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DEPARTMENT OF JUSTICE

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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-

[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.

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.)

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.

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[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.)

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*.

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

[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."

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.].)

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]

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[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

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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

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> 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. . . .
>
> **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.

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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.
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> **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.*

[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.

- *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]

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

[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.

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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.