal USA Inc.*, No. 18-5639 (S.D.N.Y., filed June 21, 2018). The plaintiffs allege that "while the containers accurately state the total amount of product contained therein," "the pumps used to dispense these Liquid Cosmetic Products fail to dispense a quarter of the Liquid Cosmetic Products, and sometimes 50% or more, because the pumps are defective and cannot adequately and reasonably dispense viscous liquids, rendering Defendant's packaging materially misleading."

Further, "the containers are often glass bottles, sealed shut and are designed to prevent consumers from opening them, thereby thwarting consumers' access to the trapped product by any reasonable and safe means. Because some of the containers are made with opaque materials, or the viscous liquids frequently stick to the sides of the containers, it is difficult for consumers to know exactly how much, if any, Liquid Cosmetic Product remains trapped in the containers. This is further exacerbated by the inherent weight of a small, yet relatively heavy, glass bottle, which leads consumers to believe that the weight of any stranded product is attributable instead to the bottle weight itself, and not to any product leftover." The plaintiffs cite independent laboratory testing, which purportedly found that "these Liquid Cosmetic Product containers only dispense between as little as 43 percent to 81 percent of the container's advertised contents."

The plaintiffs allege violations of consumer-protection statutes of several states, including New York, Florida, Kansas and Missouri, as well as negligent misrepresentation. They seek class certification, damages, restitution and attorney's fees.

Lawsuit Alleges "Revolutionary" Sports Carbohydrate is "Just Ground Up Corn"

A consumer has filed a putative class action alleging UCAN Co. falsely advertises SuperStarch, a "revolutionary, all-natural carbohydrate" and "gluten-free innovation," because the ingredient is "just ground up corn." *McCann v. UCAN Co.*, No. 18-4769 (N.D. Ill., filed July 11, 2018). According to the complaint, UCAN labels and markets its products with claims that SuperStarch "produces 'sustained energy,' 'optimized performance,' 'enhanced fat burn' and 'speedier recovery,' all

without the harmful and performance-impairing side effects associated with gastrointestinal distress." The plaintiff alleges that the products increase gastrointestinal distress and do not improve performance. Claiming violations of the Illinois Consumer Fraud Act, consumer-fraud statutes and unjust enrichment, the plaintiff seeks class certification, damages and attorney's fees.

Monat Faces Additional Putative Class Action

Another consumer has filed a putative class action alleging Monat Global Corporation's haircare products damaged her hair and scalp, joining other plaintiffs alleging similar allegations. *Stefforia v. Monat Global Corp.*, No. 18-22837 (S.D. Fla., filed July 13, 2018). Additional details on one consumer's lawsuit appear in Issue 56 of this *Bulletin*.

The plaintiff alleges that Monat knowingly sold products without warning consumers that they can cause scalp irritation and hair loss. The complaint cites social media posts to prove that other consumers have experienced the claimed side effects as well. For strict product liability, failure to warn and failure to test allegations, the plaintiff seeks class certification, an injunction, damages, attorney's fees and an "order requiring Monat to adopt and enforce a policy that requires appropriate removal of misleading claims and the inclusion of material safety information omitted from the Company's disclosures."

Super Greens Products Contain 50 Percent Slack Fill, Consumer Asserts

After purchasing Super Greens Organic Greens "for the dual purpose of enjoying its contents and determining whether the container was lawfully filled," a consumer has filed a lawsuit alleging that Windmill Health Products sells containers with unnecessary slack-fill. *Casillas v. Windmill Health Prods.*, No. 18-5484 (C.D. Cal., filed June 20, 2018). The plaintiff allegedly found that Windmill's opaque powdered-supplement package was filled with "more than 50% empty space," which is allegedly "per se illegal." For an alleged violation of the California Consumer Legal Remedies Act, the plaintiff seeks class certification, injunctive relief, damages and attorney's fees.

Companies Dispute "Organic Protein" Mark

Orgain Inc. has filed a trademark infringement suit against Northern Innovations Holding Corp. alleging infringement of the trade dress and "Organic Protein" trademark on Orgain's protein powders. *Orgain Inc. v. N. Innovations Holding Corp.*, No. 18-1253 (C.D. Cal., S. Div., filed July 18, 2018). Orgain asserts that Northern Innovations has changed the packaging of its protein supplement to mirror Orgain's, which is labeled in a green and white container with the product name displayed in black sans serif type. Northern Innovations launched its product in 2014 with a different style of branding but has evolved the marketing to be more similar to Orgain's, the complaint alleges. Orgain seeks an injunction, destruction of infringing materials and damages for allegations of statutory and common-law trademark and trade-dress infringement.

CVS Memory Supplement Ineffective, Lawsuit Alleges

A consumer has filed a putative class action alleging CVS Pharmacy Inc.'s Algal-900 DHA does not work as advertised. *Ferguson v. CVS Pharmacy Inc.*, No. 18-1529 (S.D. Cal., filed July 5, 2018). Algal-900 DHA is marketed as "clinically shown to improve memory," the complaint asserts, but "[c]omprehensive, high-quality, clinical studies of adults' cognitive performance have shown that omega-3 fatty acids, including DHA, work no better than a placebo." The plaintiff argues that CVS' marketing relies on a study that the Federal Trade Commission has concluded "does not support claims that DHA improves memory." Alleging violations of California's consumer-protection statutes, the plaintiff seeks class certification, restitution, an injunction, damages and attorney's fees.