

ADVERTISING, MARKETING & PROMOTIONS

>>ALERT

FTC AND FDA TARGET ADVERTISING OF CBD HEALTH CLAIMS

In a sign that the government will take an active enforcement role in a budding industry, the Federal Trade Commission (FTC) and the Food and Drug Administration (FDA) have sent warning letters to three companies that are advertising and selling products containing cannabidiol (CBD).

AGENCIES' CONCERNS ABOUT CBD

For decades, hemp, a close biological relative of marijuana, was regulated as a Schedule I drug under the Controlled Substances Act (CSA), alongside marijuana, heroin and other narcotics. Marijuana and marijuana-derived products – defined generally as plants containing more than .3% tetrahydrocannabinol (THC), the chemical that produces a high – remain illegal under the CSA. But the 2018 Farm Bill that was passed in December legalized hemp – defined generally as plants containing less than .3% THC – and CBD derived from hemp plants.

While the FDA has recently approved CBD use in one anti-epilepsy drug, many retailers and producers have seized the opportunity of legalization to make a wide variety of dubious medicinal claims about CBD.

In April, the agencies sent warning letters to three companies: Nutra Pure LLC, PotNetwork Holdings, Inc. and Advanced Spine and Pain, LLC (d/b/a Relievis), which market and advertise products containing CBD, such as

THE BOTTOM LINE

The legalization of hemp is a major step in establishing a potentially significant new industry. However, producers and marketers need to exercise caution when making health-related claims in connection with hemp-based product. The FTC and FDA will continue to aggressively review related advertising to ensure that products are advertised truthfully.

“CBD Salve,” “CBD for Dogs,” “Hemp Oil,” “CBD Softgels,” “Liquid Gold Gummies” and “CBD Oil.” The letters explain that the agencies had reviewed the companies’ websites and believed that the advertised products might violate the FTC Act by making false or unsubstantiated health claims about their ability to effectively treat diseases including cancer, Alzheimer’s disease, fibromyalgia and “neuropsychiatric disorders.”

The warning letter to Advanced Spine and Pain illustrates the FDA and FTC’s concerns:

1) The FDA determined that Advanced Spine and Pain’s “CBD Salve” and “CBD Oil” products were unapproved new drugs sold in

violation of the Federal Food, Drug and Cosmetic Act (the FD&C Act);

- 2) That these products were misbranded drugs under the FD&C Act; and
- 3) That the company’s “CBD for Dogs” product was an unapproved new animal drug that was unsafe and adulterated under the FD&C Act.

The agencies further explained that they determined Advanced Spine and Pain’s “CBD Salve” and “CBD Oil” products as drugs under the FD&C Act because they were intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease and/or because they were intended to affect the structure or function of the body. They reached this conclusion

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even though Advanced Spine and Pain's "CBD Oil" products were not labeled as dietary supplements because their directions for use stated "[a]s a hemp supplement. . . ." Based on this language, the agencies said, it appeared that Advanced Spine and Pain might "intend to market" the product "as a dietary supplement." According to the government, however, it did not meet the definition of a dietary supplement under the FD&C Act because the FDA concluded that CBD products were "excluded from the dietary supplement definition" and CBD may not be used as an ingredient in food or dietary supplements.

The agencies added that Advanced Spine and Pain's "CBD Oil" could not be labeled or sold as a food, and that Advanced Spine and Pain might be violating the FTC Act by advertising that its product could prevent, treat or cure human disease without possessing "competent and reliable scientific evidence," including, when appropriate, well-controlled human clinical studies, substantiating that the claims were true at the time they were made.

EXAMPLES OF CHALLENGED STATEMENTS

The letters contained many examples of statements by marketers that the agencies indicated were of concern. Among many others, they included:

>> "We carry cannabinoid oil and CBD salve for treating your conditions. If

you have any of the indications listed below, please consider trying our cannabis treatment products! . . . Anxiety . . . Chronic Inflammation . . . Cancer Pain . . . Depression . . . Chronic Pain . . ."

- >> "Here you can find a list of indications that we can treat with our hemp oil products . . . Anxiety . . . Chronic Inflammation . . . Cancer Pain . . . Depression . . . Chronic Pain . . ."
- >> "CBD successfully stopped cancer cells in multiple different cervical cancer varieties."
- >> "CBD also decreased human glioma cell growth and invasion, thus suggesting a possible role of CBD as an antitumor agent."
- >> "CBD may also protect brain cells from beta-amyloid toxicity, making it a potential therapeutic agent in Alzheimer's and Parkinson's disease."
- >> "CBD, due to its anti-inflammatory and antioxidant properties, may be a promising agent to treat and prolong survival in Amyotrophic Lateral Sclerosis (ALS) patients."
- >> "Cannabidiol may treat depression."
- >> "Researchers suggest that it may be effective for panic disorder, obsessive compulsive disorder and post-traumatic stress disorder."
- >> "Studies suggest that cannabinoids may be a new class of drugs for the treatment of chronic pain."

- >> "Cannabidiol may provide treatment for Alzheimer's disease."
- >> "CBD . . . can possibly be used as a therapeutic agent for treatment of type 1 diabetes at an early stage of the disease."
- >> "CBD reduced the rewarding effects of morphine and reduced drug seeking of heroin."
- >> "CBD may be a promising substance for people who abuse opioids."
- >> "CBD may be used to avoid or reduce withdrawal symptoms."

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