

CLIENT ALERT

FDA Cracks Down on Health Claims in CBD Advertisements

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FDA Doubles Enforcement Actions

On November 22, the U.S. Food & Drug Administration (FDA) issued 15 warning letters to companies selling CBD-infused products, more than doubling the number of warning letters directed to manufacturers of such products this year. The warning letters were announced in a [November 25 press release](#) in which FDA also stated that, at this point, it “cannot conclude that CBD is generally recognized as safe (GRAS) among qualified experts for its use in human or animal food.”

FDA accompanied its press release with a [revised Consumer Update](#) stressing its concerns about the safety of CBD products and highlighting three possible risks that can go unnoticed by consumers: (1) liver injury, (2) unsafe drug interactions that can lead to serious side effects, and (3) male reproductive toxicity. FDA also outlined three areas in which its research is ongoing: (1) the effects of cumulative exposure to CBD, (2) effects on special populations (such as children and pregnant women), and (3) effects on animals.

The FDA’s recent warning letters cited health claims disseminated on company websites, blogs, and social media pages. They targeted ingested products like essential oils and food products, as well as topical products like face creams and bath bombs. And while products for humans were an obvious concern, all but two of the warning letters also targeted products marketed for animals.

The FDA’s new warning letters are the latest evidence of the government’s interest in regulating the growing market for CBD-infused products. They build on prior warning letters sent to CBD product manufacturers and distributors by FDA and the Federal Trade Commission (FTC), which also has regulatory authority in this area. The FTC has issued warning letters to companies advertising CBD products on its [own](#) and [jointly with FDA](#) to remind companies that they are at risk for legal action if their advertising claims—including claims on labeling, websites and consumer testimonials—lack sound scientific support. The FTC has the authority to enforce violations of the FTC Act and its warnings are a reminder that advertising that a product can prevent, treat, or cure human diseases requires competent and reliable scientific evidence, which may include well-controlled human clinical studies.

What Does This Mean for Stakeholders?

The FDA and FTC’s line on CBD products has not moved: CBD *cannot* legally be added to food and beverage products and, regardless of whether or not the CBD product is ingested, it *cannot* be marketed with unsubstantiated health claims. The [FTC continues to stress](#) that companies must review any claims made for their products, including consumer testimonials, to ensure that they “are supported by competent and reliable scientific evidence.” Since her [July 25 testimony](#) before Congress, FDA Principal Deputy Commissioner Amy Abernethy has emphasized a commitment to “sound, science-based policy.” Commissioner Abernethy stressed in FDA’s November 25 press release that “a number of questions remain regarding CBD’s safety—including

reports of products containing contaminants, such as pesticides and heavy metals—and there are real risks that need to be considered.”

What's Next?

Regulators are closely scrutinizing the CBD industry. While we have seen warning letters before, we are likely to see more intense federal enforcement activity in the future. We know that the FDA still does not recognize CBD as GRAS in either conventional foods or dietary supplements. And, as FDA’s recent press release indicates, “the FDA plans to update on its progress regarding the agency’s approach to these products in the coming weeks.” Furthermore, the FTC has repeatedly reminded advertisers of the substantiation requirements for the health claims that commonly appear in advertising for CBD-infused products. Stakeholders should carefully review their advertising—including consumer testimonials—to ensure that the claims will pass muster with both agencies.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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