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FDA Remains Vigilant Against CBD-Related Health Claims

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Who Needs to Know

Manufacturers and Retailers of CBD products.

Why It Matters

In March 2021, the FDA issued four warning letters to CBD companies around the country. The administration takes a strong stance on product labelling and marketing efforts containing health claims about CBD.

Despite — or perhaps in response to — the increasingly mainstream popularity of topical and ingestible CBD products, the Food and Drug Administration (FDA) continues to issue warnings to companies selling CBD products. In March 2021, the FDA issued four warning letters to CBD companies around the country. The administration takes a strong stance on product labelling and marketing efforts containing health claims about CBD, and in two of the four March 2021 letters, the FDA called out companies for making COVID-19-related claims. In short, manufacturers and retailers of CBD products should be careful to ensure not to market their products as providing any health benefits.

Further, regardless of the content of product labels, the FDA maintains the position that it is illegal to "introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which has been added a substance which is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. § 355], or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public." *See* https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd#farmbill. This prohibition is relevant to CBD companies because CBD is an active ingredient in one known "drug product that has been approved under section 505 of the FD&C Act," but CBD does not fall into the recognized exceptions to that rule. This prohibition has not stopped the proliferation of numerous edible CBD products (*e.g.,* gummies, supplements, and similar products), however, based on earlier letters, the FDA may indeed consider such products "food" for the purposes of this prohibition.

The four March 2021 warning letters sent by the FDA were all similar in tone and substance and admonished the recipient companies to cease claiming that their products can provide health benefits. While two of the letters were based on FDA inspections of the recipient companies' facilities — and therefore those companies should have anticipated receipt of such letters — the other two letters appear to have been based solely on a review of the

recipient companies' websites and social media marketing presences. The latter set of letters should be of note to CBD companies because such letters serve as examples of the FDA's ongoing and vigilant policing of the industry for compliance.

Another important takeaway from the March 2021 letters is that one of the letters was directed at products that combined CBD with other claimed homeopathic remedies, such as magnesium and silver. The presence of more than one ingredient touted to have health benefits will surely raise a red flag at the FDA. CBD companies must exercise the greatest possible level of caution when marketing and/or selling a product that incorporates such other ingredients. Finally, one of the March 2021 letters also contained warnings regarding veterinary products, which is a welcome reminder that the FDA is also policing the CBD marketplace for products marketed for use with pets.

If your company markets and/or sells CBD products for consumption, human or otherwise, you need to take all necessary steps to keep up to date with the FDA's guidance — and particularly avoid claims related to COVID-19. And as always, Troutman Pepper's Cannabis Industry Group is available for consultation on these issues.

Our Cannabis Practice provides advice on issues related to applicable federal and state law. Marijuana remains an illegal controlled substance under federal law.

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