U.S. Hemp Roundtable

July 19, 2018

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Director
California Department of Public Health
Food and Drug Branch
P.O. Box 997435, MS 7602
Sacramento, CA 95899

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

Dear Dr. Smith:

The U.S. Hemp Roundtable writes to express significant concerns regarding a recent FAQ document issued by the California Department of Public Health ("CDPH") that prohibits the use of industrial hemp-derived cannabidiol ("CBD") oil or CBD products in food.[1] The Roundtable is the industry's national business association that represents over forty firms from across the country – at each link of the hemp supply and sales chain – and includes the ex officio membership of the industry's major grassroots and trade organizations.

As discussed further below, the FAQ document makes inaccurate statements about the status of industrial hemp-derived CBD under the Controlled Substances Act ("CSA") and the Federal Food, Drug, and Cosmetic Act ("FD&C Act"). Further, the safety profile of industrial hemp-derived CBD is well-established. The World Health Organization ("WHO") recently evaluated CBD and determined that "CBD is generally well tolerated with a good safety profile," and furthermore that "there is no evidence of recreational use of CBD or any public health-related problems associated with the use of pure CBD."[2]

[1] https://www.cdph.ca.gov/Programs/CEH/DFDCS/CDPH%20Document%20Library/FDB/FoodSafetyProgram/HEMP/Web%20template%20for%20FSS%20Rounded%20-%20Final.pdf (revised 07/06/2018).
[2] http://www.who.int/medicines/access/controlled-substances/5.2_CBD.pdf.

Hemp-Derived CBD is not a Controlled Substance

The FAQ incorrectly states that "CBD derived from hemp and cannabis is a federally-regulated controlled substance" and makes repeated references to "industrial hemp," suggesting that CBD derived from industrial hemp also falls within the scope of the CSA.

Industrial hemp that is grown and distributed pursuant to Section 7606 of the Agricultural Act of 2014 (also known as the "Farm Bill") is exempted from the CSA. Section 7606 defines "industrial hemp'' as 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.[3] California's own CSA likewise exempts "industrial hemp" from its list of controlled substances.[4]

In addition, under the CSA, "marihuana" (commonly referred to as "marijuana") is a Schedule I controlled substance and is defined as follows:

> 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* (emphasis added).[5]

Materials that are derived from the exempted plant parts –and any "compounds" thereof – are excluded from the definition of marijuana and are not considered a controlled substance. Therefore, CBD derived from either the exempted parts of the *Cannabis* plant or derived from lawfully grown and cultivated industrial hemp is not a federally-controlled substance.

This interpretation of the CSA is also supported by two cases decided by the United States Court of Appeals for the Ninth Circuit.[6] In the first case, the Court found that "marihuana is defined so as to bring within its scope all parts of the plant having the harmful drug ingredient, but so as to exclude the parts of the plant in which the drug is not present" (including "hemp").[7] In a subsequent case a year later, the same Court considered a

[3] Section 7606 of the Agricultural defines ''industrial hemp'' as 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.
[4] California Health and Safety Code, Section 11018.59(b).
[5] 21 U.S.C. § 802(16).
[6] In both cases, the conduct and products directly at issue were the importation and distribution of sterilized hemp seed and oil and cake derived from hemp seed for the manufacture and sale of food and cosmetic products containing hemp seed and oil.
[7] *Hemp Industries Assn. v. Drug Enforcement Admin*., 333 F.3d 1082, 1085 (9th Cir. 2003) ("Hemp I").

challenge of two administrative rules established by the Drug Enforcement Agency ("DEA") that sought to ban non-psychoactive hemp products that contained trace amounts of tetrahydrocannabinol ("THC").[8] The *Hemp II* Court reiterated its position from *Hemp I* and stated that "non-psychoactive hemp [that] is derived from the 'mature stalks' or is 'oil and cake made from the seeds' of the Cannabis plant…fits within the plainly stated exception to the CSA definition of marijuana."[9] The court further noted that "Congress knew what it was doing, and its intent to exclude non-psychoactive hemp from the regulation is entirely clear."[10]

Thus, it is clear (as outlined by the Court in *Hemp I* and *Hemp II*) that CBD is not a Scheduled I controlled substance if it is derived exclusively from the excluded parts of *Cannabis Sativa L*. plant, as set forth in the CSA's definition of marijuana.

A recent directive from the DEA is consistent with the above interpretation in that the source of cannabinoids such as CBD, rather than the presence, will determine whether a product falls within the scope of the CSA. It states:

> 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* (emphasis added).[11]

We also note the irony in that CDPH is making its decision based on federal law (CSA and FD&C Act) yet cannabis products are widely available to consumers for both recreational and medicinal purposes, despite being regulated as a Schedule I controlled substance at the federal level.

The Status of Hemp-Derived CBD Under the FD&C Act is Unsettled

The FAQ document also states that the U.S. Food and Drug Administration ("FDA") "has concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food…to which [THC] or CBD has been added," regardless of the source. However, the FDA's current position regarding CBD in dietary supplements or conventional food is unsettled and unsupported by law or regulations. More importantly, the agency's current position is *not* a final determination.

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[8] *Hemp Industries Assn. v. Drug Enforcement Admin*., 357 F.3d 1012 (9th Cir. 2004) ("Hemp II").
[9] *Id*. at 1017.
[10] *Id*. at 1018.
[11] *DEA Internal Directive Regarding the Presence of Cannabinoids in Products and Materials Made from the Cannabis Plant* (May 22, 2018), https://www.deadiversion.usdoj.gov/schedules/marijuana/dea_internal_directive_cannabinoids_05222018.html.

As background, the FD&C Act, as amended by the Dietary Supplement Health and Education Act of 1994 ("DSHEA"),[12] defines a "dietary supplement" as a product intended to supplement the diet that contains one or more of the following:

(a) a vitamin;
(b) a mineral;
(c) an herb or other botanical;
(d) an amino acid;
(e) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
(f) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (a) through (e).[13]

Thus, it permits a wide range of dietary ingredients in dietary supplements, including CBD which is an extract of a botanical (*Cannabis sativa L.* plant). CBD also falls under clause (e) as it is a dietary substance for use by man to supplement the diet by increasing the total dietary intake.

The FDA has taken the position – via Warning Letters sent to hemp-CBD companies[14] and an FDA Q&A document[15] – that because substantial clinical trials studying CBD as a new drug were made public prior to the marketing of any food or dietary supplements containing CBD, dietary supplements or food are therefore precluded from containing this ingredient ("IND Preclusion").[16] However, we firmly disagree that the referenced clinical trials are in fact "substantial," as the trials were extremely limited in scope, and funding and the publication of these trials were limited. The FDA also seems to misinterpret the IND Preclusion in that it believes the preclusion date is simply the date in which it authorized CBD as an IND, without giving deference to the remaining portion of the statute, which requires that substantial clinical investigation be commenced and that such substantial clinical investigation be made public. In addition, The FDA Q&A document does not have the effect of law but instead reflects FDA's opinion, which the agency suggests may change as evidenced from the FDA's own request for further input on the topic.

Rather, we believe that industrial hemp-CBD products were marketed as dietary supplements and/or foods prior to any *substantial* drug investigations being undertaken, or made public, and that based on the definition of "dietary supplement" under DSHEA, CBD is in fact a permissible dietary ingredient. Moreover, Warning Letters and agency Q&A documents are by no means final agency determinations. To date, the FDA has not taken any industrial hemp-CBD products off the market, prohibited the sale of such products, or ordered a

[12] Dietary Supplement Health and Education Act of 1994, Pub. L. No. 104-417.
[13] 21 U.S.C. § 321(ff).
[14] https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm484109.htm.
[15] FDA, *FDA and Marijuana: Questions and Answers*, https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm#dietary_supplements.
[16] 21 U.S.C. § 321(ff)(3)(B)(ii).

product recall. Further, the primary motivation for the Warning Letters issued in 2015, 2016, and 2017 concerned the improper use of disease-remediation claims by supplement/food companies.

Absent a clear safety issue, CDPH should not categorically prohibit the use of industrial hemp-derived CBD in food or dietary supplements.

Industrial Hemp-Derived CBD is Safe

Current scientific research confirms that industrial hemp-derived CBD is safe in food, supplements, and beverages and has provided health benefits to millions of Americans, including thousands of Californians. We are also not aware of any serious adverse events associated with the consumption of CBD. Indeed, the World Health Organization ("WHO") recently evaluated CBD and determined that "CBD is generally well tolerated with a good safety profile," and furthermore that "there is no evidence of recreational use of CBD or any public health-related problems associated with the use of pure CBD."[17] Because industrial hemp contains only a negligible amount of tetrahydrocannabinol ("THC"), the psychoactive component of cannabis, hemp-derived CBD products are non-psychoactive and safe. Further, hemp-derived CBD does not have the potential for abuse or addiction, and there is no potential for diversion.

Of note, the FAQ document indicates that California will continue to permit the sale of edible cannabis products and other cannabis products that contain CBD, which fall outside the statutory definition of "food" and are regulated by the Manufactured Cannabis Safety Branch ("MCSB"). However, there is no justification for making this distinction, especially from a health and safety perspective. MCSB must be reasonably certain that CBD does not pose a safety risk if it permits it to be sold in cannabis products. We also note that CDPH's policy creates a situation whereby CBD products that may contain high levels of THC are readily available, but access to supplement and food products with zero THC that are both safe and non-addictive is now restricted.

Food and supplements that contain industrial hemp-derived CBD are subject to a comprehensive regulatory framework that addresses both the safety and quality of these products. In fact, the current Good Manufacturing Practices ("cGMPs") for food and supplements (21 CFR Part 117 and Part 111, respectively) are equally if not more robust than the MCSB regulations governing the manufacture and production of cannabis products in California. Thus, as a result of the CDPH policy, California consumers will be denied access to safe, quality industrial hemp-derived CBD products at the retail level and will be limited to purchasing CBD only from licensed cannabis cultivators – absent a final determination from the FDA and without regard to the well-established safety record of industrial hemp-derived CBD.

In closing, we respectfully urge the Department of Public Health to withdraw or revise the FAQ document to permit the continued use of industrial hemp-derived CBD in dietary supplement and food products in California.

[17] http://www.who.int/medicines/access/controlled-substances/5.2_CBD.pdf.

Thank you for your consideration.

Sincerely,

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