Hemp-Derived Cannabidiol (CBD) Q & A

What is CBD?

Cannabidiol (CBD) is a compound extracted from hemp or marijuana. The Agriculture Improvement Act of 2018 (Farm Bill) excluded hemp and its constituents from the definition of marijuana, and removed it from the Controlled Substances Act (CSA). Hemp is a valuable agricultural commodity and contains only trace levels of tetrahydrocannabinol (THC), the intoxicating compound in marijuana. And hemp has been cultivated throughout human history for many purposes, including food, fiber and oil. Modern science has demonstrated that, in addition to its value as a food and fiber, hemp extracts naturally contain CBD (e.g., hemp oil, CBD-oil, hemp-derived CBD) and that CBD may have its own health-promoting benefits. Now, by excluding hemp from the definition of marijuana, hemp with less than 0.3 percent THC (and its constituents such as CBD) is no longer a controlled substance under the CSA.

What does CBD do?

CBD's prior status as a Schedule I controlled substance presented significant barriers to clinical research. However, in the past few years, changes to state and federal laws have removed some of the obstacles to conducting research. Scientists and physicians have demonstrated that CBD may have multiple benefits throughout the body. Emerging research shows that CBD interacts with cellular receptors in physiological processes that influence sleep, mood, appetite and pain, without intoxicating effects.

Is CBD safe?

Research demonstrates that CBD is safe in food, dietary supplements and beverages. It has been established that hemp-derived CBD contains negligible amount of THC, the psychoactive component of cannabis, and that it is non-psychoactive and does not cause a "high" in users. Further, hemp-derived CBD does not have the potential for abuse or addiction. The World Health Organization (WHO) Expert Committee on Drug Dependence recommended not scheduling CBD within the International Drug Control Conventions. WHO cited the fact that there are no case reports of CBD abuse or dependence; no public health problems have been associated with CBD use; CBD has been found to be generally well tolerated with a good safety profile; and that there is no evidence that CBD is liable to abuse.[1] Furthermore, the U.S. Health and Human Services Department (HHS) conducted a scientific review on CBD and concluded that it does not present a significant risk to the public health. HHS found that there is no evidence for classic drug withdrawal, no evidence that CBD causes physical or psychic dependence and no potential for abuse under the CSA.[2]

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[1] WHO Expert Committee on Drug Dependence, fortieth report. Geneva: World Health Organization; 2018 (WHO Technical Report Series, No. 1013). License: CC BY-NC-SA 3.0 IGO.

[2] Giroir, Brett P (Office of the Assistant Secretary for Health, Department of Health and Human Services, Washington, DC). Letter to: Robert W. Patterson (Drug Enforcement Administration, U.S. Department of Justice, Springfield, VA). 2018 May 16. 2 leaves. Accompanied by: U.S. Food & Drug Administration's "Basis for the Recommendation to Place Cannabidiol in Schedule V of the Controlled Substances Act."

After the 2018 Farm Bill, why does FDA maintain CBD is still unlawful?

The Farm Bill removed hemp-derived CBD from Schedule I of the CSA, which means it will not be regulated as a controlled substance by the Drug Enforcement Agency (DEA). However, the Farm Bill did not affect other agencies with jurisdiction over the substance. FDA explicitly retains jurisdiction to regulate the use of CBD in food, beverages, dietary supplements and other FDA-regulated products. FDA takes the position that CBD may not be sold in the United States due to provisions in the Food, Drug and Cosmetic Act (FDCA) related to the use of dietary supplement and food ingredients that have been previously studied as drug ingredients. If a substance has been authorized for investigation as a new drug, "substantial clinical investigations" have started, and the existence of these investigations has been made public before the substance was used in a food or supplement, then the ingredient in question falls outside the definition of a dietary supplement or a food.[3] According to FDA, there is evidence that a CBD ingredient used in a drug product met these criteria prior to CBD ingredients' use in food or supplements.

Can FDA address the problem?

Yes. The FDCA allows the Health and Human Services (HHS) Secretary to create a regulation permitting the use of an ingredient in food and dietary supplements, despite a determination that it was first subject to clinical drug investigations as described above. This alternative would allow FDA to clearly establish a legal pathway to market for hemp-derived CBD as a food and dietary supplement. FDA Commissioner Dr. Scott Gottlieb raised the possible use of this authority in a December 20, 2018 statement on CBD following the passage of the Farm Bill. Clearly, FDA is open to and exploring this pathway.[4]

Why should FDA permit CBD in food or dietary supplements? What are the advantages?

Exploring a legal path to market for food, beverages and dietary supplements containing hemp-derived CBD is consistent with FDA's strong public health goals. Recognizing CBD products as lawful foods, beverages or dietary supplements would allow the agency to impose a reasonable regulatory framework around the processing, manufacturing and marketing of hemp-derived CBD products not intended for use as drugs. It would also permit the agency to enforce existing regulations regarding registration of manufacturing facilities; observance of good manufacturing practice regulations; supply chain security; compliance with food additive and new dietary ingredient provisions for food and dietary supplements; and post-market surveillance of serious adverse events. If FDA fails to act, consumer interest in CBD will continue to grow along with a thriving but plainly unlawful array of CBD products. No one benefits from a "wild west" scenario in which companies willing to risk FDA enforcement distribute these products without appropriate FDA oversight and guidance.

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[3] 21 U.S.C. § 321(ff)(3)(B)(ii) and 21 U.S.C. 331(ll)(2)

[4] U.S. Food and Drug Administration. (2018). *Statement from FDA Commissioner Scott Gottlieb, M.D., on signing of the Agriculture Improvement Act and the agency's regulation of products containing cannabis and cannabis-derived compounds*. Retrieved from www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm628988.htm