

Legalization of Products Containing CBD? Not Quite Yet, Says FDA

The Agency plays a significant role in the evolving legal landscape governing certain cannabis-derived products.

Key Points:

- New law lifts or eases some, but not all, federal obstacles for certain cannabis-derived products.
- FDA's authority to regulate cannabis-derived products is preserved, with existing laws prohibiting the marketing of foods and dietary supplements containing CBD remaining in place.
- FDA is actively exploring potential pathways to allow for the lawful marketing of such products either through issuance of new regulations or by requesting legislative action.
- Industry must keep abreast of expected regulatory developments and the possibility of legislative action.

Introduction

With the passage of the Agriculture Improvement Act of 2018 (the 2018 Farm Bill) in December 2018,¹ the market for cannabis-derived products has generated significant public interest and excitement in light of the law's establishment of a legal framework for the commercial production of — and removal of some legal restrictions on — certain cannabis plants and cannabis-derived substances. However, a commonly misunderstood feature of the law is its express deference to the US Food and Drug Administration's (FDA's or the Agency's) authority over such products that fall within FDA's purview. Prior to the 2018 Farm Bill, FDA deemed any food or dietary supplement product containing cannabidiol (CBD) to be unlawful, and the Agency continues to reiterate this position. While FDA is actively exploring mechanisms to enable the legal marketing of such products and will be holding a public meeting to obtain feedback from the public and industry on May 31, 2019, the Agency has not been shy in enforcing its existing laws with respect to cannabis-derived products, particularly when those products are marketed with claims that render such products "drugs" by virtue of their intended use.

The 2018 Farm Bill Establishes a Framework for Commercial Hemp Production and Removes Controls Imposed by the DEA

The 2018 Farm Bill, among other things, establishes a framework for the legal production of hemp overseen by the US Department of Agriculture.² Hemp is defined under the law 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.”³ CBD and delta-9 tetrahydrocannabinol (THC) are the most widely known cannabinoids derived from the cannabis plant. Whereas THC is psychoactive, CBD is not.

The law further removes hemp from Schedule I of the US Controlled Substances Act, under which it was previously subject to stringent controls.⁴ Consequently, the 2018 Farm Bill effectively removes hemp — including CBD, to the extent that it meets the definition of hemp — from statutory scheduling, and it lifts the associated controls over such substances implemented by the US Drug Enforcement Administration (DEA).⁵

FDA Requirements Still Apply

Notwithstanding the 2018 Farm Bill’s framework for the lawful production of hemp and removal of hemp from Schedule I, the marketing of certain cannabinoids that fall within the definition of hemp remains illegal pursuant to the laws administered by FDA. Notably, the 2018 Farm Bill makes explicit that FDA’s legal authorities remain unchanged.⁶ Thus, cannabis and cannabis-derived products are subject to the same authorities and requirements as FDA-regulated products containing any other substance — *i.e.*, they must comply with FDA’s framework applicable to the particular product category at issue, such as the requirements for marketing as a food, dietary supplement, drug, or cosmetic.⁷

In the case of foods (including animal foods) and dietary supplements containing CBD, FDA has stated that it deems such products unlawful irrespective of whether they are derived from hemp and even if the products otherwise comply with the framework established by the 2018 Farm Bill. Specifically, under the Federal Food, Drug, and Cosmetic Act (FDCA), because CBD is an active ingredient in an approved drug and has been the subject of substantial clinical studies that have been made public,⁸ it cannot be marketed as, or included in, a food or dietary supplement as a matter of law unless a statutory exception applies.⁹ FDA has determined that none of the statutory exceptions has been met for CBD. Nevertheless, FDA has acknowledged that the law authorizes the Agency to engage in notice and comment rulemaking to authorize the marketing of such substances notwithstanding the statutory prohibition.¹⁰

Current Enforcement Approach and the Road Ahead

Despite FDA’s current categorical prohibition on CBD in foods and dietary supplements, the Agency is using its authority to focus enforcement actions on those products that pose a greater risk to consumers, particularly those that “make unproven claims to treat serious or life-threatening diseases, and where patients may be misled to forgo otherwise effective, available therapy and opt instead for a product that has no proven value or may cause them serious harm.”¹¹ On March 28, 2019, FDA, in collaboration with the Federal Trade Commission, issued Warning Letters to three companies making claims regarding their CBD products’ ability to limit, treat, or cure cancer, neurodegenerative conditions, autoimmune diseases, opioid use disorder, and other serious diseases, without sufficient evidence and the legally required FDA approval.¹² In connection with these Warning Letters, former FDA Commissioner Scott Gottlieb stated that he “continues to be concerned about the proliferation of egregious medical claims being made about products asserting to contain CBD that haven’t been approved by FDA.”¹³ Under the FDCA, a product is considered a “drug” if it is an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, or an article (other than food) that is intended to affect the structure or any function of the body.¹⁴ Marketing products containing CBD for these uses is permitted only upon FDA approval.

In the meantime, FDA is moving full steam ahead with plans to explore the establishment of a regulatory pathway for certain FDA-regulated products containing CBD (outside of the existing drug approval framework) either through administrative rulemaking or by requesting legislative action. Specifically:

- **Public Hearing.** FDA announced that on May 31, 2019, it will hold a public hearing to obtain scientific data and information about the safety, manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived compounds. Requests to make oral presentations at the hearing should be submitted by May 10, 2019. Although FDA does not intend for the hearing to produce any decisions or new positions on specific regulatory questions, the hearing is expected to be an important step in the Agency's continued evaluation of these products.¹⁵
- **Written Comments.** FDA has opened a public docket as part of the upcoming hearing and has requested that stakeholders submit comments on several questions intended to inform the Agency's regulatory oversight and monitoring of CBD and other cannabis-derived products. FDA is seeking comments, data, and information on a variety of topics, including, among others:
 - What levels of cannabis and cannabis-derived compounds cause safety concerns
 - How the mode of delivery (e.g., ingestion, absorption, inhalation) affects the safety of, and exposure to, cannabis-derived compounds
 - How cannabis and cannabis-derived compounds interact with other substances, such as drug ingredients
 - Whether particular standards or processes are needed to ensure manufacturing quality and consistency of cannabis-derived products
 - How consumers should be informed about associated risks

FDA will accept public comments until July 2, 2019.¹⁶

- **FDA Working Group.** FDA has formed a high-level internal working group to explore potential pathways for conventional foods and dietary supplements containing CBD to be legally marketed. While recognizing that FDA may take steps to override the statutory restrictions on such products by regulation, former Commissioner Gottlieb estimated that it could take two to four years for FDA to establish the regulations necessary to permit the lawful marketing of products containing CBD, and that a legislative fix may be more expedient. As such, the group will also contemplate whether there are legislative options that might lead to more efficient and appropriate pathways that are not available under current law. The working group plans to begin sharing information and/or findings with the public as early as this summer.¹⁷

Key Takeaways for Industry Stakeholders

Prior to his departure from FDA, former Commissioner Gottlieb acknowledged the widespread marketing of products containing CBD, as well as the common misconception that the 2018 Farm Bill legalized all products containing CBD. Notwithstanding the legal prohibitions on marketing food and dietary supplement products containing CBD under the FDCA, FDA recognizes that its enforcement resources are limited. To that end, FDA is currently taking a selective enforcement approach against companies making the most egregious claims in an effort to prompt broader industry compliance while it continues to press forward on approaches toward the legalization of such products.¹⁸ Acting FDA Commissioner Ned Sharpless appears to be taking the same approach as his predecessor and is moving full speed ahead in FDA's work to develop a regulatory framework in this area. The burgeoning CBD industry would be well-served to monitor the developing legal landscape, as well as FDA's enforcement actions, in this space.

If you have questions about this *Client Alert*, please contact one of the authors listed below or the Latham lawyer with whom you normally consult:

J. Benneville (Ben) Haas

ben.haas@lw.com
+1.202.637.1084
Washington, D.C.

Elizabeth M. Richards

elizabeth.richards@lw.com
+1.202.637.2130
Washington, D.C.

Amy E. Speros

amy.speros@lw.com
+1.650.463.4676
Silicon Valley & Washington, D.C.

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Endnotes

¹ Pub. L. No. 115-334, 132 Stat. 4490 (2018) [hereinafter "2018 Farm Bill"].

² *Id.* § 10113 (adding Subtitle G to the Agricultural Marketing Act of 1946 (7 U.S.C. § 1621, *et seq.*) [hereinafter "1946 Act"]).

³ *Id.* (adding 1946 Act § 297A(1)).

⁴ *Id.* § 12619 (amending 21 U.S.C. § 802(16)).

⁵ The 2018 Farm Bill excludes "hemp" from the statutory definition of "marihuana," effectively removing hemp from Schedule I of the Controlled Substances Act; however, DEA has not yet amended its regulations to specifically remove "hemp" from Schedule I. See 21 C.F.R. § 1308.11(d)(58). DEA's past statements suggest that it will not enforce its regulations with respect to marijuana beyond its statutory authority in the Controlled Substances Act. See DEA, *DEA Internal Directive Regarding the Presence of Cannabinoids in Products and Materials Made from the Cannabis Plant* (May 22, 2018), https://www.deadiversion.usdoj.gov/schedules/marijuana/dea_internal_directive_cannabinoids_05222018.html.

⁶ Pub. L. No. 115-334 § 10113 (adding 1946 Act § 297D(c)).

⁷ FDA, Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments, 84 Fed. Reg. 12,969 (Apr. 3, 2019) [hereinafter "FDA Public Meeting Notice"]; see also FDA, *FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers* (Apr. 2, 2019), <https://www.fda.gov/news->

[events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-questions-and-answers#dietary_supplements](#).

- ⁸ FDA has identified its June 2018 approval of the drug, Epidiolex, which contains a purified form of CBD for the treatment of seizures associated with two rare and severe forms of epilepsy, and which, prior to approval, was the subject of substantial clinical studies that had been made public.
- ⁹ 21 U.S.C. §§ 331(ll), 321(ff)(3)(B).
- ¹⁰ *Id.* §§ 331(ll)(2), 321(ff)(3)(B).
- ¹¹ FDA Press Announcement, *Statement from FDA Commissioner Scott Gottlieb, M.D., on New Steps to Advance Agency's Continued Evaluation of Potential Regulatory Pathways for Cannabis-Containing and Cannabis-Derived Products* (Apr. 2, 2019), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-advance-agencys-continued-evaluation> [hereinafter "Gottlieb Press Announcement"].
- ¹² FDA, *Warning Letters and Test Results for Cannabidiol-Related Products* (Apr. 2, 2019), <https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products>.
- ¹³ Gottlieb Press Announcement.
- ¹⁴ 21 U.S.C. § 321(g)(1)(B)-(C).
- ¹⁵ FDA Public Meeting Notice.
- ¹⁶ *Id.*
- ¹⁷ Gottlieb Press Announcement.
- ¹⁸ Transcript, *Hearing on FDA Budget Request for FY2020 Before the Subcomm. on Agriculture, Rural Development, FDA, and Related Agencies, H. Comm. on Appropriations*, BLOOMBERG GOVERNMENT (Apr. 3, 2019) ("What's happening is, we see a burgeoning market. And we can't boil the ocean. So we're trying to take a risk-based approach to our enforcement, like we do in all matters. And we're hoping by taking selective enforcement actions, you're going to see voluntary compliance from the legitimate manufacturers and retailers, because they are marketing an unlawful product.").