THE
NATIONAL LAW REVIEW

FDA Commissioner Gottlieb Says Agency Will Not Tolerate Deceptive Marketing of CBD Products; Issues Warning Letters

Wednesday, April 3, 2019

On April 2, 2019, FDA issued a press release featuring a statement from FDA Commissioner Scott Gottlieb announcing the Agency's latest enforcement actions taken against companies engaging in unlawful marketing of cannabidiol (CBD) products. Coming just days before Gottlieb's anticipated departure from the Agency, this news otherwise is unsurprising given recent events on the federal and state level. In a December 2018 press release issued on the heels of the Farm Bill's passage, FDA forecast its intention to step up enforcement against CBD products, and earlier this year state and local governments initiated seizures of CBD products from store shelves. For manufacturers, retailers, and consumers, the takeaway from these recent statements and actions is that it remains unlawful under the Federal Food Drug and Cosmetic (FD&C) Act to market conventional foods or dietary supplements containing CBD.

Article By Lauren A. Farruggia
Gail H. JavittMegan Robertson
Epstein Becker & Green, P.C.
Health Law Advisor

Administrative & Regulatory
Biotech, Food, Drug
All Federal

The April 2, 2019 press release announces the issuance of three Warning Letters to companies marketing CBD products using "egregious and unfounded claims that are aimed at vulnerable populations." Notably, the Warning Letters were issued jointly by FDA and the Federal Trade Commission, which has authority to protect consumers from unfair trade practices, including false or misleading advertising claims. As examples of unlawful claims, the Warning Letters cite assertions that CBD products stop growth of cancer cells, slow the progression of Alzheimer's, and reduce withdrawal symptoms in individuals with substance use disorders. While FDA's position is that the inclusion of CBD as an ingredient in conventional foods and dietary supplements is per se unlawful, the Agency's focus on companies making cure or treatment claims for serious diseases and conditions is consistent with the December 2018 statement that the Agency would prioritize enforcement against products the Agency believes put consumers at risk.

The press release also sets a date for the previously promised public hearing on the future of CBD product regulation. The hearing, which is scheduled for May 31, 2019, will provide a platform for interested parties to "share their experiences and challenges" under the current regulatory environment. A newly-created internal Agency working group will be tasked with reviewing and analyzing stakeholder feedback and exploring potential regulatory pathways for CBD products. FDA seeks stakeholder feedback on issues including the levels of cannabis and cannabis-derived compounds that cause safety concerns; how the mode of delivery (e.g., ingestion, absorption, inhalation) affects the safety of, and exposure to, these compounds; and how cannabis and cannabis-derived compounds interact with other substances such as drug ingredients.

Stakeholders with an interest in developing, marketing, distributing, or purchasing consumer-focused CBD products—as well as in developing other hemp-derived cannabinoid compounds for the consumer market—can submit comments or a request to make an oral presentation at the hearing by May 10, 2019. Stakeholders can also submit comments for FDA's consideration after the hearing via regulations.gov by July 2, 2019.