









July 20, 2018

David Mazzera, Ph.D Chief, Food & Drug Branch P.O. Box 997435, MS 7602 Sacramento, CA 95899

Email: david.mazzera@cdph.ca.gov

Dear Mr. Mazzera:

The signatories to this letter represent many industry leaders in industrial hemp-derived products, which contain cannabinoids including cannabidiol ("CBD") from the legal, legislative, policy and market perspective. Our coalition has been intimately involved in legislative efforts within California to continually bring California to the forefront of hemp policy and as an industry leader. We write to you regarding the California Department of Public Health's (the "Department") July 6, 2018 FAQ – Industrial Hemp and Cannabidiol in Food Products (the "FAQ") and respectfully request a meeting as soon as possible to address fundamental flaws in the FAQ and how the FAQ conflicts with state law.

The FAQ cites the United States Food and Drug Administration's ("FDA") position on CBD as justification for the Department's announcement that CBD or other hemp extracts are not an approved food additive to be included in finished products. The FDA's position, adopted several years ago, appears to be based, at least in part, on the Drug Enforcement Administration's ("DEA") conclusion that CBD is a controlled substance. CBD, however, in and of itself is not scheduled under the Controlled Substances Act ("CSA"). Rather, it is a controlled substance <u>only</u> when it is sourced from "marihuana," but not when sourced from lawfully cultivated industrial hemp.

The FAQ points out that the federal Agricultural Act of 2014 (the "Farm Bill") included an industrial hemp research amendment. The amendment defined "industrial hemp" as:

the plant Cannabis sativa L. and <u>any part of such plant</u>, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. [Emphasis added.]

Hemp flowers and leaves, the primary source of CBD and other cannabinoids, are thus lawful portions of the plant and are within the definition of "industrial hemp." Further, Congress has indicated its intention

to allow for hemp extract/CBD research and development, commercial activity, and private individual and entity involvement under the Farm Bill. 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), attached, pp. 13 - 15. Additionally, the Ninth Circuit recently held that the Farm Bill's hemp amendment preempts the CSA. See Memorandum, Hemp Indus. Ass'n. v. DEA, Case No. 17-70162 (decided April 30, 2018), attached, p. 4. Accordingly, at the federal level, when CBD is sourced from hemp pursuant to the Farm Bill it is not controlled.

On a related note, there is also evidence demonstrating the safety of CBD and other hemp extracts when consumed, as confirmed by a recent World Health Organization study and other publicly available studies. *See e.g.* Cannabidiol (CBD) Critical Review Report, available at: http://www.who.int/medicines/access/controlled-substances/CannabidiolCriticalReview.pdf. Accordingly, many other state departments of health already affirmatively regulate hemp-derived products as safe and appropriate food additives.

As you know, California passed its Industrial Hemp Farming Act ("IHFA") in 2013. In 2016, Proposition 64 expanded the definition of industrial hemp to include:

the resin extracted from any part of the plant; every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seed or resin produced therefrom. - Health and Safety Code § 11018.5.

Additionally, Proposition 64 struck a provision from the original IHFA that prohibited removing hemp flowers and leaves from the field of cultivation. These amendments made clear that hemp extracts and CBD are fully lawful in the state. Furthermore, recently enacted AB 710, a bill regarding FDA approved drugs containing CBD, states:

The availability of this new prescription medication is intended to augment, not to restrict or otherwise amend, other cannabinoid treatment modalities including, but not limited to, industrial hemp products and derivatives containing cannabidiol, currently available under state law.... (c) This section does not apply to any product containing cannabidiol that is made or derived from industrial hemp, as defined in Section 11018.5 and regulated pursuant to that section.

AB710, §§ 1; 3 (c). Accordingly, pursuant to the IHFA and other state statutes hemp extract and CBD products are fully lawful under state law. In other words, California has already made a determination that these products are safe and can be used as a food and dietary supplement thereby rendering your FAQ to be in conflict with California law.

We understand there is work to be done to further regulate these products to ensure their safety and remain willing to discuss sensible regulation with the Department in lieu of the FAQ.

Kindest regards,

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