U.S. Hemp Roundtable

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STATEMENT ON THE STATUS OF HEMP-DERIVED CBD UNDER FEDERAL LAW

Upon the December 20, 2018 signing of the 2018 Farm Bill, the era of hemp prohibition is over. Questions continue to be raised, however, about the legality of one of the country's most popular hemp products, hemp-derived cannabidiol (CBD). The U.S. Hemp Roundtable, the industry's leading business advocate for the full and permanent legalization of hemp and hemp products, strongly believes that U.S. federal law protects the retail sale of hemp-derived CBD. Our analysis follows:

Hemp-derived CBD is no longer a controlled substance under federal law.

As a consequence of the 2018 Farm Bill, hemp is now permanently removed from the Controlled Substances Act (CSA). It is now deemed an agricultural commodity, no longer able to be classified as a controlled substance, like marijuana.

Furthermore, by redefining hemp to include its "extracts, cannabinoids and derivatives," Congress explicitly removed popular hemp products – such as hemp-derived CBD -- from the purview of the CSA. Accordingly, the Drug Enforcement Administration (DEA) no longer has any claim to interfere with the interstate commerce of hemp products, so as long as the THC level is at or below 0.3%. This should give comfort to federally regulated institutions – pharmacies, banks, merchant services, credit card companies, e-commerce sites and advertising platforms -- to conduct commerce with the hemp and hemp CBD industry.

State and Tribal governments may impose separate restrictions or requirements on hemp growth and the sale of hemp products – however, they cannot interfere with the interstate transport of hemp or hemp products.

The FDA's position on CBD is unsettled and unsupported by law.

While the DEA is now officially out of the hemp regulation business, the U.S. Food and Drug Administration (FDA) retains its authority to regulate ingestible and topical products, including those that contain hemp and hemp extracts such as CBD. Much public attention has focused on a non-binding Q&A posted on the FDA web site starting about three years ago[1] -- reiterated in a December 20, 2018 statement by the FDA Commissioner[2] -- which suggests that CBD products cannot be marketed as foods or dietary supplements.

This position, however, is unsettled and rests on questionable legal grounds. More importantly, the agency's current position is *not* a final determination and should not be interpreted as the law.

[1] https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm
[2] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm628988.htm

As background, the Food, Drug & Cosmetics Act, as amended by the Dietary Supplement Health and Education Act of 1994 (DSHEA),[3] 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).[4]

Thus, the law 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,[5] as well as the FDA Q&A posting – that because a product containing CBD was approved as a drug and 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 (referred to as the "IND Preclusion").[6]

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 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.

It is of significant import that, to date, the FDA has not prohibited the sale of hemp-derived CBD products or ordered a 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. No Warning Letter has been issued to a company that merely sold legitimate hemp-derived CBD products without making inappropriate disease-remediation claims.

Scientists, even FDA's own, have concluded that CBD is safe as an ingestible product.

Current scientific research confirms that hemp-derived CBD is safe in food, supplements, and beverages and has provided general health and wellness benefits to millions of Americans. Because hemp contains only a negligible amount of tetrahydrocannabinol (THC), the psychoactive component of cannabis, hemp-derived CBD products

[3] Dietary Supplement Health and Education Act of 1994, Pub. L. No. 104-417.
[4] 21 U.S.C. § 321(ff).
[5] https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm484109.htm.
[6] 21 U.S.C. § 321(ff)(3)(B)(i) and (ii).

are non-psychoactive and do not cause a "high" in users. Further, hemp-derived CBD does not have the potential for abuse or addiction, and there is no potential for diversion.

Food and supplements that contain 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 for food and supplements (21 CFR Part 117 and Part 111, respectively) are equally if not more robust than the regulations governing the manufacture and production of cannabis products in most states.

Indeed, the World Health Organization (WHO) Expert Committee on Drug Dependence recommended in August 2018 that "preparations considered to be pure CBD should not be scheduled within the International Drug Control Conventions." Some key findings from the WHO:

- "There are no case reports of abuse or dependence relating to the use of pure CBD."
- "No public health problems have been associated with CBD use."
- "CBD has been found to be generally well tolerated with a good safety profile."
- "There is no evidence that CBD is liable to similar abuse and similar ill-effects as substances…such as cannabis or THC."[7]

Perhaps more significantly, a May 2018 memorandum from FDA Assistant Secretary Brett Giroir concludes that "CBD and its salts…could be removed from control under the CSA." After a thorough scientific review and analysis, the FDA opined:

- "There is little indication that CBD has abuse potential or presents a significant risk to the public health."
- "No evidence for a classic drug withdrawal syndrome for CBD, and no evidence that CBD causes physical or psychic dependence."
- "CBD does not appear to have abuse potential under the CSA."
- "There is no signal for the development of substance use disorder in individuals consuming CBD-containing products."
- "It is unlikely that CBD would act as an immediate precursor to THC for abuse purposes."[8]

The FDA foresees a path toward full recognition of hemp-derived CBD as a dietary supplement and food additive.

Shortly after the Farm Bill signing, a letter was released by FDA Commissioner Scott Gottlieb that restated FDA's current position, opining that it's a violation of federal law to introduce CBD ingredients "into the food supply or market them as dietary supplements."[9] While that portion of the statement provoked a few breathless media reports, it was old news.

The real news provided by the Gottlieb letter was that it also contained, for the very first time, a clear new path toward FDA's permanent and formal acceptance of hemp-derived CBD as a food additive or nutritional

[7] https://www.who.int/medicines/access/controlled-substances/ecdd_40_meeting/en/
[8] https://hempindustrydaily.com/wp-content/uploads/2018/10/DHS-DEA-letter-2018-0014-0002.pdf?_ga=2.205388819.221633313.1538568567-731547511.1538568567
[9] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm628988.htm

supplement. For the very first time, the FDA is seriously considering using its authority to issue a regulation that will specifically allow hemp-derived ingredients in foods and supplements:

> *[P]athways 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.*

This is unprecedented; the FDA has never used this authority for any ingredient determined to only be permissible in pharmaceutical drugs per the IND Preclusion. As it makes this decision, the FDA is reaching out to the industry and the public:

> *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.*

We can assure that the Roundtable will be in the room where it happens. With the partnership of other industry organizations such as the American Herbal Products Association and the Hemp Industries Association, the pursuit of this approval path will be one of our top priorities for 2019.

There was also more good news from the FDA on December 20. That same day, FDA issued a statement opining that the "agency has no questions" about the conclusion that hulled hemp seed, hemp seed protein powder and hemp seed oil are generally recognized as safe (GRAS) under their intended conditions of use.[10] While the GRAS evaluation was made at the request of a specific company, Fresh Hemp Foods, "the GRAS conclusions can apply to ingredients from other companies, if they are manufactured in a way that is consistent with the notices and they meet the listed specifications. Some of the intended uses for these ingredients include adding them as source of protein, carbohydrates, oil, and other nutrients to beverages (juices, smoothies, protein drinks, plant-based alternatives to dairy products), soups, dips, spreads, sauces, dressings, plant-based alternatives to meat products, desserts, baked goods, cereals, snacks and nutrition bars."

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10 http://app.info.fda.gov/e/es?s=2027422842&e=174367&elqTrackId=78D8A052C380BCBFF284D754BEBE9730&elq=920ad70cfc794cdd98d105ed04048730&elqaid=6391&elqat=1

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There is still work to be done. But incautious media reports that broadly suggest that hemp-derived CBD is now federally illegal must be rejected. With the backing of consensus scientific research, and the evolving viewpoints of the FDA, the clear and permanent recognition of the legality of hemp-derived CBD as a food and dietary supplement ingredient is within our sites.

Sincerely,

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