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One Week Away: Upcoming FDA Hearing on CBD

By Madison Lisotto Whalen

Anyone involved in the Cannabis or related industries should pay close attention to an upcoming Food and Drug Administration ("FDA") hearing which is scheduled to obtain scientific data and information about the safety, manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived compounds. The hearing is scheduled for May 31, 2019 from 8 a.m. to 6 p.m. Eastern Time. Electronic or written comments will be accepted until July 2, 2019. The full FDA notice is available here.

Hemp production was legalized in the 2018 Farm Bill (Agricultural Improvement Act of 2018) in December of last year. Hemp was removed from the federal list of controlled substances so long as certain conditions and concentration levels are met (cannabis and cannabis derivatives with tetrahydrocannabinol (THC) concentrations of no more than 0.3 percent on a dry weight basis). The Farm Bill also provided for the interstate commerce of legally produced hemp and hemp products. However, the FDA made it clear that CBD as an ingredient in foods and beverages was prohibited by the Federal Food, Drug, and Cosmetic Act. In addition, regarding the use of CBD in health and wellness products, cannabis or hemp products with any claim to medical benefits must still be approved by the FDA.

At the state level, Senate Bill 57, which would decriminalize hemp and create a state regulated hemp program, unanimously passed the Ohio Senate and is currently under consideration by the Ohio House of Representatives.The Ohio Department of Agriculture would be responsible for regulating hemp.

There are many issues related to CBD that the FDA is specifically looking for information on, including:

- Are there particular safety concerns that the FDA should consider regarding its regulatory oversight and monitoring of these products (such as levels of cannabis and mode of delivery)?
- Are there special human or animal populations (e.g., pregnant and lactating women) that should be considered when assessing safety?
- What would be a successful system to collect representative safety information at the national and state levels?
- What endpoints or outcomes would define a maximal acceptable daily intake from all products?
- Are there any data known that would support the safe use of cannabis and cannabis-related compounds in general food use?
- How does the existing commercial availability of food products containing cannabis-derived compounds affect the incentives for/feasibility of, drug-development programs involving such compounds?

Roetzel will keep you abreast of all the latest news on this topic. Please contact any of the attorneys listed below for further information.

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