Dietary Supplement and Personal Care Product Regulatory and Litigation Highlights – March 2021

Kristi L. Wolff, Jaclyn M. Metzinger

April 16, 2021

Welcome to our curated selection of highlights of regulatory and litigation developments in the dietary supplement and personal care product industries for March 2021. In case you were wondering what pain relief, teeth whitening, and CBD have in common (and, who wasn't?) it seems that one year into the pandemic, these are the advertising battles being fought in multiple forums. Read on…

National Advertising Division

NAD addressed some unique superiority and comparative claims in the OTC drug space in finding that Hisamitsu America, Inc., supported its duration claims that Salonpas Pain Relief Patch Large "works for up to 12 hours" and "provides relief for up to 12 hours." However, NAD found that comparative claims such as "All OTC pain relievers, including Voltaren, have one thing in common. None are proven stronger or more effective against pain than Salonpas Pain Relief Patch Large" and "only pain reliever labeled to relieve mild to tougher, moderate pain" and "the strongest labeled OTC topical pain reliever" were not substantiated and recommended that they be discontinued. This is an interesting discussion of comparative advertising for two products approved by FDA where the claims at issue were outside of the FDA approvals. Anyone looking to understand how NAD navigates that jurisdictional issue will want to check out this decision.

NAD extended its already robust body of precedent involving teeth whitening claims with a decision finding that Colgate-Palmolive Company supported advertising claims that its Optic White Renewal Toothpaste has "unprecedented whitening power," "contains 3% hydrogen peroxide," and has "the most hydrogen peroxide in a whitening toothpaste." However, NAD recommended that Colgate discontinue the claim that its product "removes 10 years of yellow stains." Colgate is appealing that recommendation.

Colgate's ad campaign for Optic White Renewal Toothpaste cleverly highlights several dubious fads from the last decade (jeggings and shake weights, anyone?). However, NAD's concerns about Colgate's substantiation for the "removes 10 years of yellow stains" claims included that Colgate failed to consider the results of the negative control as to two studies that NAD agreed were otherwise reliable. As to a third study, NAD expressed concern about its reliability relative to converting to a years of yellow staining calculation. Many companies in the beauty and personal care space are interested in making claims relating to years of impact for their products. This case provides insights on what to consider for those types of claims.

On the dietary supplement front, NAD revisited the issue of energy claims relative to Vitamin B12 in recommending that Goli Nutrition modify its "Vitamin B12 to help support energy production" claim to make it clear that Goli is referring to cellular energy and to avoid conveying the impression that consumers taking its apple cider vinegar gummies will feel a noticeable increase in energy or become more energetic." NAD also recommended that Goli discontinue claims that folic acid supports skin health as unsubstantiated.

FDA

FDA announced two warning letters issued to makers of topical CBD products labeled as OTC drugs. Amidst a backdrop of facility inspections that revealed significant good manufacturing compliance concerns, the most important takeaways in this round of CBD enforcement are as follows: FDA does not think that CBD is an appropriate inactive ingredient in OTC drugs, a position that we do not believe the agency has previously articulated publicly. In addition, reaffirming a position that the agency has previously asserted, FDA really frowns on companies using terms such as "FDA registered" to implicitly suggest agency approval. Check out our blog post on these warning letters.

Litigation Developments

Staying with CBD, another CBD class action was stayed pending FDA action. This complaint in *Dasilva v. Infinite Product Co. LLC* (C.D. Cal.) alleges that the FDA had previously sent a letter to the defendant advising that a variety of its CBD products were "unapproved new drugs" and "misbranded drugs" in violation of the Food, Drug, and Cosmetics Act, and that consumers would not have purchased the defendant's products if they were aware of the misleading labeling. The court joined a number of previous courts in granting the defendant's motion to stay pursuant to the primary jurisdiction doctrine, finding that the FDA and Congress have separately expressed interest in regulating CBD and that it was unclear how the court could adjudicate the plaintiffs' claims given the lack of clarity as to whether the products are drugs, dietary supplements or food products. Specifically, the court noted that any forthcoming legislation or regulation may apply retroactively and inform the court's consideration of the merits of the dispute.

A judge in the Eastern District of New York granted in part and denied in part a motion to dismiss claims asserted against Bactolac Pharmaceutical, which manufactures the "All Day Energy Greens" supplement marketed and sold by co-defendant NaturMed, Inc. The complaint alleges that the supplement was not safe for human consumption because Bactolac failed to follow NaturMed's contractual instructions by adding inferior ingredients. The court dismissed six breach of warranty and consumer protection claims, but ruled that the 15 remaining claims must proceed into discovery. The court also denied Bactolac's motion to strike the plaintiffs' request for punitive damages

Class Action Settlements

Reckitt Bensicker LLC agreed to settle two parallel class actions (one in California and one in Illinois) alleging that that it falsely advertised joint health benefits of its glucosamine dietary supplement "Move Free Advanced." After four years of litigation, including a grant of class certification in June 2019 and denial of the defendant's motion for summary judgment in March 2020, the defendant agreed to pay $53 million to a nationwide class of purchasers, which the plaintiffs characterized as "the largest dietary supplement class action settlement ever reached." The settlement provides for a cash refund for up to three purchases for a total of $66 ($22 per purchase) or for up to $225 worth of a variety of consumer products of the class member's choosing ($75 per purchase). Any funds that remain after all claims are processed will be distributed to the Orthopaedic Research Society in

accordance with the *cy pres* doctrine. The settlement further provides that the named plaintiffs will receive up to $7,500 for their participation and that the defendant would not oppose class counsel's application for attorneys' fees so long as the application did not exceed $12.5 million. The plaintiffs' motion for preliminary approval is pending.

Bayer Healthcare and Beiersdorf agreed to pay $2.25 million to settle a federal California class action alleging that their Coppertone "mineral based" sunscreen products deceived consumers into believing that the products contained only mineral active ingredients when, in fact, they contained chemical active ingredients. Class members who submit proof of purchase may receive $2.50 per unit purchased with no limitations. Consumers who do not submit proof of purchase may receive $2.50 per unit purchased up to a maximum of four units per household. The settlement further provides that the named plaintiffs can apply for service awards up to $5,000 each to be paid out of the settlement fund, that class counsel can apply for an award of attorneys' fees not to exceed one-third of the total fund, and that the cost of notice and administration will also be paid from the fund at a maximum of $530,000 plus postage. Any remaining funds will be disbursed *cy pres* to the charitable organization Look Good Feel Better. The defendants also agreed to discontinue the "mineral based" labeling and other injunctive relief. A preliminary approval hearing is scheduled for April 21, 2020.

New Class Action Filings/Trends

One new putative class action was filed in California state court challenging "oil free" claims made with respect to various Smashbox cosmetics products. This filing follows a series of similar cases.

A number of new class actions were filed in the Southern District of New York against Tom's of Maine and Colgate Palmolive involving their charcoal activating toothpaste products. The complaints allege that defendants' products are marketed as contributing to "healthy gums" and providing "enamel safe whitening" and "gentle cleaning" when, in fact, they are abrasive to enamel and the gums, and pose other safety hazards. A similar action was also filed against Proctor & Gamble in Missouri state court.

Five new class actions were filed in the Northern District of California alleging that "Max Strength" or "Maximum Strength" Lidocaine products contained 4% lidocaine when, in fact, most similar prescription patches contain 5% lidocaine. Three actions were filed against Sanofi-Aventis US LCC and two were filed against Hisamitsu America Inc.

There was also an uptick in pet product class action filings in March. Three actions were filed in California against Elanco Animal Health Inc. alleging that its Seresto flea and tick product contained pesticides and other ingredients that cause seizures, thyroid gland damage, and death to the dogs and cats for which the products were marketed, as well as other harm to humans. These filings followed a March report discussing the EPA's failure to issue warnings about the Seresto products.

(some links from Law360, subscr. req'd.)

****

Thanks for joining us again this month. See you in May!