Dietary Supplement and Personal Care Products Regulatory Highlights – February 2021

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Welcome to our monthly roundup of regulatory and litigation highlights impacting the dietary supplement and personal care products industries. Sit back, relax, and enjoy the read. February was a short month, with a lot going on.

NAD

Health claim substantiation was front and center before NAD in a monitoring case involving Pendulum Therapeutics and a "medical probiotic" product featuring claims such as "The only medical probiotic clinically shown to lower A1C & blood glucose spikes for the dietary management of T2D*" (*Consult your physician as part of your total diabetes management plan. Results may vary from person to person.")

The advertiser submitted a 12-week multi-center, randomized, double-blind, placebo-controlled study (the "Perraudeau Study") to assess Pendulum Glucose Control's safety and effectiveness in improving glycemic control in Type 2 diabetics and, ultimately, their dietary management of the disease – specifically, the role of certain probiotic strains found in prior research to be associated with the promotion of a healthy gut microbiome through the production of short-chain fatty acids (SCFAs).

The advertiser also provided clinical studies and research articles demonstrating the roles of A1C, fasting glucose and postprandial glucose levels in managing Type 2 diabetes. The advertiser also referred to the FDA's Guidance document (Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention) to demonstrate what level of reduction in HbA1c was clinically meaningful.

While NAD expressed some concerns about the evidence, ultimately, NAD determined that the Perraudeau Study was a good fit for the challenged claim "The only medical probiotic clinically shown to lower A1C & blood glucose spikes for the dietary management of T2D*" (*Consult your physician as part of your total diabetes management plan. Results may vary from person to person.") but recommended the following modifications: (1) limiting the claim to individuals who are taking metformin; (2) modifying the claim to clarify that the product can be used as part of the dietary management of type 2 diabetes; and (3) removing the references to percent reductions in blood glucose spikes in the absence of evidence in the record demonstrating that the reductions were clinically relevant.

This decision is a helpful discussion of the competent and reliable scientific evidence standard. Anyone seeking to understand health claims substantiation better should check it out.

FTC

Continuing with the diabetes management theme, the FTC announced a settlement with Agora Financial, LLC, a Baltimore-based company that the FTC charged tricked seniors into buying pamphlets, newsletters, and other publications that falsely promised a cure for type 2 diabetes or promoted a phony plan to help them cash in on a government-affiliated check program. In addition to the monetary judgment, which will be used to provide refunds to defrauded consumers, the proposed settlement also bars Agora and the other defendants from making such false or unsupported claims.

FDA

FDA's pandemic-related enforcement took a new turn in February, with the issuance of warning letters to 10 companies selling dietary supplements that feature depression, anxiety, and mood-related claims. Examples of claims identified in the warning letters include the following:

- A treatment for depression, anxiety and stress
- Reduces anxiety
- Effective for mild to moderate depression
- the ONLY prebiotic that's been proven to help with anxiety
- "Constantly struggling with symptoms of anxiety and depression can have an incredibly detrimental impact on your life. . . . Our vision for the future of mental health is that we reach for probiotics as a first line of defense and even prevention for mental health issues."
- A new natural supplement is providing relief to people across America suffering with severe anxiety and stress!'"
- "Enlifta is the only natural remedy depression supplement designed & created by a Psychiatrist."
- For the relief of temporary depression or occasional feelings of sadness and melancholy.
- Reduce Anxiety by Affecting Serotonin

The claims were of concern to FDA because they indicate that the products can be used to cure, treat, mitigate, or prevent depression and other mental health disorders – claims that are not allowed on dietary supplements, and none of the products had FDA approval to make the claims. As FDA's constituent update notes: Consumers who rely on dietary supplements in lieu of discussing their symptoms with a health care professional could potentially suffer harm and may not receive appropriate therapies that have been determined to be safe and effective to treat depression and other mental health disorders.

The pandemic has changed many things, but it has not changed the rules around marketing dietary supplements. If anything, companies selling in this space will want to be extra mindful of the pandemic context when crafting marketing copy.

In addition to that enforcement, FDA continued its prior COVID-related enforcement with warning

letters related to subpotent and adulterated hand santizer primarily from Mexico.

Prop 65

Related to the need to kill germs, our sister blog, Kelley Green Law, featured two articles relating to EPA enforcement on disinfectant claims. One of the few areas of EPA policy continuity between the Biden and Trump eras is the aggressive enforcement attention being paid to products that claim to fight the SARS-CoV-2 coronavirus. EPA has issued "stop sale" orders to Amazon directing the company to take steps to prevent the continued sale "of potentially dangerous or ineffective unregistered pesticides and pesticide devices making illegal and misleading claims, including multiple products that claimed to protect against viruses."

Class Action Litigation

A California federal judge tossed a proposed class action alleging the label on Walgreens' Infants' Pain & Fever Acetaminophen is false and misleading and violates California consumer protection statutes, ruling that the product's "undisputed" labeling would not be likely to confuse reasonable consumers. The plaintiff alleged that the labeling was misleading because the packaging and marketing on the infants' product misleads consumers into thinking it is specially formulated and therefore deceives them into paying more than the cost of the children's version, even though they have the exact same level of the active ingredient. In dismissing the case, the judge noted that the packaging was clearly labeled with the milligrams contained and also included a special dosing cup and syringe for use with children and infants.

Just as marketers are exploring immune system claims as of late, the plaintiffs' bar is as well, with elderberry and immunity being challenged in California.

Dandruff brand Selsun Blue is the subject of an ingredient-related attack in the Northern District of Illinois relating to allegations that its active ingredient, selenium sulfide, causes scalp irritation and hair loss and another ingredient, preservative DMDM hydantoin, is known to slowly release formaldehyde.

Online cosmetics company Dermaset allegedly engaged in false advertising for failing to adequately disclose that consumers who pay $4.95 for shipping and handling for a 30-day free trial of cosmetics and a two-ounce free trial of cream will be enrolled in an automatic renewal offer resulting in consumers being charged recurring fees without their consent.

And if that isn't enough for you…..

State Legislation

A California legislator introduced a bill that would restrict sale of certain weight loss supplements to anyone under age 18. Similar legislation has been considered in New York and Massachusetts.

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Thanks for reading our monthly highlights! Take a deep breath and let's see if March continues the madness of February.

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