

Upcoming FDA Hearings May Have Huge Impact on Cannabis Industry

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There could be big changes on the horizon regarding the regulation of CBD (cannabidiol), the non-psychoactive chemical compound which can be extracted from hemp and marijuana. It is gaining popularity in various health and wellness products for the relief of pain, anxiety, and inflammation among other things, as well as in CBD edibles.

Hemp production was legalized in the Farm Bill (Agricultural Improvement Act of 2018) in December of last year. Hemp was removed from the federal list of controlled substances if it meets certain conditions and concentration levels, specifically, it is defined in Sec. 10113 as, “the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.” The Farm Bill also provides for the interstate commerce of legally produced hemp and hemp products.

This all became more complicated when the Food and Drug Administration issued a press release upon the signing of the Farm Bill reinforcing the fact that CBD as an ingredient in foods and beverages was prohibited by the Federal Food, Drug, and Cosmetic Act. Commissioner Scott Gottlieb, M.D., stated the FDA’s policy that it was illegal to “introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements...” Regarding the use of CBD in health and wellness products, Gottlieb reiterated that a cannabis or hemp product with any claim to medical benefits must still be approved by the FDA. Commissioner Gottlieb announced that the FDA will hold its first public hearings on CBD in April. He followed that with an announcement that he will be leaving the agency in April.

The emerging CBD industry will be dramatically affected by any regulations the FDA may put into place, which is why the upcoming public hearings are eagerly anticipated. Issues on the table include labeling requirements, concentration levels, manufacturing plant requirements, supply chain monitoring, and the use of CBD in food. Retail giant CVS recently started selling CBD products in eight states, which might be the impetus for other retailers to follow suit. The industry is poised for huge growth, but the current uncertainty surrounding it means increased product liability and compliance issues for manufacturers and increased risks to consumers.

Businesses, consumers and the legal industry in general need guidance regarding CBD products, and any federal rule-making process could take years to formulate and implement. Whether being used for health benefits and/or as food additives, CBD has become a focus of the Food and Drug

Administration and the upcoming hearings may determine the direction the agency will take in addressing these issues and determining the direction of the entire industry.

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