XAVIER BECERRA
Attorney General

State of California
DEPARTMENT OF JUSTICE

455 GOLDEN GATE AVENUE, SUITE 11000
SAN FRANCISCO, CA 94102-7004

January 24, 2019

Anne Sodergren
Interim Executive Officer
California State Board of Pharmacy
1625 North Market Blvd., Suite N-219
Sacramento, CA 95834

Re: Update on Legal Status of Products Containing Cannabidiol (CBD), In Light of Federal 2014 and 2018 Farm Bills

Dear Ms. Sodergren:

At the request of the President of the Board of Pharmacy, and your request, I write in further follow-up to my letter-opinions dated August 29, 2018 and October 12, 2018 (both enclosed), which pertained to the status, under federal and California law, of products containing cannabidiol (CBD), a cannabinoid derived from and/or a component of the cannabis sativa/marijuana plant. I was asked to address public comments made at the October 23-24, 2018 Board meeting regarding the impact of the 2014 federal Farm Bill on the legality of industrial hemp products, and by extension on products containing CBD, or other components or derivatives collected from industrial hemp, or from cannabis/marijuana. In the interim, on December 20, 2018, the U.S. President signed into law the Agriculture Improvement Act of 2018 (hereinafter "2018 Farm Bill"), which expands the legal status for domestic production of industrial hemp products. So this letter will also address that change.[1]

My prior letter-opinions concluded that three things combined to make lawful, under both federal and California law, prescribing and dispensing of Epidiolex (*or other subsequently approved equivalents*): (1) the June 25, 2018 federal Food and Drug Administration (FDA) approval of Epidiolex, a CBD oral solution, for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome, and Dravet syndrome, in patients two years of age and older; (2) the passage of AB 710 (Wood), an urgency statute which added section 11150.2 to the California Health and Safety Code; and (3) the DEA's September 28, 2018 addition of new subdivision (f) to 21 C.F.R. § 1308.15, creating a new classification in Schedule V of the federal controlled substance schedules for "*Approved cannabidiol drugs*," – "A drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols." (See my October 12, 2018 letter, enclosed.)

---

[1] I remind you that this letter expresses solely my own opinion, and is my best effort to provide legal assistance to you and the Board. This is <u>not</u> an official "opinion" of the Attorney General.

As my October 12, 2018 letter-opinion pointed out, this specific treatment of Epdiolex (or subsequently-approved equivalents) had no impact on the legality of other products derived from cannabis or containing CBD. The DEA so indicated in its Final Order:

> By virtue of this order, Epidiolex (and any generic versions of the same formulation that might be approved by the FDA in the future) will be a schedule V controlled substance. Thus, all persons in the distribution chain who handle Epidiolex in the United States (importers, manufacturers, distributors, and practitioners) must comply with the requirements of the CSA and DEA regulations relating to schedule V controlled substances. As further indicated, any material, compound, mixture, or preparation other than Epidiolex that falls within the CSA definition of marijuana set forth in 21 U.S.C. 802(16), including any non-FDA-approved CBD extract that falls within such definition, remains a schedule I controlled substance under the CSA.

In other words, my October 12, 2018 letter-opinion concluded, only FDA-approved drugs with CBD derived from cannabis and no more than 0.1 percent residual tetrahydrocannabinols (THC) were moved to federal Schedule V. The status of the vast majority of cannabis and/or CBD products was unchanged: they remained Schedule I under federal and California law (21 C.F.R. § 1308.11(d), (d)(23), (d)(38), (d)(58); Health & Saf. Code, §§ 11018, 11018.1, 11054, subds. (d), (d)(13), (d)(20)), and drugs containing cannabis and/or its components or derivatives, including non-FDA approved CBD drugs, could not be prescribed or dispensed. (21 U.S.C. §§ 841, 842, 843; Health & Saf. Code, §§ 11054, 11210; 62 Ops.Atty.Gen. 65 (1979).)[2]

At the October 23-24, 2018 Board meeting, public comment focused on the treatment of domestic production of hemp under the 2014 Farm Bill, and on July 2018 guidance given by the California Department of Public Health (CDPH) regarding the use of CBD as a food additive or dietary supplement. It was suggested that the legal status given to industrial hemp in the 2014 Farm Bill might have expanded the possible legal status of CBD derived from industrial hemp, though a countervailing suggestion was made that the CDPH guidance might limit or eliminate any advantaged status so bestowed. I was asked to look into and report back on these subjects and, once the 2018 Farm Bill became law, to incorporate that development into an update.

The legal status of hemp/industrial hemp has been substantially changed by the 2018 Farm Bill. To provide context for the public comments at the October 23-24, 2018 Board meeting and for the July 2018 CDPH guidance, I first discuss its legal status under the 2014 Farm Bill. I then conclude that although the 2018 Farm Bill made significant changes to this legal status, this actually *has very little impact on the legality of products containing CBD.*

---

[2] As before, my opinion does not address the possession or use of cannabis or cannabis products, including CBD derived from the cannabis plant, or the sale thereof, made lawful under certain conditions by Proposition 64 (2016) and ensuing statutes (Medicinal and Adult-Use Cannabis Regulation and Safety Act [MAUCRSA], e.g., Health & Safety Code § 11362.1 et seq., Business & Professions Code § 26001 et seq.), and regulations (e.g., 16 CCR § 5700 et seq.)

Legal Status of Hemp and Cannabis/Marijuana Prior to the 2018 Farm Bill

First, some definitions and historical context. Both hemp/industrial hemp and cannabis[3] are derived from the same plant variety, Cannabis sativa L. In order for the plant to be cultivated for hemp, it is seeded and contains extremely low levels of THC. Under both state and federal law, the plant must contain less than 0.3 percent concentration of THC to be cultivated as hemp. Where the plant contains higher levels of THC, it is considered cannabis or marijuana. But prior to 2018, U.S. law had been somewhat inconsistent in whether it drew a legal distinction between hemp and cannabis. For instance, the federal 1970 Controlled Substances Act (CSA) did not distinguish between "hemp" and "marihuana," arguably making "hemp" subject to the CSA, but at the same time the CSA did carve out from "marihuana" something similar to "hemp" –

> The term "marihuana" means all 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 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 plan which is incapable of germination.

(21 U.S.C. § 802(16).)

This somewhat confusing definition placed the non-psychoactive parts of the cannabis plant in uncertain status. (See, e.g., *New Hampshire Hemp Council, Inc. v. Marshall* (1st Cir. 2000) 203 F.3d 1, 6-8 [holding that industrial hemp, grown for the fiber in its stalks, used to produce rope and other products, with low THC content, was nonetheless "marijuana" and thus prohibited by federal drug statutes]; *U.S. v. White Plume* (8th Cir. 2006) 447 F.3d 1067, 1075-1076 [holding that hemp is "marijuana" subject to the CSA, which does not distinguish between marijuana and hemp, and farming hemp requires growing entire marijuana plant which at some point contains psychoactive levels of THC]; but see *Hemp Industries Assoc. v. DEA* (9th Cir. 2004) 357 F.3d 1012, 1012-1018 [invalidating DEA finding that listing of THC in Schedule I of CSA included natural as well as synthetic THC, such that sale or possession of edible items containing oil or sterilized seeds from hemp was prohibited even if items contained only non-psychoactive trace amounts of THC, because this finding contravened the unambiguously expressed intent of Congress, which maintained "marijuana" as a category separate from "THC," and DEA's regulations consistent with its determination were scheduling actions that would place non-psychoactive hemp in Schedule I for the first time, such that the regulations were void due to DEA's failure to follow CSA's scheduling rules.].)

---

[3] In the last two years, California has shifted from using "marijuana" to using "cannabis" to describe the parts of the plant containing THC used for medicinal or recreational purposes. But it is still common to find "marijuana" in California statutes and publications, and the federal statutes still use "marihuana." To maintain consistency with other California authorities, the text of this letter uses "cannabis," where appropriate, interchangeably with "marijuana."

Industrial hemp remained in this shadow legal status for decades, wherein it was legal to import hemp/industrial hemp and products that were made of these substances, but it was illegal to cultivate or distribute hemp domestically. The prohibition on domestic hemp production has been steadily relaxing in recent years, and legalization of this activity was substantially advanced by the 2014 Farm Bill. Section 7606 proclaimed the "Legitimacy of Industrial Hemp Research," and set forth conditions for "agricultural pilot programs" on industrial hemp to be conducted by institutions of higher education or state departments of agriculture. As of 2017, at least 39 U.S. universities and dozens of researchers had begun studying hemp. There are also many clinical studies of CBD currently underway investigating anecdotal uses of CBD to treat various (26+) medical conditions. But these "agricultural pilot programs" were obviously limited in scope.

The 2014 Farm Bill also did not resolve the definitional problem in the CSA, since the growing of industrial hemp still required cultivation of "marihuana" as defined by the CSA.[4] The DEA still felt bound by the definition in the CSA. So there was additional litigation against the DEA to prevent its interference with hemp cultivation, etc. There were also various political actions intended to prevent this, including that in 2016, 2017, and 2018, additional funding bills enacted into law, and statements from federal USDA officials, sought to prevent enforcement actions by the DEA or others that would interfere with domestic industrial hemp production.[5]

---

[4] In fact, the 2014 Farm Bill defined "Industrial Hemp" by reference to the entire cannabis plant: "The term 'industrial hemp' means the plant Cannabis sativa L. and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis." (7 U.S.C. § 5940, subd. (b)(2).)

[5] Effective in 2014, California also enacted legislation recognizing and differentiating "industrial hemp." Unlike the federal law, California law did exempt "industrial hemp" from the definition of "marijuana." California Health and Safety Code section 11018 was amended to read:

> **11018**. "Marijuana" means all parts of the plant Cannabis sativa L., whether growing or not, the seeds of that plant, the resin extracted from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin. It does not include industrial hemp, as defined in Section 11018.5, except where the plant is cultivated or processed for purposes not expressly allowed for by Division 24 (commencing with Section 81000) of the Food and Agricultural Code.

And both Food and Agricultural Code section 81000 and Health and Safety Code section 11018.5 were also added by that legislation – SB 566 (2013).

> **81000**. For purposes of this division, the following terms have the following meanings:
> (a) "Board" means the Industrial Hemp Advisory Board.
> * * *
> (d) "Industrial hemp" has the same meaning as that term is defined in Section 11018.5 of the Health and Safety Code. . . .

The uneasy status of industrial hemp, and by extension of cannabis derivatives including CBD, continued. This legal picture was only complicated by the legalization of medicinal and/or adult-use cannabis by various states, including California.[6] This is illustrated by the interplay between various federal and state agencies on these issues, particularly agencies having to do with enforcement regarding controlled substances (e.g., DEA and the Board), and those having to do with public health and food safety (e.g., FDA and CDPH). For instance, in July 2018, following on similar comments made by the FDA, CDPH released its "FAQ – Industrial Hemp and Cannabidiol (CBD) in Food Products." A copy is enclosed. This was the document that was referenced at the October 23-24, 2018 Board meeting, relating to CBD additives to food. That document addressed the question of whether it was lawful to add CBD oil or CBD derived from industrial hemp to food items, "since the legalization of medicinal and adult-use marijuana (cannabis) in California." It concluded that it was not legal to do so, under federal law:[7]

> California incorporates federal law regarding food additives, dietary use products, food labeling, and good manufacturing practices for food. The Controlled Substances Act of 1970 classified all forms of cannabis as a Schedule I drug, making it illegal to grow it in the United States. Currently, the United States Food and Drug Administration (FDA) has 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 tetrahydrocannabinol (THC) or CBD has been added. This is regardless of the source of the CBD – derived from industrial hemp or cannabis.

> **11018.5**. "Industrial hemp" means a fiber or oilseed crop, or both, that is limited to nonpsychoactive types of the plant Cannabis sativa L. and the seed produced therefrom, having no more than three-tenths of 1 percent tetrahydrocannabinol (THC) contained in the dried flowering tops, and that is cultivated and processed exclusively for the purpose of producing the mature stalks of the plant, fiber produced from the stalks, oil or cake made from the seeds of the plant, or any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks, except the resin or flowering tops extracted therefrom, fiber, oil, or cake, or the sterilized seed, or any component of the seed, of the plant that is incapable of germination.

The text of these statutes has since changed slightly, but not materially as to this point.

[6] Medical use of cannabis (then called marijuana) was initially decriminalized in California in 1996 by Proposition 215. Then adult (non-medical) use of cannabis (still called marijuana at that time) was authorized in California in 2016 by Proposition 64.

[7] The FAQ did, however, note that the definition of "food" in Health and Safety Code section 109935, which formed the basis for the conclusions in the FAQ, included pet food (and feed), but "does not include products containing cannabis (which are, instead, cannabis edibles)." So this is yet another layer of complication and overlapping jurisdiction between various agencies.

> **Therefore, although California currently allows the manufacturing and sales of cannabis products (including edibles), the use of industrial hemp as the source of CBD to be added to food products is prohibited. Until the FDA rules that industrial hemp-derived CBD oil and CBD products can be used as a food or California makes a determination that they are safe to use for human and animal consumption, CBD products are not an approved food, food ingredient, food additive, or dietary supplement.**

The FAQ went on to say that the only industrial hemp-derived products allowed in food in California are seeds derived from industrial hemp and industrial hemp seed oil or hemp seed oil derived from industrial hemp. It also included the following Q and A, which encapsulates and illustrates the complexity of questions surrounding these issues:

> 3. What is the difference between industrial hemp and cannabis (marijuana) derived cannabidiol (CBD/CBD oil)?
>
> - *CBD can be derived from both hemp and cannabis. CBD derived from hemp and cannabis is a federally-regulated controlled substance. CBD derived from cannabis is regulated within California as a cannabis product and may only be sourced from, produced, and sold by those with commercial cannabis licenses. CBD derived from industrial hemp is not an approved food additive, and therefore it cannot be added to human or animal foods in California.*
> - *CBD derived from cannabis is a prohibited food additive. Cannabis cannot be sold in food retail.*
> - *CBD derived from a licensed cannabis cultivator, per MCSB regulations, is an allowed additive in cannabis products only.*

As of the October 23-24, 2018 Board meeting, therefore, there were a lot of different, overlapping, and potentially confusing legal regimes operating with regard to cannabis, hemp/industrial hemp, and their derivatives and component parts. At the federal level, hemp/industrial hemp was still technically covered by the CSA, since it was not possible to cultivate industrial hemp without cultivating the entire Cannabis sativa L. plant, so both industrial hemp and its derivatives were still Schedule I drugs. On the other hand, under the 2014 Farm Bill, limited cultivation of industrial hemp by universities and state departments of agriculture was expressly permitted, and various funding bills prohibited expense of enforcement funds to interfere in domestic hemp production. California went even further, exempting industrial hemp from the definition of "marijuana," making it no longer a controlled substance. And California followed this up by legalizing cultivation and adult use of cannabis. But as was demonstrated by the FDA statement and the FAQ document from CDPH, at neither the federal nor the state level did this make it open season for sale or use of cannabis/marijuana/hemp-derived products and derivatives, including CBD or CBD oil, at least with regard to food.

The Impact of the 2018 Farm Bill

Subsequent to the Board meeting, the 2018 Farm Bill, signed December 20, 2018, added to the mix by finally following California's lead and changing the definition of "marihuana" in the CSA to specifically exempt hemp. Section 10113 of the bill added "Hemp Production" to the list of legitimate domestic agricultural activities, and used a definition of "Hemp" very similar to the definition of "Industrial Hemp" that had been in the 2014 Farm Bill:

> "[H]emp" means 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.

Section 12619 of the bill then amended 21 U.S.C. § 802(16), the CSA definition of "marihuana," to add that "'marihuana' does not include . . . hemp, as defined" in Section 10113. As such, for the first time under federal law, hemp is no longer a controlled substance. Because the definition of "hemp" in the 2018 Farm Bill also includes derivatives, extracts, cannabinoids, etc. from the cannabis plant with a THC level at or below 0.3 percent, such trace-THC components are also presumably not covered by the definition of "marihuana" in the CSA.

How this will play out in practice, at both the federal and the California level, still needs to be determined. And that determination will have to await the end of the federal shutdown, as both the DEA and the FDA are among the affected agencies. But there are a few things we can say about what has and has not changed, because of the 2018 Farm Bill.

Clearly, the biggest change is that hemp/industrial hemp is no longer part of the federal definition of "marihuana," and as a result is no longer a federal controlled substance. California had already taken this step in 2014. There are some differences in how the federal law and the California law define "hemp" and "industrial hemp" that may be significant. For instance, the federal law includes low-THC derivatives, cannabinoids, and other components in the definition of "hemp," and thereby exempts those components from the CSA. (2018 Farm Act, §§ 10113, 12619.) California, by contrast, takes a different approach, continuing to include derivatives and compounds in the base definition of "marijuana" – it is not clear whether CBD or other low-THC cannabinoids or derivatives are included in the scope of "industrial hemp" that is exempted from the definition of "marijuana" under California law. (Health & Saf. Code, §§ 11018, 11018.5.) These and similar questions will likely be the subject of additional guidance, rulemaking, and/or litigation as implementation of the 2018 Farm Act gets underway.

Prior to the federal government shutdown, on the day the 2018 Farm Bill was signed by the President, the FDA already took action to demonstrate its limits. Specifically, in a statement similar to those that had been issued by the FDA previously, and similar to the FAQ document previously issued by CDPH, the FDA Commissioner issued a statement on December 20, 2018 making clear that despite the 2018 Farm Bill, two important restrictions remain:

> (1) Any cannabis product (hemp-derived or otherwise), including those that claim to contain CBD or other cannabis-derived compounds, marketed with a claim of therapeutic benefit, or with any other disease claim, has to be approved by the FDA for its intended use before it may be introduced into interstate commerce, because any products claiming to be intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases are considered new drugs or new animal drugs and must go through the FDA drug approval process.
>
> (2) It is unlawful 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. This is because both CBD and THC are active ingredients in FDA-approved drugs.

A copy of the FDA Commissioner's December 20, 2018 statement is enclosed. It goes on to say that three parts of the hemp plant *may* be added to foods, because the FDA has completed its evaluation of these three ingredients and has designated them "Generally Recognized as Safe." These three ingredients are hulled hemp seeds, hemp seed protein, and hemp seed oil. Other than these three, however, all other parts of the hemp plant remain unapproved as food additives. Also on December 20, 2018, the FDA updated its "FDA and Marijuana: Questions and Answers" pages to incorporate information from the 2018 Farm Bill. A copy of those pages is also enclosed. (See Q&As 13, 14, 23.)

The Food and Drug Branch (FDB) of the CDPH has not yet updated its FAQ document to incorporate the 2018 Farm Bill. It is not anticipated that it will change the conclusions in the July 2018 version of that document, however, because as was stated by the FDA Commissioner, it remains true under federal law that CBD and THC, as active ingredients in approved drugs, may not be added to any food or dietary supplement, or be marketed as same.[8]

---

[8] The FDA has concluded that adding active ingredients to food or dietary supplements renders them "adulterated" pursuant to 21 U.S.C. § 342. California has its own equivalent prohibition on adulterating foods, in Health and Safety Code sections 110445, 110545, and 110550 et seq. But at least the California version of that prohibition may be changing. AB 228 (Aguiar-Curry) was introduced on January 17, 2019. That bill would add Health and Safety Code section 110611, stating that a "food or beverage is not adulterated by the inclusion of industrial hemp products, including cannabidiol derived from industrial hemp. The sale of food or beverages that include industrial hemp products or cannabidiol derived from industrial hemp shall not be restricted or prohibited based solely on the inclusion of industrial hemp products or cannabidiol derived from industrial hemp." Another provision of the bill creates the same exemption for cosmetics. This bill was just introduced, and has not yet been heard in committee, so it is not clear yet whether it might become law. And even if it does, it is not clear whether changing California law on this adulteration issue would be sufficient to alter the decision calculus of the CDPH, which has to this point relied on the FDA's interpretation of federal law. That is, it might be the conclusion of these agencies that federal law still prohibits adding CBD to food or dietary supplements, even where derived from industrial hemp. Regardless, this would be an additional complication.

Conclusion: Very Little Practical Change in Legality of CBD Products

So where does this leave CBD or CBD-containing products? The federal legal status of CBD, assuming that it fits within the definition of "hemp" as being a part of the cannabis plant with less than 0.3 percent THC concentration, has clearly changed, in that it is no longer part of the "marihuana" category, and thus no longer a controlled substance.[9] As noted above, it is less clear under the California definition whether CBD is excluded from "marijuana."

As a practical matter, though, it is not clear that very much has actually changed. As the FDA and CDPH have made clear, it remains unlawful to add CBD or CBD oil to food or dietary supplements (with the exception, under California law, of cannabis edibles). It likewise remains unlawful to market any CBD-containing products with health claims. This seems to leave only a very narrow slice of lawful sales of CBD or CBD-containing products, *other than the Epidiolex (*or subsequent CBD-containing drug) approved by the FDA. Presumably, other CBD products can be marketed lawfully only so long as there are no purported health benefits claimed. This does not seem to leave much opportunity for general retail sales of CBD-containing products.

I hope this clarification of the law is helpful to you and the Board.

Sincerely,

JOSHUA A. ROOM
Supervising Deputy Attorney General

For XAVIER BECERRA
Attorney General

Enclosures: My August 29, 2018 and October 12, 2018 letter-opinions
CDPH: FAQ – Industrial Hemp and Cannabidiol (CBD) in Food Products (July 6, 2018)
Statement from FDA Commissioner Scott Gottlieb, M.D. (December 20, 2018)
FDA and Marijuana: Questions and Answers (updated December 20, 2018)

---

[9] This is less of a change in California and other areas covered by the Ninth Circuit U.S. Court of Appeals than it is in other areas, because of its 2004 decision in *Hemp Industries Assoc. v. DEA*, *supra*, 357 F.3d 1012, 1012-1018. This decision had already blunted DEA efforts to treat non-psychoactive plant components as controlled substances.

Epidiolex, which is a CBD drug, is a federal Schedule V controlled substance, as would be any other CBD drug meeting the regulatory definition that is subsequently approved by the FDA. It is perhaps ironic that this form of CBD approved by the FDA is a controlled substance, while all other forms of CBD appear to be excluded from the CSA.

XAVIER BECERRA
Attorney General

State of California
DEPARTMENT OF JUSTICE

455 GOLDEN GATE AVENUE, SUITE 11000
SAN FRANCISCO, CA 94102-7004

Public: (415) 510-4400
Telephone: (415) 510-3512
Facsimile: (415) 703-5480
E-Mail: Joshua.Room@doj.ca.gov

August 29, 2018

Virginia K. Herold
Executive Officer
California State Board of Pharmacy
1625 North Market Blvd., Suite N-219
Sacramento, CA 95834

Re: Legal Status of Products Containing Cannabidiol (CBD), In Light of Approval of Epidiolex and AB 710 (Wood)

Dear Ms. Herold:

As you requested, the following is my opinion regarding the status, under federal and California law, of products containing cannabidiol (CBD), a cannabinoid that may be derived from and/or is a component part of the cannabis sativa/marijuana plant.[1] As you may be aware, another component part of the plant, tetrahydrocannabinol (THC), is the primary psychoactive component of marijuana. CBD does not cause intoxication or euphoria.

The Board has received inquiries regarding the legal status of CBD and CBD-containing products following (1) the June 25, 2018 FDA approval of Epidiolex, a CBD oral solution, for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome, and Dravet syndrome, in patients two years of age and older, and (2) the passage of AB 710 (Wood), an urgency statute which added, effective July 9, 2018, section 11150.2 to the California Health and Safety Code. That statute now reads in pertinent part:

> 11150.2. (a) Notwithstanding any other law, if cannabidiol is excluded from Schedule I of the federal Controlled Substances Act and placed on a schedule of the act other than Schedule I, or if a product composed of cannabidiol is approved by the federal Food and Drug Administration and either placed on a schedule of the act other than Schedule I, or exempted from one or more provisions of the act, so as to permit a physician, pharmacist, or other authorized healing arts licensee acting within his or her scope of practice, to prescribe, furnish, or dispense that product, the physician, pharmacist, or other authorized healing arts licensee who prescribes, furnishes, or dispenses that product in accordance with federal law shall be deemed to be in compliance with state law governing those acts.

[1] I remind you that what follows is solely my own opinion, my best effort to provide legal assistance to you and/or to the Board. This is not an official "opinion" of the Attorney General.

In response to the inquiries received, the short answer is that neither Epidiolex, nor any other CBD or CBD-containing product, may yet be legally prescribed or dispensed, under either federal or California law.[2] Cannabis/marijuana, and all of its component parts and derivatives, remain Schedule I under both federal and California law. (21 C.F.R. § 1308.11(d), (d)(23), (d)(38), (d)(58); Health & Saf. Code, §§ 11018, 11018.1, 11054, subds. (d), (d)(13), (d)(20).) Drugs containing cannabis/marijuana or any of its component parts or derivatives, including CBD, may therefore not currently be lawfully prescribed or dispensed. (21 U.S.C. §§ 841, 842, 843; Health & Saf. Code, §§ 11054, 11210; 62 Ops.Atty.Gen. 65 (1979).)

While it is true that the FDA approved Epidiolex for limited purposes on June 25, 2018, it did so subject to a separate requirement that the DEA take action to re-schedule either Epidiolex or its CBD component. The DEA was supposed to do so within 90 days, by September 23, 2018. But the DEA has not yet done so, and there is no publicly-available information indicating that the DEA has even begun the process to do so. Nor is there any publicly-available information on the nature or scope of any re-scheduling the DEA might undertake, e.g., whether only Epidiolex would be exempted from Schedule I, whether CBD would be exempted, or some other outcome.

The lack of action by the DEA also precludes any change in California law effected by AB 710 (Wood). New Health and Safety Code section 11150.2 predicates legal prescribing, furnishing, or dispensing of a CBD product on either (1) CBD being excluded from Schedule I of the federal Controlled Substances Act and placed on a schedule of the act other than Schedule I, or (2) a product composed of cannabidiol being approved by the federal Food and Drug Administration and either placed on a schedule of the act other than Schedule I, or exempted from one or more provisions of the act. Neither of these predicates has taken place. Thus, there has been no change in California law effected by operation of AB 710 (Wood).

Accordingly, neither the approval of Epidiolex nor the enactment of AB 710 has made any change in the legal status of CBD or any products containing this cannabinoid.

I hope this clarification of the law is helpful to you and the Board.

Sincerely,

JOSHUA A. ROOM
Supervising Deputy Attorney General

For XAVIER BECERRA
Attorney General

---

[2] This opinion does not address the possession or use of cannabis or cannabis products made lawful by Proposition 64 (2016) and ensuing statutes (the Medicinal and Adult-Use Cannabis Regulation and Safety Act [MAUCRSA]) and regulations, including Health & Safety Code § 11362.1 et seq., Business & Professions Code § 26001 et seq., and 16 CCR § 5700 et seq.

XAVIER BECERRA
Attorney General

State of California
DEPARTMENT OF JUSTICE

455 GOLDEN GATE AVENUE, SUITE 11000
SAN FRANCISCO, CA 94102-7004

October 12, 2018

Virginia K. Herold
Executive Officer
California State Board of Pharmacy
1625 North Market Blvd., Suite N-219
Sacramento, CA 95834

Re: Update on Legal Status of Products Containing Cannabidiol (CBD), In Light of FDA and DEA Approval of Epidiolex and AB 710 (Wood)

Dear Ms. Herold:

On August 29, 2018, I provided you with a letter-opinion regarding the status, under federal and California law, of products containing cannabidiol (CBD), a cannabinoid that may be derived from and/or is a component part of the cannabis sativa/marijuana plant. A copy of that prior letter is enclosed. That opinion addressed the impact of (1) a June 25, 2018 federal Food and Drug Administration (FDA) approval of Epidiolex, a CBD oral solution, for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome, and Dravet syndrome, in patients two years of age and older, and (2) the passage of AB 710 (Wood), an urgency statute which added section 11150.2 to the California Health and Safety Code. I said that neither Epidiolex, nor any other CBD or CBD-containing product, could be prescribed or dispensed, because cannabis/marijuana, and all of its component parts and derivatives, remained Schedule I under federal and California law. Because FDA approval of Epidiolex was expressly conditioned on subsequent rulemaking by the federal Drug Enforcement Agency (DEA) to re-schedule either Epidiolex or CBD more generally, neither of the above-listed developments had as yet made any change in the legal status of CBD or any products containing this cannabinoid.

Since issuance of that opinion, by way of a Final Order published in the Federal Register on September 28, 2018, the DEA amended 21 C.F.R. § 1308.15 to add new subdivision (f), creating a new classification in Schedule V of the federal controlled substance schedules for "*Approved cannabidiol drugs*," namely "A drug product in finished dosage formulation that has been approved by the U.S. Food and Drug Administration that contains cannabidiol (2-[1R-3-methyl-6R-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols." A copy of the Final Order is enclosed. In response, I will hereby update my August 29, 2018 opinion.[1]

[1] I remind you that what follows is solely my own opinion, my best effort to provide legal assistance to you and/or to the Board. This is not an official "opinion" of the Attorney General.

The re-scheduling, though prompted by FDA approval of Epidiolex and applicable only to FDA-approved drugs, is not by its terms expressly limited to Epidiolex. It could eventually apply to other FDA-approved CBD drugs. The Final Order is explicit on this point, as well as on the lack of impact of this re-scheduling on marijuana or non-approved CBD extracts:

> By virtue of this order, Epidiolex (and any generic versions of the same formulation that might be approved by the FDA in the future) will be a schedule V controlled substance. Thus, all persons in the distribution chain who handle Epidiolex in the United States (importers, manufacturers, distributors, and practitioners) must comply with the requirements of the CSA and DEA regulations relating to schedule V controlled substances. As further indicated, any material, compound, mixture, or preparation other than Epidiolex that falls within the CSA definition of marijuana set forth in 21 U.S.C. 802(16), including any non-FDA-approved CBD extract that falls within such definition, remains a schedule I controlled substance under the CSA.

In other words, only FDA-approved drugs containing CBD derived from cannabis and no more than 0.1 percent residual tetrahydrocannabinols (THC) have been moved to federal Schedule V. So far, this is a category that only includes Epidiolex. No other CBD products or products that contain CBD have been approved by the FDA as yet.

Therefore, the status of the vast majority of cannabis and/or CBD products remains the same: these products are Schedule I under federal and California law (21 C.F.R. § 1308.11(d), (d)(23), (d)(38), (d)(58); Health & Saf. Code, §§ 11018, 11018.1, 11054, subds. (d), (d)(13), (d)(20)), and therefore drugs containing cannabis/marijuana or any of its component parts or derivatives, including non-FDA approved CBD drugs, may not be prescribed or dispensed. (21 U.S.C. §§ 841, 842, 843; Health & Saf. Code, §§ 11054, 11210; 62 Ops.Atty.Gen. 65 (1979).)[2]

However, the DEA re-scheduling of FDA-approved drugs containing CBD with no more than 0.1 percent THC to Schedule V *does mean* that Epidiolex, and any subsequent CBD drug that meets these criteria of FDA approval and THC content, *can be lawfully prescribed and dispensed under federal law*. And although CBD drugs remain Schedule I under the separate California controlled substance schedules, *the enactment of AB 710 makes the prescribing and dispensing of Epidiolex (or other subsequently FDA-approved equivalents) also lawful under California law*. That bill bypassed a corollary re-scheduling of CBD drugs in the California controlled substance schedules in favor of a more direct authorization dependent on federal action. Health and Safety Code section 11150.2 now reads in pertinent part:

---

[2] As before, this opinion does not address the possession or use of cannabis or cannabis products, including CBD derived from the cannabis plant, or the sale thereof, made lawful under certain conditions by Proposition 64 (2016) and ensuing statutes (Medicinal and Adult-Use Cannabis Regulation and Safety Act [MAUCRSA], e.g., Health & Safety Code § 11362.1 et seq., Business & Professions Code § 26001 et seq.), and regulations (e.g., 16 CCR § 5700 et seq.)

> 11150.2. (a) Notwithstanding any other law, if cannabidiol is excluded from Schedule I of the federal Controlled Substances Act and placed on a schedule of the act other than Schedule I, or if a product composed of cannabidiol is approved by the federal Food and Drug Administration and either placed on a schedule of the act other than Schedule I, or exempted from one or more provisions of the act, so as to permit a physician, pharmacist, or other authorized healing arts licensee acting within his or her scope of practice, to prescribe, furnish, or dispense that product, the physician, pharmacist, or other authorized healing arts licensee who prescribes, furnishes, or dispenses that product in accordance with federal law shall be deemed to be in compliance with state law governing those acts.

The second prong of the conditional requirement has been met, so prescribing, furnishing, and dispensing of Epidiolex is now "deemed to be in compliance with state law."

I hope this clarification of the law is helpful to you and the Board.

Sincerely,

JOSHUA A. ROOM
Supervising Deputy Attorney General

For XAVIER BECERRA
Attorney General

Enclosures: August 29, 2018 letter-opinion
DEA Final Order published September 28, 2018

FAQ – Industrial Hemp and Cannabidiol (CBD) in Food Products

California Department of Public Health (CDPH), Food and Drug Branch (FDB) has received numerous inquiries from food processors and retailers who are interested in using industrial hemp-derived cannabidiol (CBD) oil or CBD products in food since the legalization of medicinal and adult-use marijuana (cannabis) in California.

In California, the CDPH Manufactured Cannabis Safety Branch (MCSB) regulates medicinal and adult-use manufactured cannabis products. However, food products derived from industrial hemp are not covered by MCSB regulations. Instead, these products fall under the jurisdiction of CDPH-FDB.

California defines "food" as follows:

(a) Any article used or intended for use for food, drink, confection, condiment, or chewing gum by man or other animal.
(b) Any article used or intended for use as a component of any article designated in subdivision (a).[1]

The definition of food includes pet food, but does not include products containing cannabis (which are, instead, cannabis edibles). Meat, dairy, poultry or eggs are regulated by the California Department of Food and Agriculture (CDFA).

The federal Agricultural Act of 2014, also known as the Farm Bill, only legalized the growing or cultivating of industrial hemp by state departments of agriculture and institutions of higher education (as defined in Title 20 of the United States Code section 1001) for purposes of research under a state pilot program or other agricultural or academic research. In addition, growing or cultivation is only permitted under the Farm Bill if growing or cultivating is allowed under the laws of the State in which such state department or institution is located and such research occurs. In California, the cultivation of industrial hemp is regulated by the CDFA.

"Industrial Hemp" is defined as follows:

> *"a fiber or oilseed crop, or both, that is limited to types of the plant Cannabis sativa L. having no more than three-tenths of 1 percent tetrahydrocannabinol (THC) contained in the dried flowering tops, whether growing or not; the seeds of the plant; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin produced therefrom."*[2]

Please refer to the CDFA for further questions about state requirements for cultivation of industrial hemp in California in accordance with the California's Industrial Hemp Law (Division 24 of the Food and Agricultural Code).

California incorporates federal law regarding food additives, dietary use products, food labeling, and good manufacturing practices for food. The Controlled Substances Act of 1970 classified all forms of cannabis as a Schedule I drug, making it illegal to grow it in the United States.[3] Currently, the United

States Food and Drug Administration (FDA) has 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 tetrahydrocannabinol (THC) or CBD has been added. This is regardless of the source of the CBD – derived from industrial hemp or cannabis.

Therefore, although California currently allows the manufacturing and sales of cannabis products (including edibles), the use of industrial hemp as the source of CBD to be added to food products is prohibited. Until the FDA rules that industrial hemp-derived CBD oil and CBD products can be used as a food or California makes a determination that they are safe to use for human and animal consumption, CBD products are not an approved food, food ingredient, food additive, or dietary supplement.

---

[1] California Health & Safety Code section 109935.

[2] California Food and Agriculture Code section 81000(d) which references California Health and Safety Code (HSC) section 11018.5.

[3] 21 United States Code section 802(16) *"The term "marihuana" means all 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 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."*

Frequently Asked Questions

1. What forms of Industrial hemp derived products will and <u>will NOT</u> be allowed in food in California?

   Will be allowed in food (without any claim for health benefits):
   - Seeds derived from Industrial hemp
   - Industrial hemp seed oil or hemp seed oil derived from industrial hemp

   <u>Will NOT be allowed in food:</u>
   - Any CBD products derived from cannabis
   - Any CBD products including CBD oil derived from industrial hemp
   - Hemp oil that is not derived from industrial hemp seeds
   - Industrial hemp seed oil enhanced with CBD or other cannabinoids

2. Is hemp seed oil the same as CBD oil?

   Industrial hemp seed oil and hemp-derived CBD oil are two different products. Industrial hemp seed oil is derived from the seeds limited to types of the Cannabis sativa L. plant and may contain trace amounts of CBD (naturally occurring) and other cannabinoids. Food grade Industrial hemp seed oil is available from a variety of approved sources.

However, CBD or CBD oil derived from industrial hemp is NOT approved for human and animal consumption by the FDA as food and therefore cannot be used as food ingredient, food additive, or dietary supplement.

3. What is the difference between industrial hemp and cannabis (marijuana) derived cannabidiol (CBD/CBD oil)?

    - *CBD can be derived from both hemp and cannabis. CBD derived from hemp and cannabis is a federally-regulated controlled substance. CBD derived from cannabis is regulated within California as a cannabis product and may only be sourced from, produced, and sold by those with commercial cannabis licenses. CBD derived from industrial hemp is not an approved food additive, and therefore it cannot be added to human or animal foods in California.*
    - *CBD derived from cannabis is a prohibited food additive. Cannabis cannot be sold in food retail.*
    - *CBD derived from a licensed cannabis cultivator, per MCSB regulations, is an allowed additive in cannabis products only.*

4. Does California consider food products that contain CBD or CBD oil from Industrial hemp a cannabis product?

    Although in California, foods containing industrial hemp are not considered cannabis products (products that are subject to Proposition 64), CBD is an unapproved food additive and NOT allowed for use in human and animal foods per the FDA, and thus it is not approved in California.

5. Can industrial hemp-derived CBD oils be approved as a food ingredient, food additive or dietary supplement to be added in food?

    Currently Industrial hemp derived CBD Oil and CBD products are NOT an approved food, food ingredient, food additive or dietary supplement and therefore cannot be used in any human and animal food.

6. If CDPH, MCSB regulates and licenses cannabis (marijuana) derived product manufacturers, which agency oversees CBD oil produced from industrial hemp?

    There is currently no regulatory agency that provides oversight over the production of CBD oil from industrial hemp. However, CDPH-FDB has authority oversight over food additives, dietary use products, food labeling; and good manufacturing practices for food. Industrial hemp used as a food additive or dietary supplement falls under the authority of CDPH-FDB.

7. Can industrial hemp derived CBD products be allowed for sale in California if they come from other States? For example, if industrial hemp derived CBD oil is manufactured in another state and sold to customers in California via distributors and retailers?

No, CBD is an unapproved food additive and NOT allowed for use in human and animal foods in California regardless of where the CBD products originate.

FDA Statement

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

For Immediate Release

December 20, 2018

Statement

Today, the Agriculture Improvement Act of 2018 was signed into law. Among other things, this new law changes certain federal authorities relating to the production and marketing of hemp, defined as cannabis (*Cannabis sativa L.*), and derivatives of cannabis with extremely low (less than 0.3 percent on a dry weight basis) concentrations of the psychoactive compound delta-9-tetrahydrocannabinol (THC). These changes include removing hemp from the Controlled Substances Act, which means that it will no longer be an illegal substance under federal law.

Just as important for the FDA and our commitment to protect and promote the public health is what the law *didn't* change: Congress explicitly preserved the agency's current authority to regulate products containing cannabis or cannabis-derived compounds under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and section 351 of the Public Health Service Act. In doing so, Congress recognized the agency's important public health role with respect to all the products it regulates. This allows the FDA to continue enforcing the law to protect patients and the public while also providing potential regulatory pathways for products containing cannabis and cannabis-derived compounds.

We're aware of the growing public interest in cannabis and cannabis-derived products, including cannabidiol (CBD). This increasing public interest in these products makes it even more important with the passage of this law for the FDA to clarify its regulatory authority over these products. In short, we treat products containing cannabis or cannabis-derived compounds as we do any other FDA-regulated products — meaning they're subject to the same authorities and requirements as FDA-regulated products containing any other substance. This is true regardless of the source of

the substance, including whether the substance is derived from a plant that is classified as hemp under the Agriculture Improvement Act. To help members of the public understand how the FDA's requirements apply to these products, the FDA has maintained a **webpage (/NewsEvents/PublicHealthFocus/ucm421168.htm)** with answers to frequently asked questions, which we intend to update moving forward to address questions regarding the Agriculture Improvement Act and regulation of these products generally.

In view of the proliferation of products containing cannabis or cannabis-derived substances, the FDA will advance new steps to better define our public health obligations in this area. We'll also continue to closely scrutinize products that could pose risks to consumers. Where we believe consumers are being put at risk, the FDA will warn consumers and take enforcement actions.

In particular, we continue to be concerned at the number of drug claims being made about products not approved by the FDA that claim to contain CBD or other cannabis-derived compounds. Among other things, the FDA requires a cannabis product (hemp-derived or otherwise) that is marketed with a claim of therapeutic benefit, or with any other disease claim, to be approved by the FDA for its intended use before it may be introduced into interstate commerce. This is the same standard to which we hold any product marketed as a drug for human or animal use. Cannabis and cannabis-derived products claiming in their marketing and promotional materials that they're intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases (such as cancer, Alzheimer's disease, psychiatric disorders and diabetes) are considered new drugs or new animal drugs and must go through the FDA drug approval process for human or animal use before they are marketed in the U.S. Selling unapproved products with unsubstantiated therapeutic claims is not only a violation of the law, but also can put patients at risk, as these products have not been proven to be safe or effective. This deceptive marketing of unproven treatments raises significant public health concerns, as it may keep some patients from accessing appropriate, recognized therapies to treat serious and even fatal diseases.

Additionally, 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. This is because both CBD and THC are active ingredients in FDA-approved drugs and were the subject of substantial clinical investigations before they were marketed as foods or dietary supplements. Under the FD&C Act, it's illegal to introduce drug ingredients like these into the food supply, or to market them as dietary supplements. This is a requirement that we apply across the board to food products that contain substances that are active ingredients in any drug.

We'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. The FDA has sent **warning letters (/NewsEvents/PublicHealthFocus/ucm484109.htm)** in the past to companies illegally selling CBD products that claimed to prevent, diagnose, treat, or cure serious diseases, such as cancer. Some of these products were in further violation of the FD&C Act because they were marketed as dietary supplements or because they involved the addition of CBD to food.

While products containing cannabis and cannabis-derived compounds remain subject to the FDA's authorities and requirements, there are pathways available for those who seek to lawfully introduce these products into interstate commerce. The FDA will continue to take steps to make the pathways for the lawful marketing of these products more efficient.

These pathways include ways for companies to seek approval from the FDA to market with therapeutic claims a human or animal drug that is derived from cannabis. For example, in June 2018, the FDA approved a drug, **Epidiolex (/NewsEvents/Newsroom/PressAnnouncements/ucm611046.htm)**, that contains cannabis-derived CBD for the treatment of seizures associated with two rare and severe forms of epilepsy. That approval was based on adequate and well-controlled clinical studies, which gives prescribers confidence in the drug's uniform strength and consistent delivery that support appropriate dosing needed for treating patients with these complex and serious epilepsy syndromes.

In addition, pathways remain available for the FDA to consider whether there are circumstances in which certain cannabis-derived compounds might be permitted in a food or dietary supplement. Although such products are generally prohibited to be introduced in interstate commerce, the FDA has authority to issue a regulation allowing the use of a pharmaceutical ingredient in a food or dietary supplement. We are taking new steps to evaluate whether we should pursue such a process. However, the FDA would only consider doing so if the agency were able to determine that all other requirements in the FD&C Act are met, including those required for food additives or new dietary ingredients.

It should also be noted 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. We are able to advance the lawful marketing of three such ingredients today. We are announcing that the agency has completed our evaluation of three **Generally Recognized as Safe (/Food/NewsEvents/ConstituentUpdates/ucm628910.htm)** (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. Therefore, these products can be legally marketed in human foods for these uses without food additive approval, provided they comply with all other requirements and do not make disease treatment claims.

Given the substantial public interest in this topic and the clear interest of Congress in fostering the development of appropriate hemp products, we intend to hold a public meeting in the near future for stakeholders to share their experiences and challenges with these products, including information and views related to the safety of such products.

We'll use this meeting to gather additional input relevant to the lawful pathways by which products containing cannabis or cannabis-derived compounds can be marketed, and how we can make these legal pathways more predictable and efficient. We'll also solicit input relevant to our regulatory strategy related to existing products, while we continue to evaluate and take action against products that are being unlawfully marketed and create risks for consumers.

At the same time, we recognize the potential opportunities that cannabis or cannabis-derived compounds could offer and acknowledge the significant interest in these possibilities. We're committed to pursuing an efficient regulatory framework for allowing product developers that meet the requirements under our authorities to lawfully market these types of products.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

###

Inquiries

Media

Lyndsay Meyer (mailto:lyndsay.meyer@fda.hhs.gov)
240-402-5345

Consumers

888-INFO-FDA

Follow FDA

Follow @US_FDA (https://twitter.com/US_FDA) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)

Follow FDA (https://www.facebook.com/FDA) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)

Follow @FDAmedia (https://twitter.com/FDAMedia) (/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)

More in Press Announcements (/NewsEvents/Newsroom/PressAnnouncements/default.htm)

2017 (/NewsEvents/Newsroom/PressAnnouncements/2017/default.htm)

2016 (/NewsEvents/Newsroom/PressAnnouncements/2016/default.htm)

FDA and Marijuana: Questions and Answers

1. How is marijuana therapy being used by some members of the medical community?

A. The FDA is aware that marijuana or marijuana-derived products are being used for a number of medical conditions including, for example, AIDS wasting, epilepsy, neuropathic pain, treatment of spasticity associated with multiple sclerosis, and cancer and chemotherapy-induced nausea.

2. Why hasn't the FDA approved marijuana for medical uses?

A. To date, the FDA has not approved a marketing application for marijuana for any indication. The FDA generally evaluates research conducted by manufacturers and other scientific investigators. Our role, as laid out in the Federal Food, Drug, and Cosmetic (FD&C) Act, is to review data submitted to the FDA in an application for approval to assure that the drug product meets the statutory standards for approval.

The FDA has approved Epidiolex, which contains a purified drug substance cannabidiol, one of more than 80 active chemicals in marijuana, for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older. That means the FDA has concluded that this particular drug product is safe and effective for its intended indication.

The agency also has approved Marinol and Syndros for therapeutic uses in the United States, including for the treatment of anorexia associated with weight loss in AIDS patients. Marinol and Syndros include the active ingredient dronabinol, a synthetic delta-9- tetrahydrocannabinol (THC) which is considered the psychoactive component of marijuana. Another FDA-approved drug, Cesamet, contains the active ingredient nabilone, which has a chemical structure similar to THC and is synthetically derived.

3. Is marijuana safe for medical use?

A. The study of marijuana in clinical trial settings is needed to assess the safety and effectiveness of marijuana for the treatment of any disease or condition.

The FDA will continue to facilitate the work of companies interested in appropriately bringing safe, effective, and quality products to market, including scientifically-based research concerning the medicinal uses of marijuana.

4. How does FDA's role differ from the role of other federal agencies when it comes to the investigation of marijuana for medical use?

A. Conducting clinical research using marijuana involves interactions with several federal agencies. This includes: a registration administered by the Drug Enforcement Administration (DEA); obtaining the marijuana for research from the National Institute on Drug Abuse (NIDA), within the National Institutes of Health, or another DEA-registered source; and review by the FDA of an investigational new drug (IND) application and research protocol. Additionally:

- As a Schedule I controlled substance under the Controlled Substances Act, DEA provides researchers with investigator and protocol registrations and has Schedule I-level security requirements at the site marijuana will be studied.
- NIDA provides research-grade marijuana for scientific study. The agency is responsible for overseeing the cultivation of marijuana for medical research and has contracted with the University of Mississippi to grow marijuana for research at a secure facility. Marijuana of varying potencies and compositions is available. DEA also **may allow additional growers (https://www.federalregister.gov/documents/2016/08/12/2016-17955/applications-to-become-registered-under-the-controlled-substances-act-to-manufacture-marijuana-to)** to register with the DEA to produce and distribute marijuana for research purposes.
- Researchers work with the FDA and submit an IND application to the appropriate division in the Office of New Drugs, in the Center for Drug Evaluation and Research (CDER), depending on the therapeutic indication.

The roles of the three agencies are the same for investigations of marijuana for use as an animal drug product, except that researchers would establish an investigational new animal drug (INAD) file with the Center for Veterinary Medicine to conduct their research, rather than an IND with CDER.

5. Does the FDA object to the clinical investigation of marijuana for medical use?

A. No. The FDA believes that scientifically valid research conducted under an IND application is the best way to determine what patients could benefit from the use of drugs derived from marijuana. The FDA supports the conduct of that research by:

1. Providing information on the process needed to conduct clinical research using marijuana.
2. Providing information on the specific requirements needed to develop a drug that is derived from a plant such as marijuana. In June 2004, the FDA finalized its **Guidance for Industry: Botanical Drug Products (/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM458484.pdf)**, which provides sponsors with guidance on submitting IND applications for botanical drug products.
3. Providing specific support for investigators interested in conducting clinical research using marijuana and its constituents as a part of the IND process through meetings and regular interactions throughout the drug development process.
4. Providing general support to investigators to help them understand and follow the procedures to conduct clinical research through the FDA Center for Drug Evaluation and Research's **Small Business and Industry Assistance (/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm2007049.htm)** group.

6. What kind of research is the FDA reviewing when it comes to the efficacy of marijuana?

A. The FDA reviews applications to market drug products to determine whether those drug products are safe and effective for their intended indications. The FDA reviews scientific investigations, including adequate and well-controlled clinical trials, as part of the FDA's drug approval process.

The FDA relies on applicants and scientific investigators to conduct research. Our role, as outlined in the Federal Food, Drug, and Cosmetic Act, is to review data submitted to the FDA in a marketing application to determine whether a proposed drug product meets the statutory standards

for approval. Additional information concerning research on the medical use of marijuana is available from the National Institutes of Health, particularly the **National Cancer Institute (http://www.cancer.gov/)** (NCI) and **NIDA (http://www.drugabuse.gov/drugs-abuse/marijuana/nida-research-therapeutic-benefits-cannabis-cannabinoids)**.

7. How can patients get into expanded access program for marijuana for medical use?

A. Manufacturers may be able to make investigational drugs available to individual patients in certain circumstances through expanded access, as described in the FD&C Act and implementing regulations.

8. Does the FDA have concerns about administering a cannabis product to children?

A. We understand that parents are trying to find treatments for their children's medical conditions. However, the use of untested drugs can have unpredictable and unintended consequences. Caregivers and patients can be confident that FDA-approved drugs have been carefully evaluated for safety, efficacy, and quality, and are monitored by the FDA once they are on the market. The FDA continues to support sound, scientifically-based research into the medicinal uses of drug products containing marijuana or marijuana constituents, and will continue to work with companies interested in bringing safe, effective, and quality products to market.

9. Does the FDA have concerns about administering a cannabis product to pregnant and lactating women?

A. The FDA is aware that there are potential adverse health effects with use of marijuana in pregnant or lactating women. Published scientific literature reports potential adverse effects of marijuana use in pregnant women, including fetal growth restriction, low birth weight, preterm birth, small-for-gestational age, neonatal intensive care unit (NICU) admission, and stillbirth. [1, 2, 3] Based on published animal research, there are also concerns that use of marijuana during pregnancy may negatively impact fetal brain development. [4, 5, 6] The American College of Obstetricians and Gynecologists (ACOG) recommends that women who are pregnant or contemplating pregnancy should be encouraged to discontinue marijuana use. In addition, ACOG notes that there are insufficient data to evaluate the effects of marijuana use on breastfed infants; therefore, marijuana use is discouraged when breastfeeding. [7] Pregnant and lactating women should talk with a health care provider about the potential adverse health effects of marijuana use.

10. What is FDA's reaction to states that are allowing marijuana to be sold for medical uses without the FDA's approval?

A. The FDA is aware that several states have either passed laws that remove state restrictions on the medical use of marijuana and its derivatives or are considering doing so. It is important to conduct medical research into the safety and effectiveness of marijuana products through adequate and well-controlled clinical trials. We welcome the opportunity to talk with states who are considering support for medical research of marijuana and its derivatives to provide information on Federal and scientific standards.

11. Has the agency received any adverse event reports associated with marijuana for medical conditions?

A. The agency has received reports of adverse events in patients using marijuana to treat medical conditions. The FDA is currently reviewing those reports and will continue to monitor adverse event reports for any safety signals attributable to marijuana and marijuana products, with a focus on serious adverse effects associated with the use of marijuana.

Information from adverse event reports regarding marijuana use is extremely limited; the FDA primarily receives adverse event reports for approved products. General information on the potential adverse effects of using marijuana and its constituents can come from clinical trials using marijuana that have been published, as well as from spontaneously reported adverse events sent to the FDA. Additional information about the safety and effectiveness of marijuana and its constituents is needed. Clinical trials of marijuana conducted under an IND application could collect this important information as a part of the drug development process.

12. Can products that contain THC or cannabidiol (CBD) be sold as dietary supplements?

A. No. Based on available evidence, FDA has concluded that THC and CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the FD&C Act, respectively. Under those provisions, if a substance (such as THC or CBD) is an active ingredient in a drug product that has been approved under 21 U.S.C. § 355 (section 505 of the FD&C Act), or 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. FDA considers a substance to be "authorized for investigation as a new drug" if it is the subject of an Investigational New Drug application (IND) that has gone into effect. Under FDA's regulations (21 CFR 312.2), unless a clinical investigation meets the limited criteria in that regulation, an IND is required for all clinical investigations of products that are subject to section 505 of the FD&C Act.

There is an exception to sections 201(ff)(3)(B)(i) and (ii) if the substance was "marketed as" a dietary supplement or as a conventional food before the drug was approved or before the new drug investigations were authorized, as applicable. However, based on available evidence, FDA has concluded that this is not the case for THC or CBD. For more information on this provision, including an explanation of the phrase "marketed as," see **Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues (/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm257563.htm)**.

FDA is not aware of any evidence that would call into question its current conclusions that THC and CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the FD&C Act. 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.

13. Is it legal, in interstate commerce, to sell a food to which THC or CBD has been added?

A. No. Under section 301(ll) 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.

14. In making the two previous determinations about THC, why did FDA conclude that THC is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act? In making the two previous determinations about CBD, why did FDA determine that substantial clinical investigations have been authorized for and/or instituted, and that the existence of such investigations has been made public?

A. THC (dronabinol) is the active ingredient in the approved drug products, Marinol capsules (and generics) and Syndros oral solution.

The existence of substantial clinical investigations regarding CBD has been made public. For example, two such substantial clinical investigations include GW Pharmaceuticals' investigations regarding Sativex and Epidiolex. (See **Sativex Commences US Phase II/III Clinical Trial in Cancer Pain (https://www.gwpharm.com/about-us/news/sativex%C2%AE-commences-us-phase-iiiii-clinical-trial-cancer-pain) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)** and **GW Pharmaceuticals Receives Investigational New Drug (IND) from FDA for Phase 2/3 Clinical Trial of Epidiolex in the Treatment of Dravet Syndrome (https://www.gwpharm.com/about-us/news/gw-pharmaceuticals-receives-investigational-new-drug-ind-fda-phase-23-clinical-trial) (http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm)**).

15. Will FDA take enforcement action regarding THC and CBD products that are marketed as dietary supplements? What about foods to which THC and CBD has been added?

A. When a product is in violation of the FD&C Act, FDA considers many factors in deciding whether or not to initiate an enforcement action. Those factors include, among other things, agency resources and the threat to the public health. FDA also may consult with its federal and state partners in making decisions about whether to initiate a federal enforcement action.

16. What does the FDA think about making cannabidiol available to children with epilepsy?

A. The FDA has approved Epidiolex, which contains a purified drug substance cannabidiol, one of more than 80 active chemicals in marijuana, for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older. That means the FDA has concluded that this particular drug product is safe and effective for its intended indication.

17. What should I do if my child eats something containing marijuana?

A. It is important to protect children from accidental ingestion of marijuana and products containing marijuana. FDA recommends that these products are kept out of reach of children to reduce the risk of accidental ingestion.

If the parent or caregiver has a reasonable suspicion that the child ingested products containing marijuana, the child should be taken to a physician or emergency department, especially if the child acts in an unusual way or is/feels sick.

18. I've seen marijuana products being marketed for pets. Are they safe?

A. FDA has recently become aware of some marijuana products being marketed to treat diseases in animals. We want to stress that FDA has not approved marijuana for any use in animals, and the agency cannot ensure the safety or effectiveness of these products. For these reasons, FDA cautions pet-owners against the use of such products.

19. Can I give my pet marijuana products for medical purposes, such as to relieve the pain of a sick or dying pet?

A. Marijuana needs to be further studied to assess the safety and effectiveness for medical use in animals. To date, FDA has not approved marijuana for any use in animals (see **question and answer #4** above). If your pet is in pain, we urge you to talk with your veterinarian about appropriate treatment options.

20. I gave my pet marijuana and I'm concerned my pet is suffering adverse effects. What should I do?

A. Signs that your pet may be suffering adverse effects from ingesting marijuana may include lethargy, depression, heavy drooling, vomiting, agitation, tremors, and convulsions.

If you have concerns that your pet is suffering adverse effects from ingesting marijuana or any substance containing marijuana, consult your veterinarian, local animal emergency hospital or an animal poison control center immediately.

21. Has the agency received any adverse event reports associated with marijuana for animals?

A. While the agency is aware of reports of pets consuming various forms of marijuana, to date, FDA has not directly received any adverse event reports associated with giving marijuana to animals via our safety reporting portals. However, adverse events from accidental ingestion are well-documented in scientific literature. If you feel your animal has suffered from ingesting marijuana, we encourage you to report the adverse event to the FDA. Please visit **Reporting Information about Animal Drugs and Devices (/AnimalVeterinary/SafetyHealth/ReportaProblem/ucm055305.htm#Drugs_and_Devices)** to learn more about how to report an adverse event related to an animal food or drug.

22. What is FDA doing about marijuana products currently on the market for pets?

A. FDA is currently collecting information about marijuana and marijuana-derived products being marketed for animals. FDA reminds consumers that these products have not been evaluated by FDA for safety and effectiveness, and we recommend that you talk with your veterinarian about appropriate treatment options for your pet.

23. What is the effect of the Agricultural Improvement Act of 2018 on the FD&C Act?

A. The Agriculture Improvement Act of 2018 changes certain federal authorities relating to the production and marketing of hemp, defined as cannabis (Cannabis sativa L.), and derivatives of cannabis with extremely low (less than 0.3 percent on a dry weight basis) concentrations of the psychoactive compound delta-9-tetrahydrocannabinol (THC). These changes include removing hemp from the Controlled Substances Act, which means that it will no longer be an illegal substance under federal law. However, Congress explicitly preserved the agency's current authority to regulate products containing cannabis or cannabis-derived compounds under the FD&C Act and section 351 of the Public Health Service Act. Please see the **FDA's statement (/NewsEvents/Newsroom/PressAnnouncements/ucm628988.htm)** on the signing of the Agriculture Improvement Act of 2018.

[1] Gray, et al. Identifying Prenatal Cannabis Exposure and Effects of Concurrent Tobacco Exposure on Neonatal Growth. Clinical Chemistry. 2010; 56(9): 1442-1450.
[2] Gunn, et al. Prenatal Exposure to cannabis and maternal and child health outcomes: a systematic review and meta-analysis. BMJ Open. 2016; 6:e009986.
[3] Hayatbakhsh, et al. Birth Outcomes associated with cannabis use before and during pregnancy. Pediatric Research. 2012; 71 (2): 215-219.
[4] Silva, et al. Prenatal tetrahydrocannabinol (THC) alters cognitive function and amphetamine response from weaning to adulthood in the rat. Neurotoxicol and Teratol 2012; 34(1): 63-71.
[5] Trezza, et al. Effects of perinatal exposure to delta-9-tetrahydrocannabinol on the emotional reactivity of the offspring: a longitudinal behavioral study in Wistar rats. Psychopharmacology (Berl) 2008; 198(4): 529-537.
[6] Campolongo, et al. Perinatal exposure to delta-9-tetrahydrocannabinol causes enduring cognitive deficits associated with alteration of cortical gene expression and neurotransmission in rats. Addict Biol 2007; 12(3-4): 485–495.
[7] **http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Marijuana-Use-During-Pregnancy-and-Lactation (http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Marijuana-Use-During-Pregnancy-and-Lactation)**

Related Information

- **FDA and Marijuana (/NewsEvents/PublicHealthFocus/ucm421163.htm)**
- **Marijuana Research with Human Subjects (/NewsEvents/PublicHealthFocus/ucm421173.htm)**

More in Public Health Focus (/NewsEvents/PublicHealthFocus/default.htm)

Expanded Access (Compassionate Use) (/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm)