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WHAT'S IN YOUR CANNABIDIOL PRODUCT CLAIM? FDA AND FTC WANT TO KNOW

It isn't only the U.S. Food & Drug Administration ("FDA") and Drug Enforcement Agency ("DEA") that are interested in all things cannabis. Today, the FDA followed earlier warning letters[1] by posting yet another press release regarding an October 10, 2019 warning letter that was issued jointly by the FDA and the Federal Trade Commission ("FTC") related to sales of unapproved cannabidiol products accompanied by unsubstantiated product claims. This continued joint regulatory activity illustrates the growing need for companies marketing cannabidiol products as dietary or nutritional supplements to fully inform themselves about the various laws implicated when dealing with cannabis and cannabis-derived products.

BACKGROUND

In light of the meteoric rise of cannabidiol and cannabis-derived products over the past several months, the FDA has continued to focus its messaging and enforcement efforts[2] to provide for continued protection of public health. The relatively complex chemistry of cannabis coupled with the fact that most of the products currently marketed in this space have not been approved by the FDA, fully characterized through proper laboratory testing nor manufactured under a standard of controls such as the federal good manufacturing practices for finished pharmaceuticals, has compelled FDA to raise concerns about these products. Moreover, the rapid proliferation of cannabis-derived products, if left unchecked and unregulated, could undermine the FDA's drug approval process, the mechanism by which drugs marketed in the U.S. are typically evaluated for safety and efficacy for their intended use(s).

As indicated in this most recent warning letter, and in at least five other warning letters relating to this issue that have been posted during 2019 year-to-date,[3] the FTC is now also directly expressing its concerns with respect to certain claims made in the marketing of cannabis-derived products to consumers. Specifically, under the Federal Trade Commission Act,[4] Congress intended that consumers be protected from "*unfair or deceptive actions or practices in commerce*," and this protection extends to advertising or promotional claims related to a product's alleged propensity to prevent, treat or cure disease when made without adequate substantiation (*i.e.,* through scientific evidence or human clinical studies).[5] Consequently, the rising numbers of jointly issued 2019 warning letters and their numerous references to efficacy claims made by manufacturers and marketers about their products makes the views of the FDA *and* FTC quite clear – unsubstantiated claims made about unapproved products, particularly when those claims relate to use in vulnerable populations such as infants (as was the case in the October 10, 2019 Warning Letter), will result in swift,[6] dual agency enforcement action.

KEY TAKEAWAYS

Although the current regulatory landscape of the cannabis industry remains in flux, it is clear that cannabis-derived products have taken a foothold in the United States such that operating without knowledge of the applicable laws, both federal and state, can prove daunting if not akin to strolling through a minefield. The FDA has proven very effective at ferreting out any non-compliant actors through basic internet searches of company websites and various social media outlets. The increased transparency and interagency collaboration also heighten surveillance capabilities.

Regardless of the point of market entry in this space, interested parties should carefully consider the impact that increased enforcement activities could have on their organization and should maintain vigilance over their legal and compliance efforts, including assessing the potential for enforcement actions by other agencies including the DEA and FTC, among other federal and state agencies.

Hall Render will continue to monitor regulatory and enforcement developments related to the sale of cannabidiol and cannabis-derived products. For more information, please contact:

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For more information Hall Render's FDA & Life Sciences services, click here.

[references]

[1] Warning Letters and Test Results for Cannabidiol-Related Products, U.S. Food & Drug Administration, https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products (last accessed 10/22/2019).

[2] U.S. Food & Drug Administration, Warning Letter 579289, https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/curaleaf-inc-579289-07222019, (last accessed 10/22/2019).

[3] Refer to endnote (1), *supra*.

[4] Refer specifically to Sections 5(a) and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45(a) and 52.

[5] See *POM Wonderful LLC v. FTC*, 777 F.3d 478, 504-05 (D.C. Cir. 2015).

[6] Refer to the relatively close proximity in the timing between date(s) of FDA/FTC review versus date of Warning Letter issuance in endnote (3), *supra*.

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