LEGAL UPDATES

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FDA States CBD Is Not GRAS for Use in Food, Issues More Warning Letters

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The U.S. Food and Drug Administration (FDA) issued a press release on the evening of Monday, November 25 concerning its recent enforcement actions and a regulatory decision concerning products that contain cannabidiol (CBD). The Warning Letters follow FDA's trend of focusing its CBD product enforcement on unapproved drug claims. The regulatory decision stated in the press release concerns FDA's decision that CBD is not generally recognized as safe (GRAS) for use as a food additive.

The fifteen (15) Warning Letters, each dated November 22, 2019, were issued to companies for marketing various CBD products. The products identified in the Warning Letters spanned conventional foods, dietary supplements and animal products. FDA made specific mention in several Warning Letters about statements regarding the use of CBD products in infants and children.

The press release also included a statement that the agency cannot conclude that CBD is generally recognized as safe (GRAS) among qualified experts for use in human or animal food. Based on this conclusion, the FDA updated its Consumer Update on CBD: "What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD." The Consumer Update now provides additional information regarding safety concerns. Regarding these changes and its decision on CBD's use in food, the FDA states:

Many unanswered questions and data gaps about CBD toxicity exist, and some of the available data raise serious concerns about potential harm from CBD. The revised Consumer Update outlines specific safety concerns related to CBD products, including potential liver injury, interactions with other drugs, drowsiness, diarrhea, and changes in mood. In addition, studies in animals have shown that CBD can interfere with the development and function of testes and sperm, decrease testosterone levels and impair sexual behavior in

males. Questions also remain about cumulative use of CBD and about CBD's impacts on vulnerable populations such as children and pregnant or breastfeeding women.

Apart from the press release and Consumer Update, it does not appear that the FDA has provided any other documentation on its GRAS decision, such as in a formal report or white paper. Such documentation will be valuable to establish what data and information needs to be gathered to establish the safety of CBD.

The Warning Letters issued late last week highlight FDA's continued concerns related to the use of CBD. Common to most Warning Letters are unapproved human drug claims associated with serious diseases, including cancer, autism, opioid addiction, post-traumatic stress disorder, diabetes and Alzheimer's disease, among others. The one exception appears to be the Warning Letter issued to Apex Hemp Oil LLC, of Redmond, Oregon. That Warning Letter cites only limited claims such as "helps cells regenerate," "the answer for sore muscle aches," and "balances the mind and body by promoting natural healing through the endocannabinoid system." The Warning Letter includes a number of animal health claims, including one for treatment of "Arthritis & joint discomfort." It is not known if this Warning Letter is an outlier, or suggests the agency will increase its focus on CBD veterinary claims or human structure/function claims.

Along with these issues, the FDA raised issues with the use of CBD in:

Animal food, especially when it is intended for consumption by food-producing animals as there is a lack of data establishing safe CBD residue levels.

Conventional food, as CBD is not GRAS and there is no food additive regulation that authorizes the use of CBD as an ingredient in human food.

Dietary supplements, as CBD products do not meet the definition of dietary supplement.

Products marketed for infants and children as children may be at greater risk for adverse reactions due to differences in the ability to absorb, metabolize, distribute, or excrete CBD.

Over the last several years, FDA has sent warning letters to other companies that sell products containing CBD that claim to prevent, diagnose, mitigate, treat, or cure diseases, such as cancer and Alzheimer's. This most recent action makes it clear that FDA will take action against products that make claims that could result in consumers putting off obtaining important medical care due to the unsubstantiated claims. Additionally, this action underscores FDA's need for additional data to establish safety for the use of CBD in human and animal food and dietary supplements.

Contact Us

Husch Blackwell has experience working with companies on how to market CBD products in light of

FDA and FTC's enforcement actions. Our Cannabis and FDA lawyers have the necessary scientific and regulatory expertise to assist companies considering making or marketing CBD or cannabis containing products. Contact Seth Mailhot, Steve Levine, Emily Lyons or your Husch Blackwell attorney.