

January 7, 2019

It's Still Gray: The 2018 Farm Bill and the Legality of CBD Under Federal Law

By [Suzie Trigg](#) and [Kayla Johnson](#)

President Trump recently signed the Agriculture Improvement Act of 2018 (also known as the 2018 Farm Bill) and the cannabis industry quickly and widely celebrated passage as clearing the way to sell products containing cannabidiol (better known as CBD). But is it really? As one might expect, this lawyer's answer is that "it depends."

CBD has become known for its purported health benefits in relation to a wide range of conditions. CBD is currently available for purchase in various forms and product types online and over the counter, and retail CBD sales are projected to be as high as \$1.9 billion by 2020.¹ Despite its proliferation in the U.S. market, most CBD sales to-date were made in violation of the Controlled Substances Act (CSA) and the federal Food, Drug, and Cosmetic Act (FD&C Act).

The 2018 Farm Bill has been widely regarded as the solution to this paradox, as its enactment, according to many stakeholders, signifies the nationwide legalization of all CBD-product sales under federal law. It is true that the 2018 Farm Bill legalizes hemp-derived CBD (with THC concentration below 0.3 percent) under a federal law (the CSA). While the 2018 Farm Bill is an important step in clarifying the legal status of CBD, the Act does not legalize *all* CBD under *all* federal laws. Important for the food and supplement industries—as well as retailers who find themselves caught in the crosshairs of what industry and consumers want and what state and federal regulators might enforce—the FDA's position is that the 2018 Farm Bill and its legalization of hemp does not impact the FD&C Act, under which the FDA continues to take the position that it is still illegal to market foods, beverages, or dietary supplements containing CBD.

Upon the President's signing of the Agriculture Improvement Act of 2018, FDA Commissioner Scott Gottlieb, M.D., promptly released a statement that reiterates the FDA's focus on enforcement against companies that illegally market products with cannabis-derived compounds that pose a significant risk to the public.² But, notably, Commissioner Gottlieb's statement also spells out the agency's efforts to make available lawful pathways for marketers of these products and indicates the FDA's continued focus is on products that do not make unapproved drug claims.

Changes from the 2018 Farm Bill

As a Schedule I controlled substance, marijuana has long been illegal under federal law. While the 2018 Farm Bill does not amend the CSA, such that marijuana is no longer on schedule I, it does effectively remove hemp-derived CBD from schedule I by promulgating an exception to the CSA's definition of marijuana.

Section 102(16) of the CSA defines "marihuana" as follows:

[A]ll parts of the plant *Cannabis sativa* L., whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. Such term does not include the mature

¹ Jamie Corroon and Rod Knight, *Regulatory Status of Cannabidiol in the United States: A Perspective*, 3 CANNABIS & CANNABINOID RESEARCH 190, 190–94 (Sept. 27, 2018).

² Press Release, U.S. Food and Drug Admin., [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](#) (Dec. 20, 2018).

stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination.³

Under Section 102(16) of the CSA, as amended by the 2018 Farm Bill, “[t]he term ‘marihuana’ does not include—‘hemp, as defined in [S]ection 297A of the Agricultural Marketing Act of 1946 [AMA].’”⁴ Accordingly, pursuant to the 2018 Farm Bill, excluded from the definition of marijuana and, thus, schedule I of the CSA is:

[T]he 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 [THC] concentration of not more than 0.3 percent on a dry weight basis.⁵

As amended by the 2018 Farm Bill, the CSA distinguishes between marijuana and hemp. The practical effect in relation to the legality of CBD under the CSA is that it is generally permissible to import, manufacture, distribute, and/or sell hemp-derived CBD in interstate commerce, whereas marijuana-derived CBD remains a Schedule I controlled substance.⁶

The Catch for Marketers

As a preliminary matter, because marijuana-derived CBD (with THC > 0.3 percent) is still illegal as a schedule I controlled substance under the CSA, it is not assessed under the FD&C Act (as any lawfulness thereunder will have no impact on its legality under federal law as long as it remains on schedule I of the CSA). Accordingly, the FD&C Act analysis is limited to hemp-derived CBD (with < 0.3 percent THC).⁷

The 2018 Farm Bill expressly provides that “[n]othing in this subtitle shall affect or modify—(1) the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*); . . . or (3) the authority of the Commissioner of Food and Drugs and the Secretary of Health and Human Services” under that Act.⁸ Accordingly, notwithstanding the 2018 Farm Bill’s legalization of hemp-derived CBD (with a THC concentration of less than 0.3 percent) under the CSA, the introduction of many CBD products into interstate commerce remains a violation of federal law under the FD&C Act. However, unlike under the CSA, the sale of certain CBD products is unlawful under the FD&C Act, not based on an express statutory prohibition, but rather, the FDA’s interpretation of the FD&C Act as applied to CBD. Importantly, the FDA has consistently maintained that it would reconsider its stance on the legality of certain CBD products under the FD&C Act if it becomes aware of evidence that calls into question its current conclusions.⁹ Until such time, it is important to understand:

- (i) The legal status of CBD when marketed as, or within, drug products, dietary supplements, food items, and cosmetics; and

³ 21 U.S.C. § 802(16).

⁴ [2018 Farm Bill, § 7706](#).

⁵ *Id.* § 7702.

⁶ There may be exceptions where hemp-derived CBD contains more than 0.3 percent THC and marijuana-derived CBD contains less, in which case, this general rule will not apply, as the THC content, not the name of the sub-species, is the dispositive factor.

⁷ All references to CBD hereinafter refer to hemp-derived CBD with THC < 0.3 percent, unless explicitly stated otherwise.

⁸ *Id.* § 297D(b)(1)–(3).

⁹ “FDA is not aware of any evidence that would call into question these conclusions. Interested parties may present the agency with any evidence that they think has bearing on this issue. Our continuing review of information that has been submitted thus far has not called our conclusions into question.” [FDA and Marijuana: Questions and Answers](#), 13, U.S. FOOD AND DRUG ADMIN.

- (ii) The spectrum of enforcement risk based on the FDA's publicly stated current policies and priorities.

Current Legal Status of CBD Products by Category

Conventional Foods or Beverages

In his statement about the 2018 Farm Bill, Commissioner Gottlieb reiterated that "it's unlawful under the FD&C Act to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements, regardless of whether the substances are hemp-derived."¹⁰

The FDA's explanation as to *why* food with CBD is prohibited under the FD&C Act is as follows:

. . . Under section 301(II) of the FD&C Act, it is prohibited to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which has been added a substance which is an active ingredient in a drug product that has been approved under 21 U.S.C. § 355 (section 505 of the Act) or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public. There are exceptions, including when the drug was marketed in food before the drug was approved or before the substantial clinical investigations involving the drug had been instituted or, in the case of animal feed, that the drug is a new animal drug approved for use in feed and used according to the approved labeling. However, based on available evidence, FDA has concluded that none of these is the case for THC or CBD. FDA has therefore concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which THC or CBD has been added. FDA is not aware of any evidence that would call into question these conclusions. Interested parties may present the agency with any evidence that they think has bearing on this issue. Our continuing review of information that has been submitted thus far has not called our conclusions into question.¹¹

In his recent statement regarding the 2018 Farm Bill, Commissioner Gottlieb expressed that "some foods are derived from parts of the hemp plant that may not contain CBD or THC, meaning that their addition to foods might not raise the same issues as the addition of drug ingredients like CBD and THC." He went on to state that "the agency has completed [its] evaluation of three Generally Recognized as Safe (GRAS) notices related to hulled hemp seeds, hemp seed protein and hemp seed oil and that the agency had no questions regarding the company's conclusion that the use of such products as described in the notices is safe."¹² That means that such ingredients can be lawfully used in foods provided that the marketer meets other requirements of the FD&C Act and other applicable laws.

Dietary Supplements

Most CBD products offered for sale in the U.S. are marketed as dietary supplements; however, as noted above, the FDA has continued to express its view that such dietary supplements violate the FD&C Act.

¹⁰ Statement from FDA Commissioner Scott Gottlieb, *supra* note 2.

¹¹ *FDA and Marijuana: Questions and Answers*, 13, *supra* note 9.

¹² Statement from FDA Commissioner Scott Gottlieb, *supra* note 2.

The FDA has concluded, based on available evidence, that CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(ii) of the FD&C Act.¹³ As the FDA has explained in warning letters and other guidance, under the FD&C Act, if an article (such as CBD) has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted, and for which the existence of such investigations has been made public, then products containing that substance are outside the definition of a dietary supplement.

There is an exception if the substance was “marketed as” a dietary supplement or as a conventional food before the new drug investigations were authorized; however, the FDA has concluded that available evidence does not support this being the case for CBD.¹⁴ The agency has, however, indicated a possible receptivity to evidence that supports other views and some in industry have speculated that various industry stakeholders have expressed approaches that could persuade the FDA to permit the marketing of dietary supplements that contain CBD.

Cosmetics

Cosmetics, when there are no claims or indications for use that render them unapproved new drugs, may be the one type of FDA-regulated product to which hemp-derived CBD may be added without running afoul of the FD&C Act *so long as* other requirements are satisfied. The FD&C Act defines cosmetics by their intended use as “articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body . . . for cleansing, beautifying, promoting attractiveness, or altering the appearance.”¹⁵ Among the products included in this definition are skin moisturizers, perfumes, lipsticks, fingernail polishes, eye and facial makeup preparations, cleansing shampoos, permanent waves, hair colors, and deodorants, as well as any substance intended for use as a component of a cosmetic product. Some examples of drug claims cited in connection with products marketed as cosmetics include: acne treatment, cellulite reduction, stretch mark reduction, wrinkle removal, dandruff treatment, hair restoration, and eyelash growth.¹⁶

Drugs

Those marketing CBD-containing products with claims that render such products unapproved new drugs are the most likely to find themselves the target of an FDA enforcement action.

In general, a product is considered a drug under the FD&C Act when it is intended (objectively, based on the totality of circumstances) (i) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and (ii) to affect the structure or any function of the body.¹⁷ If such a product is not generally recognized by qualified experts as safe and effective when used as labeled, it is a “new drug” and requires an approved New Drug Application to be marketed legally in the United States. To date, only one drug containing naturally derived CBD has been approved (others containing synthetic compounds that mirror that of naturally derived CBD have also been approved).¹⁸ Whether a product constitutes a drug from the FDA’s perspective depends primarily on the nature of the claims made about the product in marketing, particularly those made online and/or within the product’s labeling. Accordingly, based on the nature of the claims made in relation to CBD products currently

¹³ 21 U.S.C. 321(ff)(3)(B)(ii).

¹⁴ *FDA and Marijuana: Questions and Answers*, 12, *supra* note 9.

¹⁵ 21 U.S.C. § 321(i).

¹⁶ *Warning Letters Address Drug Claims Made for Products Marketed as Cosmetics*, U.S. FOOD AND DRUG ADMIN.

¹⁷ 21 U.S.C. 321(g)(1).

¹⁸ See *Sativex® Commences US Phase II/III Clinical Trial in Cancer Pain; GW Pharmaceuticals Receives Investigational New Drug (IND) from FDA for Phase 2/3 Clinical Trial of Epidiolex® in the Treatment of Dravet Syndrome*.

offered for sale in interstate commerce, the FDA has concluded that most constitute unapproved, new drugs and are, thus, being sold in violation of the FD&C Act.

Spectrum of Enforcement Risk

The number of enforcement actions taken in connection with such products seems almost negligible, as compared to the number of CBD products that are currently offered for sale in the United States. In particular, from 2015–2018, the FDA has issued **44 warning letters**¹⁹ citing FD&C Act violations based on CBD product sales. However, in multiple instances, the same company received multiple warning letters. Accordingly, warning letters related to CBD products were only issued against:

- Six companies in 2015
- Eight companies in 2016
- Four companies in 2017
- One company, thus far, in 2018

Moreover, the number of warning letters has *decreased* as the apparent prevalence of CBD products has *increased*. In Commissioner Gottlieb’s recent statement on the 2018 Farm Bill, he indicated that “[w]e’ll take enforcement action needed to protect public health against companies illegally selling cannabis and cannabis-derived products *that can put consumers at risk* and are being marketed in violation of the FDA’s authorities” (emphasis ours).²⁰

While it remains to be seen the extent to which the 2018 Farm Bill will cause the FDA to reevaluate its position on products containing hemp-derived CBD with less than 0.3 percent THC—with many expecting the FDA will continue to focus on the products that present the biggest risk to public health—some notable enforcement trends and patterns have emerged from the FDA’s warning letters, press releases, and other guidance. These documents have made clear that enforcement in the CBD context is not black and white, but rather, a spectrum, depending on the types of products, the claims made about such products, and the presence of other aggravating circumstances that the FDA has identified. Absent from any public FDA enforcement action are (i) cosmetics making no unapproved drug claims; (ii) food products to which CBD has been added, which do not make any unapproved drug claims; and (iii) (purported) dietary supplements that do not make any claims about the health benefits of CBD or any unapproved drug claims. This is consistent with Commissioner Gottlieb’s often-indicated emphasis on focusing enforcement activities on those companies and products that most endanger public health.

Every warning letter issued in connection with CBD products has been based on the unapproved drug claims made about such products. The following claims are examples of claims cited in FDA warning letters as evidence that the products’ intended uses rendered them unapproved new drugs:

- From **Warning Letter issued on July 31, 2018**:²¹
 - “For hundreds of years, people have used preparations made from C. Sativa, including CBD for a variety of disorders, including gout, rheumatism, malaria, pain, and fever.”
 - “[P]eople have reported reduced pain or positive results from taking CBD as a dietary supplement for ailments and neurological disorders such as . . . Alzheimer’s Disease . . .

¹⁹ See *Warning Letters and Test Results for Cannabidiol-Related Products*, U.S. FOOD AND DRUG ADMIN.

²⁰ Statement from FDA Commissioner Scott Gottlieb, *supra* note 2.

²¹ **Warning Letter from U.S. Food & Drug Admin. to John R. Rose, President, Signature Formulations LLC (July 31, 2018)**.

Cancer . . . Crohn's Disease . . . Diabetes . . . Fibromyalgia . . . Glaucoma . . . Gout . . . HIV
Dementia . . . Parkinson's Disease . . . Rheumatism . . . Schizophrenia . . . Stress Disorders like
PTSD”

- “Fast absorbing gel reduces inflammation and pain quickly with triple active ingredients. Our gel combines the natural anti-inflammatory power of CBD with the soothing effects of Camphor and Menthol. CBD Gel helps relieve arthritis pain and sore, overworked muscles.”
- From [Warning Letter issued on October 31, 2017](#):²²
 - “Scientific research by doctors have [sic] shown it actually kills cancer cells and provides a protective coating around our brain cells.”
 - “CBD makes cancer cells commit ‘suicide’ without killing other cells.”
 - “CBDs are effective against MRSA (antibiotic-resistant bug).”
 - *Social Media Posts:*
 - “Research showing benefits of cannabinoids for #alzheimers.”
 - “Research showing benefits of cannabinoids for your #heart . . . #atherosclerosis.”
 - “Research showing benefits of cannabinoids for #autism.”
- From [Warning Letter issued on February 4, 2016](#):²³
 - “Cannibidiol – CBD - is a cannabis compound that has significant medical benefits.”
 - “Scientific and clinical studies underscore CBD’s potential as a treatment for a wide range of conditions, including arthritis, diabetes, alcoholism, MS, chronic pain, schizophrenia, PTSD, antibiotic-resistant infections . . . and other neurological disorders.”
 - “[T]here may be extensive potential therapeutic uses of CBD, those being evaluated at Project CBD include Cancer . . . Anxiety, ADD/ADHD, ALS, Mood Disorders, Heart Disease, sleep disorders”
 - “Potential Therapeutic Uses of Medical Hemp . . . ADD/ADHD, Addiction, AIDS, ALS, Alzheimer’s . . . Atherosclerosis, Arthritis, Autism, Bipolar, Cancer, Colitis/Crohn’s, Depression, Diabetes . . . Fibromyalgia, Glaucoma, Heart disease, Huntington’s, [sic] . . . Irritable bowel, Kidney disease, Liver disease, . . . Migraine, Multiple sclerosis . . . Obesity[,] OCD, Osteoporosis, Parkinson’s, Prion/Mad Cow disease, PTSD, Rheumatism, Schizophrenia, Sickle cell anemia . . . Spinal cord injury . . . Stroke/TB.”
 - *Customer Testimonials:*
 - “I LOVE THIS CBD VAP-OIL!!! I suffer chronic pain . . . and I have COPD, and lastly . . . I have diabetes. Some days, I can barely move. My feet and hands look swollen and I feel joint pain. In just a few minutes I feel so much better, and no side effects, like from the pills the VA doctors prescribe.”
 - “My wife’s fibromyalgia and anxiety are controlled really well – we use a vape – 3 drags every few hours is all it takes.”

²² [Warning Letter from U.S. Food and Drug Admin. to Tisha T. Casida, That’s Natural! Marketing & Consulting \(Oct. 31, 2017\)](#).

²³ [Warning Letter from U.S. Food and Drug Admin. to Justin Barrick, Green Garden Gold, LLC \(Feb. 4, 2016\)](#).

- “The oil . . . beat other psychiatric medicines out there . . . It helped stabilize my . . . anxiety.”

As shown by the claims cited above, the FDA has taken seriously its pledge to “take action when [it] see[s] the illegal marketing of CBD-containing products with serious, unproven medical claims.”²⁴ The FDA’s rationale is that “[m]arketing unapproved products, with uncertain dosages and formulations can keep patients from accessing appropriate, recognized therapies to treat serious and even fatal diseases.”²⁵ Additionally, in issuing warning letters against CBD-product manufacturers, the FDA tested the chemical content of cannabinoid compounds in some of the products and noted that many were found to not contain the levels of CBD they claimed to contain. Indeed, in 2015, seven of the warning letters issued involved CBD claims made about products that actually contained no CBD or a negligible amount.

Key Takeaways

Now that the 2018 Farm Bill has been signed into law, companies itching to enter the CBD market should understand that, under the existing FDA perspective, doing so remains a violation of the FD&C Act unless FDA approval is obtained or the product is a cosmetic with no accompanying health/drug claims. The following actions heighten the risk of FDA enforcement: (i) selling CBD products labeled with inaccurate chemical content (or that otherwise make inaccurate claims about chemical content); (ii) marketing CBD products online or promoting them via online networks; and, most importantly, (iii) making health-related claims, particularly in connection with serious illnesses.

²⁴ Press Release, U.S. Food and Drug Admin., [FDA approves first drug comprised of an active ingredient derived from marijuana to treat rare, severe forms of epilepsy](#) (June 25, 2018).

²⁵ *Id.*