FDA CLARIFIES POSITION ON CBD AFTER PASSAGE OF 2018 FARM BILL

The United States Food and Drug Administration (“FDA”) issued a statement (the “Statement”) clarifying its position on cannabidiol (“CBD”) products in the wake of the Agriculture Improvement Act of 2018 (the “2018 Farm Bill”) signed December 20, 2018.¹ The 2018 Farm Bill is a broad piece of legislation that regulates agricultural programs ranging from income support to rural development.² While Congress enacts a new Farm Bill approximately every five years, the 2018 Farm Bill is unlike any of its predecessors, as it notably legalizes hemp cultivation and declassifies hemp as a Schedule I controlled substance.³

In its Statement, the FDA emphasizes that although hemp is no longer an illegal substance under federal law, the FDA continues to regulate cannabis products under the Food, Drug, and Cosmetic Act (“FD&C Act”) and Section 351 of the Public Health Service Act. Therefore, any cannabis product marketed with a claim of therapeutic benefit, regardless of whether it is hemp-derived, must be approved by the FDA before it can be sold. The Statement also confirms that the addition of CBD to food products and dietary supplements is unlawful. However, the FDA recognizes pathways for the lawful introduction of cannabis and cannabis-derived products into the market as further described below.

DISCUSSION

What Is “Hemp”?  

The 2018 Farm Bill defines “hemp” as any part or derivative of the Cannabis sativa L. plant containing less than 0.3 percent tetrahydrocannabinol (“THC”) by weight.⁴ This definition includes hemp plants that produce the concentrated liquid extract known as cannabidiol (or CBD) oil. CBD oil has rapidly gained traction through recent years as a wellness product and is now legal in numerous states.

2018 Farm Bill

The 2018 Farm Bill is the first piece of federal legislation legalizing hemp and removing its Drug Enforcement Administration (“DEA”) Schedule I controlled substance designation. While the 2014 Farm Bill permitted research on industrial hemp under narrow circumstances,⁵ the 2018 Farm Bill significantly broadens these allowances and legalizes hemp cultivation in accordance with certain regulations. The 2018 Farm Bill also amends the Controlled Substances Act of 1970 (“CSA”) by declassifying hemp as a Schedule I controlled substance and shifting its supervision from the DEA to the United States Department of Agriculture (“USDA”).⁶ Under the CSA, Schedule I substances receive the DEA’s strictest form of regulatory treatment and are the only category that cannot be prescribed by a physician. Hemp is now excluded from this designation.

FDA Statement

The Statement notes that Congress expressly preserved the FDA’s authority over cannabis products in the 2018 Farm Bill. All cannabis and cannabis-derived products therefore remain subject to the same rules as any other FDA-regulated products. The FDA requires that any product marketed with a therapeutic claim must be approved prior to its introduction into interstate commerce. The Statement clarifies that the FDA does not distinguish the substance’s source when exercising its regulatory authority, including whether a product originates from hemp or otherwise. The agency cites deceptive marketing practices as a chief concern and clearly establishes that selling unapproved products with a therapeutic claim is unlawful. The FDA further prohibits the introduction of CBD products into the food supply and dietary supplements even if they are hemp-derived. The agency’s rationale is that CBD is an active ingredient in FDA-approved drugs, and its addition to the food supply and dietary supplements is illegal under the FD&C Act.

In its Statement, the FDA vows to take enforcement action against those who partake in the illicit sale of cannabis products with a therapeutic claim. The FDA previously sent warning letters⁷ to companies illegally selling CBD-infused substances claiming to offer health benefits, such as the prevention or treatment of serious diseases. Additionally, the agency targeted the sale of CBD-infused food products marketed as dietary supplements in violation of the FD&C Act.
However, the FDA also recognizes pathways for legal introduction of cannabis and cannabis-derived products into interstate commerce. One such route is for the FDA to approve drugs containing CBD, as the agency has done in the past. For example, in 2018, the FDA approved Epidiolex, a seizure medication containing cannabis-derived CBD. Furthermore, the FDA identifies three lawful hemp derivatives in its Statement, including hulled hemp seeds, hemp seed protein and hemp seed oil. These products can be marketed legally, provided they are not promoted with a therapeutic claim. Additionally, although the FDA generally prohibits the introduction of cannabis products into the food supply and dietary supplements, the agency would consider issuing regulations allowing the use of a pharmaceutical ingredient for such purposes provided all other FD&C Act requirements are met.

While the FDA statement addresses the federal landscape, stakeholders must remain mindful of varying state laws and requirements applicable to CBD. State CBD legislation ranges from legalization (subject to certain restrictions) to prohibition. For example, Indiana legalized the sale of CBD oil in March 2018, provided it contains no more than 0.3 percent THC and complies with labeling requirements. Conversely, in August 2018, the Ohio Board of Pharmacy issued an FAQ proclaiming that CBD oil derived from hemp is illegal and can only be sold through the state's medical marijuana program.

Impact of 2018 Farm Bill

The 2018 Farm Bill triggers a significant shift in federal cannabis policy by legalizing industrial hemp cultivation and removing hemp from the CSA. Numerous states have enacted laws legalizing CBD oil in recent years, some stricter than others. However, confusion persisted due to the federal designation of cannabis as a Schedule I controlled substance. Furthermore, in the wake of more states legalizing CBD oil, a U.S. Court of Appeals for the Ninth Circuit decision emerged confirming CBD’s status as a Schedule I controlled substance. The 2018 Farm Bill’s exclusion of hemp from the DEA’s Schedule I controlled substance list will likely clarify the murkiness caused by conflicting state and federal laws. Additionally, hemp will now become a legal agricultural commodity and is expected to experience significant market growth as a result. According to the Brightfield Group, a research firm, the legalization of hemp could create a market boom for CBD worth more than $20 billion by 2022.

PRACTICAL TAKEAWAYS

The FDA continues to regulate cannabis products under the FD&C Act despite hemp’s removal from the Controlled Substance Act of 1970. This means that any cannabis product marketed with a therapeutic claim, whether derived from hemp or otherwise, must receive FDA approval before it can be sold. The sale of unapproved products is a clear violation of the law, and the FDA will take enforcement action upon those who partake in such activity. The FDA also regulates and prohibits the introduction of CBD into the food supply and dietary supplements. However, the FDA provides numerous pathways to lawfully market CBD and other hemp-derived products. While the FDA Statement addresses the federal law surrounding CBD, stakeholders must also remain cognizant of local CBD requirements in the states where they operate.

We will continue to monitor all developments related to the Statement and the 2018 Farm Bill’s impact on the hemp industry. We have also written about employment issues related to medical marijuana legislation and will publish a series of articles in 2019 titled “Marijuana in the Workplace: Legal Issues for Employers to Consider.” The series will cover legal implications related to emerging marijuana trends and highlight key takeaways for employers when dealing with marijuana and CBD in the workplace.

If you have any questions or would like additional information about this topic, please contact:

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1 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, FDA (January 10, 2019), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm628988.htm.

3 Id.

4 Id.


6 Id.

7 Warning Letters and Test Results for Cannabidiol-Related Products, FDA (January 10, 2019), https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm484109.htm.

8 FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy, FDA (January 10, 2019), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm611046.htm.

9 Indiana Code § 24-4-22-3.

10 Ohio Medical Marijuana Control Program CBD Oil FAQ, State of Ohio Board of Pharmacy (January 10, 2019), https://www.pharmacy.ohio.gov/Documents/Pubs/Special/MedicalMarijuanaControlProgram/CBD%20Oil%20FAQ.pdf.
