Tucker Ellis LLP

CLIENT ALERT

FDA CANNABIS REGULATION: HELP US MAKE YOUR VOICE HEARD

APRIL 2019

PUBLIC HEARING: SHARE YOUR CONCERNS WITH US TO HELP SHAPE REGULATION

Since the passage of the Farm Bill, which legalized the production and transportation of hemp and hemp products, many companies have become increasingly uncertain as to how to lawfully operate in this new and complicated area.

Tucker Ellis can help companies find their way as the new regulatory environment unfolds, as well as make your questions and concerns known. FDA has announced its first public hearing on cannabis regulation to be held **May 31, 2019** and invited written public comment on the regulation of cannabis products. Our attorneys will attend the hearing and provide written comment on behalf of our stakeholder clients. This hearing and comment period is an opportunity for you to (1) give input on regulatory strategy relating to existing products, as well as lawful pathways for products to be marketed; and (2) help shape the policies that will govern the cannabis industry for years to come.

FDA regulation is critical to establishing the legality and legitimacy of cannabis products across the United States. Please contact us with your questions, concerns, or issues no later than **May 24, 2019** so that we can consider raising them at the public hearing and/or during the written comment period.

CANNABIS UPDATE

It has been an eventful couple of weeks for the CBD industry as FDA has issued a statement on future regulatory steps, and its outgoing commissioner voiced concerns about the expansion of sales of cannabis and cannabis-derived products. FTC also joined FDA in issuing three new warning letters to CBD companies.

FDA REITERATES ITS POSITION ON WHAT IT CONSIDERS TO BE UNLAWFUL

FDA again explained what it considers to be unlawful with respect to cannabis and hemp. It is unlawful to:

- Market cannabis products or hemp-derived products with a claim of therapeutic benefit without FDA approval;
- Introduce into interstate commerce food containing added CBD or THC; and
- Market CBD or THC products as dietary supplements.

FDA restated its position that because CBD and THC products are active ingredients in FDA-approved drugs (Epidiolex and Sativex), which were the subject of substantial clinical investigations, adding CBD or THC to food or marketing them as dietary supplements is not permissible unless FDA first issues a regulation through notice-and-comment rulemaking to allow such use.

FDA INSIGHTS INTO CBD HEALTH AND SAFETY RISKS

FDA also provided additional insight into health and safety risks it is examining with respect to CBD products, including:

- The potential for liver injury identified in the clinical trials for Epidiolex, GW Pharmaceuticals' CBD-based seizure disorder drug; and
- Open questions concerning the safety of CBD products, including:
  - cumulative exposure to CBD;
  - the intended functionality of CBD in products; and/or
  - whether some threshold level of CBD could be allowed in foods without undermining the drug approval process or diminishing commercial incentives for further clinical study of the relevant drug substance.

CREATION OF AN INTERNAL CANNABIS WORKING GROUP

As part of FDA's regulatory steps, it announced the creation of a high-level internal FDA working group to explore potential pathways for dietary supplements or foods containing CBD to be lawfully marketed.

FDA AND FTC JOINTLY ISSUE THREE NEW WARNING LETTERS TO CBD COMPANIES

FDA and FTC issued three new warning letters to companies that market and sell CBD products. The letters followed FDA's usual pattern of cracking down on companies that market products with unsubstantiated health claims, such as claims that CBD may be effective in treating arthritis, diabetes, Alzheimer's, depression, skin conditions, inflammation, anxiety, and pain.

FTC also reiterates in these letters that it is unlawful to advertise that a product can prevent, treat, or cure human disease unless the seller possesses competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies substantiating that the claims are true at the time they are made.

GOTTLIEB'S CONCERN OVER MAJOR RETAILERS' DECISION TO SELL CBD TOPICAL PRODUCTS

Outgoing FDA commissioner Scott Gottlieb, M.D. commented on recent announcements by CVS and Walgreens that they will begin carrying topical products containing hemp-derived CBD in a select number of states. On April 2, Gottlieb tweeted that he was "concerned to hear recently that several national pharmacy chains and other major retailers have begun to sell or will soon begin to sell cannabidiol (CBD) products in several states." He continued, "We'll be contacting them to remind them of #FDA obligations and our commitment to protect consumers against products that can put them at risk."

In comments at a House Appropriations Committee hearing the next day, Gottlieb reiterated his concerns, stating, "So you now see big-box stores seeking to market CBD products for some uses where the claims seem to be potentially over the line, for the treatment of pain for example."

QUICK TAKEAWAYS

The good news is that FDA is taking steps toward regulation of cannabis and cannabis-derived products and inviting stakeholders to participate in the public hearing and comment process. The bad news is that FDA acknowledges that this process could take some time.

In the meantime, FDA has made clear that companies should not market or sell food or dietary supplements containing CBD products and that they should avoid any structure function or health claims for any products containing cannabis or cannabis-derived products, including hemp.

ADDITIONAL INFORMATION

Please contact us with your questions, concerns, or issues no later than **May 24, 2019** so that we can consider raising them at the public hearing and/or during the written comment period.

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