



ROBERT HOBAN, MANAGING PARTNER  
303-674-7000

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*Via US Certified Mail and Email*

Dr. Smith:

Our firm represents numerous clients engaged in the cultivation, processing, manufacture, distribution, and use of products which contain derivatives of industrial hemp (the “Products”) across the United States. This letter is in response to a certain *FAQ – Industrial Hemp and Cannabidiol (CBD) in Food Products* (the “FAQ”) issued by the California Department of Public Health (“CDPH”) on July 6, 2018.

In short, the FAQ mischaracterizes relevant federal and state law and regulation and is fundamentally flawed for many reasons including, without limitation, the following:

1. The FAQ neither acknowledges or addresses all relevant provisions of California law, legislation which indicates the intent to provide for the Products;
2. The FAQ mischaracterizes the scope of Section 7606 of the Agricultural Act of 2014 (the “Farm Bill”) and corresponding legislation more narrowly than Congress intended;
3. CDPH mistakenly asserts “CBD derived from hemp . . . is a federally-regulated controlled substance” and gives inappropriate deference to the (erroneous) interpretations of law proffered by the Drug Enforcement Agency (“DEA”) and other agencies, in contradiction of guidance provided explicitly and directly by Congress; and
4. CDPH inappropriately mischaracterizes cannabidiol (“CBD”) as a prohibited food additive or dietary ingredient.

Correspondingly, we implore the CDPH to seriously reconsider the implementation of the FAQ and thereby rescind it. We request a meeting with CDPH at its earliest convenience to engage in further discussion with appropriate stakeholders to sensibly regulate the Products without implementing the FAQ. For years, California has been at or near the forefront of policy reform, having first enacted hemp legislation years ago. However, the FAQ stands to threaten an entire

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newly emerging industry, causing California to fall far behind the rest of the nation for years to come in its treatment and regulation of these Products. Simply put, the adverse impact of this FAQ would be devastating and irreparable.

### *Factual Background*

“Industrial hemp,” as defined by the Farm Bill, is a variety of *Cannabis sativa L.* which contains less than 0.3% tetrahydrocannabinol (“THC”), the psychoactive compound typically associated with “marihuana.” The Farm Bill legalizes industrial hemp including, but not limited to, the cultivation, transport, processing, sale and use thereof.<sup>1</sup>

Moreover, the intent of Congress – as described by 29 bipartisan members of Congress in a congressional amicus brief – in enacting the Farm Bill was to confirm that industrial hemp, or cannabinoids derived from industrial hemp, are not to be treated as controlled substances.<sup>2</sup> Contrary to the treatment of controlled substances, the Farm Bill sought to specifically allow for many activities relating to industrial hemp, including but not limited to certain commercial activities, development of the Products, exploring the economic impact of hemp-derived cannabinoids including the Products and creating a retail marketplace for the Products.<sup>3</sup>

Cannabinoids – including THC and CBD – are compounds which naturally occur in *Cannabis*, both “marihuana” and “industrial hemp,” but also an array of non-*Cannabis* sources including cacao, human breast milk, and even other flower varieties, as DEA acknowledges.<sup>4</sup> Naturally occurring cannabinoids, *per se*, are not controlled substances (with the exception of *synthetic* THC).<sup>5</sup> DEA even recently issued an internal and external directive confirming the same.<sup>6</sup>

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<sup>1</sup> See Pub. L. 113-79, §7606; see also Consolidated Appropriations Act, 2018 (Pub. L. No. 114-441 (Sec. 537, 729)).

<sup>2</sup> See *Amicus Brief of Members of United States Congress in Support of Petitioners with Consent of All Parties* at 3, 26, *Hemp Indus. Ass’n. v. DEA*, Case No. 17-70162 (argued February 15, 2018), available at: [https://polis.house.gov/uploadedfiles/amicus\\_brief.pdf](https://polis.house.gov/uploadedfiles/amicus_brief.pdf).

<sup>3</sup> *Id.* at 13-15.

<sup>4</sup> See *Denial of Petition to Initiate Proceedings to Reschedule Marijuana*, 81 Fed. Reg. 83,688-765, 53,692, 53,698, 53,753 (Aug. 12, 2016) (citing Giovanni Appendino et al., *Cannabinoids: occurrence and medicinal chemistry*, 18 *Curr. Med. Chem.* 1085 (2011)); see also *Brief of Petitioners* at 7, fn 3, *Hemp Indus. Ass’n. v. DEA*, Case No. 17-70162 (decided April 30, 2018).

<sup>5</sup> See *Hemp Indus. Ass’n. v. DEA*, 357 F.3d 1012, 1014 (9th Cir. 2004); *Hemp Indus. Ass’n. v. DEA*, 333 F.3d 1082, 1089 (9th Cir. 2003).

<sup>6</sup> DEA Internal Directive Regarding the Presence of Cannabinoids in Products and Materials Made from the Cannabis Plant (May 22, 2018), available at:



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### *Discussion*

Below, this letter addresses the flaws inherent within the FAQ. In light of these irreparable flaws, we respectfully request that CDPH not implement the FAQ, and instead engage in further dialogue with stakeholders, including our firm, to discuss California's regulatory scheme.

1. *FAQ Assertion: California law does not render the Products lawful under state law.*

Response:

California's legislature initially enacted the Industrial Hemp Farming Act in 2013 (the "Act") and subsequently Proposition 64, in 2016, which amended the Act. As amended, the Act specifically legalizes "industrial hemp," which is now defined in the Health and Safety Code, in relevant part, to include the flowering tops and leaves of the hemp plant, along with resins, manufacture, derivatives, mixtures and preparations thereof.<sup>7</sup>

Moreover, recently enacted AB 710 specifically indicates the intent that Section 11018.5 is intended to contemplate as lawful, and to preclude restriction of access to, the Products containing cannabidiol ("CBD").<sup>8</sup>

2. *FAQ Assertion: CBD derived from hemp is a federally-regulated controlled substance.*

Response:

*Congress knew what it was doing and its intent to exclude nonpsychoactive hemp from regulation is entirely clear.*<sup>9</sup>

Or, alternatively, in DEA's own words, "*DEA is not seeking to schedule cannabinoids.*"<sup>10</sup> Further, DEA "*does not purport to override the [Farm Bill].*"<sup>11</sup> Perhaps even most convincingly, in DEA's own internal and external directive, which our firm was involved in penning, DEA again confirmed that cannabinoids are not controlled substances:

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[https://www.deadiversion.usdoj.gov/schedules/marijuana/dea\\_internal\\_directive\\_cannabinoids\\_05222018.html](https://www.deadiversion.usdoj.gov/schedules/marijuana/dea_internal_directive_cannabinoids_05222018.html).

<sup>7</sup> California Health and Safety Code, Section 11018.5

<sup>8</sup> California Assembly Bill 710 §§ 1; 3(c) (enacted July 9, 2018).

<sup>9</sup> *Id.*

<sup>10</sup> *See Brief for Respondents at 29, Hemp Indus. Ass'n. v. DEA*, Case No. 17-70162 (decided April 30, 2018).

<sup>11</sup> *Id.* at 32.

*Products and materials that are made from the cannabis plant and which fall outside the CSA definition of marijuana . . . are not controlled under the CSA. Such products may accordingly be sold and otherwise distributed throughout the United States without restriction under the CSA or its implementing regulations. The mere presence of cannabinoids is not itself dispositive as to whether a substance is within the scope of the CSA; the dispositive question is whether the substance falls within the CSA definition of marijuana.<sup>12</sup>*

To expound on the above points, the federal Controlled Substances Act (“CSA”) does not illegalize the entire *Cannabis* plant. “Marihuana” only includes certain portions of the *Cannabis* plant, and neither includes “industrial hemp,” pursuant to the Farm Bill, nor the exempted stalk, stem, fiber and non-viable seeds of the plant. Those exempted portions and varieties of the *Cannabis* plant are still lawful, *even if they contain naturally occurring cannabinoids such as THC*.<sup>13</sup> In these early 2000s cases, the Court found against DEA, and DEA did not appeal these decisions.

Relatedly, the Court also found that although the CSA lists “THC” as a controlled substance, this reference is merely to *synthetic* THC, and not THC which naturally occurs in lawful portions and varieties of *Cannabis* – such as industrial hemp.<sup>14</sup>

As noted above, in writing as well as during argument before the Ninth Circuit Court of Appeals, DEA itself has admitted that DEA is not seeking to control cannabinoids and that cannabinoids may be found in parts of the *Cannabis* plant, or other lawful sources, which DEA does not control.<sup>15</sup> Importantly, DEA also admits that where the Farm Bill applies, the DEA has no jurisdiction.<sup>16</sup> Accordingly, the Ninth Circuit Court of Appeals confirmed that the Farm Bill pre-empts the federal CSA and DEA’s authority or jurisdiction.<sup>17</sup>

As noted above, the Farm Bill specifically makes lawful “industrial hemp” which includes all derivatives therefrom. It would, in fact, be a perverse interpretation of the Farm Bill for

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<sup>12</sup> DEA Internal Directive Regarding the Presence of Cannabinoids in Products and Materials Made from the Cannabis Plant (May 22, 2018), available at: [https://www.deadiversion.usdoj.gov/schedules/marijuana/dea\\_internal\\_directive\\_cannabinoids\\_05222018.html](https://www.deadiversion.usdoj.gov/schedules/marijuana/dea_internal_directive_cannabinoids_05222018.html).

<sup>13</sup> 357 F.3d at 1018; *Hemp Indus. Ass’n. v. DEA*, 333 F.3d 1082, 1089 (9th Cir. 2003).

<sup>14</sup> *Id.*

<sup>15</sup> See *Brief for Respondents* at 26-29, *Hemp Indus. Ass’n. v. DEA*, Case No. 17-70162 (decided April 30, 2018).

<sup>16</sup> *Id.* at 13-14, 32; see also Consolidated Appropriations Act, 2018 (Pub. L. No. 114-441 (Sec. 537, 729)).

<sup>17</sup> See *Memorandum* at 4, *Hemp Indus. Ass’n. v. DEA*, Case No. 17-70162 (decided April 30, 2018).



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“industrial hemp” to be made lawful, but that the crop must then be destroyed because it contains alleged controlled substances.

For these reasons, the FAQ mischaracterizes CBD and hemp as controlled substances and far too narrowly interprets the scope of the Farm Bill. As a result, the FAQ fails to accurately reflect the law and fails to acknowledge that cannabinoids derived from “industrial hemp” are in fact lawful.

3. *FAQ Assertion: CBD is an unapproved food additive or dietary ingredient, or otherwise inappropriate for inclusion in products intended for human or animal consumption, as regulated by the U.S. Food and Drug Administration (“FDA”).*

Response: For the reasons noted above, including DEA’s own admissions, cannabinoids derived from “industrial hemp” are lawful. Thus, such cannabinoids cannot be deemed an “adulterant” or an unapproved food additive or dietary ingredient by virtue of alleged illegality. Further, there are no other sources of federal or state law which specifically classify “CBD” or other hemp derivatives as an “adulterant.”

The Products would, at minimum, be appropriately regulated as dietary supplements pursuant to the Dietary Supplement Health and Education Act of 1994,<sup>18</sup> if not also as a conventional food pursuant to the Federal Food, Drug and Cosmetic Act.<sup>19</sup> This treatment would be appropriate given the longstanding prevalence in the marketplace of products containing derivatives of industrial hemp, including various amounts of cannabinoids such as CBD. Such products were even the subject of above-referenced litigation in the early 2000s.<sup>20</sup>

Moreover, the FAQ inappropriately defers to FDA’s position statements concerning CBD, which are unsettled and are not a *final* decision by FDA. FDA’s citation of certain provisions under the Federal Food, Drug and Cosmetic Act are in error, given that the prerequisite requirements for FDA to invoke those provisions do not appear to have been timely satisfied. Thus, the Department and the FAQ should not rely upon FDA’s positions in making definitive statements and conclusions.

FDA’s mission and underlying authority – as well as that of CDPH– is ensuring the safety of products intended for human consumption; given the FDA’s statutory positions are

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<sup>18</sup> See generally *Dietary Supplement Health and Education Act of 1994*, 108 Stat. 4325, Pub. L. No. 103-417 (1994).

<sup>19</sup> See generally *Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. 301, *et seq.*

<sup>20</sup> See 357 F.3d at 1014; 333 F.3d at 1089.



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erroneous, CDPH and the FAQ should not preclude the Products unless there is a showing that the Products undermine that safety purpose.

To this end, evidence demonstrates the Products are safe. Studies, and even the World Health Organization, conclude CBD maintains a good safety profile and has not been shown to cause dependence, abuse or harm.<sup>21</sup> Moreover, other publicly available studies confirm the safety of the Products.

Accordingly, the FAQ's determination that the Products do not comply with FDA regulations is both premature and in error. Thus, the FAQ should not be implemented to regulate upon these flawed determinations.

For the reasons set forth above, we implore CDPH to not implement the FAQ, and instead propose that CDPH engage in further dialogue with stakeholders to appropriately regulate hemp-derived products, such as the Products, in the State of California.

Thank you for your thoughtful consideration of the above commentary. Our firm also extends a standing offer to further discuss these sensitive issues to ensure that any policy considered and promulgated accurately reflects both the law and sensible policymaking regarding the Products. Please do not hesitate to contact myself or my colleagues, Garrett Graff or Patrick Goggin, with any questions. Thank you.

Very truly yours,

/s/ Robert T. Hoban  
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<sup>21</sup> See *Kerstin, Iffland and Grotenhermen Franjo*, AN UPDATE ON SAFETY AND SIDE EFFECTS OF CANNABIDIOL: A REVIEW OF CLINICAL DATA AND RELEVANT ANIMAL STUDIES, available at: <https://www.liebertpub.com/doi/10.1089/can.2016.0034> (June 1, 2017); *World Health Organization*, CANNABIDIOL (CBD) PRE-REVIEW REPORT, available at: [http://www.who.int/medicines/access/controlled-substances/5.2\\_CBD.pdf](http://www.who.int/medicines/access/controlled-substances/5.2_CBD.pdf); 21 C.F.R. 53,693; *Researching Marijuana for Therapeutic Purposes: The Potential Promise of Cannabidiol (CBD)*, NATIONAL INSTITUTE OF DRUG ABUSE, available at: <https://www.drugabuse.gov/about-nida/noras-blog/2015/07/researching-marijuana-therapeutic-purposes-potential-promise-cannabidiol-cbd> (July 20, 2015).