



July 16, 2019  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: Docket ID: FDA-2019-N-1482, “Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments”**

To Whom It May Concern:

Vote Hemp is the nation’s leading advocacy organization for federal policy regarding hemp farming and hemp product manufacturing in the United States. We share the following comments with the U.S. Food and Drug Administration (“FDA”) as the Agency considers how to properly regulate hemp-derived products containing cannabidiol (“CBD”) and other useful phytocompounds.

Hemp is a variety of cannabis that produces a range of useful herbal compounds, including cannabinoids and terpenes.<sup>1</sup> Cannabinoids, such as CBD, interact with the body’s endocannabinoid system.<sup>2</sup> The human endocannabinoid system consists of cannabinoid receptors located throughout the central and peripheral nervous system and immune system.<sup>3</sup> These receptors bind to both endocannabinoids and external cannabinoids, such as CBD.<sup>4</sup> The hypothalamus contains cannabinoid receptors, and research shows that the endocannabinoids that bind to these receptors help regulate homeostasis, a dynamic state of equilibrium in the body.<sup>5</sup>

The *Agriculture Improvement Act of 2018* (the “2018 Farm Bill”) defines hemp as legally distinct from marijuana to include any part of the *Cannabis sativa L.* plant, including “all derivatives, extracts, [and] cannabinoids,” with a delta-9 tetrahydrocannabinol concentration of not more than 0.3%, and removed hemp from the schedules of controlled substances under the *Controlled Substances Act of 1970* (the “CSA”).<sup>6</sup> The 2018 Farm Bill also established hemp as a legal agricultural commodity and authorized the production, consumption, and sale of hemp and

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<sup>1</sup> Joshua A. Hartsel, et. al., *Chapter 53 - Cannabis sativa and Hemp*, in NUTRACEUTICALS EFFICACY, SAFETY AND TOXICITY, 735 (Academic Press 2016).

<sup>2</sup> Maria-Paz Viveros, et. al., *Critical role of the endocannabinoid system in the regulation of food intake and energy metabolism, with phylogenetic, developmental, and pathophysiological implications*, 8(3) ENDOCRINE, METABOLIC & IMMUNE DISORDERS - DRUG TARGETS, 220 (2008).

<sup>3</sup> *Id.*

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> H.R. 2, 115th Cong. § 10111 (2018).

hemp-derived products in the United States, consistent with other laws, such as the *Federal Food, Drug, and Cosmetic Act* (the “FD&C Act”).<sup>7</sup>

The passage of the 2018 Farm Bill illustrates the clear intent of Congress to authorize and support the domestic production and sale of hemp and hemp derivatives, including CBD. In addition, the United States Department of Agriculture (“USDA”) has issued a legal opinion through the USDA’s Office of the General Counsel, which, among other things, recognizes the federal legality of hemp extracts.<sup>8</sup>

FDA staff has publicly stated on multiple occasions that the Agency is committed to sound, science-based policy.<sup>9</sup> FDA staff has also committed to treat substances from hemp and cannabis just like the Agency treats any other herbal substance.<sup>10</sup> Vote Hemp fully agrees with this approach and believes that the science supports the safe use of hemp supplements, including those containing CBD, when manufactured according to existing FDA standards for food and dietary supplements.

Hemp-derived herbal extracts are no different than other herbal supplements and should be treated by FDA the same as any other herb. Thus, existing federal regulations for food and dietary supplements must apply to hemp-derived extract products, including those containing CBD, to assure consumers of the same production safety and integrity of ingredients met by other FDA-regulated supplements.

Whole-plant hemp extracts can be part of a healthy diet, are beneficial to consumers, and are not pharmaceutical drugs, especially when they are not marketed to have a therapeutic effect on consumers. Many of the hemp extracts that are currently sold as dietary supplements and foods are “full spectrum” hemp extracts that contain the complete range of phytochemicals found in the hemp plants they are derived from. These include CBD and other cannabinoids, as well as terpenoids, which act synergistically to regulate homeostasis.<sup>11</sup> FDA should recognize that whole-plant hemp extracts are distinct from any substance that has been submitted to FDA for approval as a pharmaceutical drug. Additionally, the case for whole-plant hemp extract synergy via the “entourage effect” is sufficiently strong as to suggest that one isolated molecule is

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<sup>7</sup> *Id.*

<sup>8</sup> *Legal Opinion on Authorities for Hemp Production*, U.S. DEP’T. OF AGRIC., AGRIC. MARKETING SERV. (May 28, 2019), <https://www.ams.usda.gov/content/legal-opinion-authorities-hemp-production>.

<sup>9</sup> *See* Amy Abernethy, M.D., Lowell Schiller, J.D., *FDA is Committed to Sound, Science-based Policy on CBD*, U.S. FOOD AND DRUG ADMIN., <https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-committed-sound-science-based-policy-cbd>.

<sup>10</sup> *Id.*

<sup>11</sup> *Dr. Ethan Russo: CBD & Clinical Endocannabinoid Deficiency*, PROJECT CBD (June 21, 2016), <https://www.projectcbd.org/science/dr-ethan-russo-cbd-clinical-endocannabinoid-deficiency>.

unlikely to match the therapeutic and even industrial potential of cannabis itself as a phytochemical factory.<sup>12</sup>

Importantly, Vote Hemp recommends that FDA regulation of products containing cannabinoids, including CBD, as food and dietary supplements apply only to *plant*-derived products. Synthetic cannabinoids do not meet the 2018 Farm Bill definition of “hemp,” as they are not derived from the cannabis plant, and should not be regulated like food or dietary supplements.<sup>13</sup> If FDA eventually approves synthesized cannabinoids for human consumption and these synthetic products are deemed safe, the public needs full transparency in labeling to distinguish whole-plant, naturally derived CBD from synthetic CBD.

Vote Hemp further recommends that hemp-derived CBD products, like other botanical supplements, be eligible for organic certification under the USDA’s National Organic Program. Consumers deserve to know whether or not they are ingesting a whole-plant, naturally derived product.

In line with these recommendations, FDA must ensure transparency in labeling regarding extraction and manufacturing methods, use of additives, ingredients, cannabinoid concentration and serving size for all hemp-derived consumer products. To this end, Vote Hemp urges FDA to quickly issue an Interim Final Rule with an accelerated effective date authorizing the sale of hemp-derived dietary supplements and foods containing CBD, which: (1) have a CBD concentration of no more than 50mg/mL; and (2) meet existing FDA requirements for the manufacturing and marketing of dietary supplements and foods. A CBD concentration of 50 mg/mL is half the concentration found in Epidiolex, thereby preserving a pharmaceutical avenue for highly concentrated cannabinoid products.

In addition to limiting the allowable concentration of CBD in a product, Vote Hemp supports serving size recommendations intended to address certain safety concerns with CBD that have already been identified by the Agency, namely liver injury at doses of 20 milligrams CBD per kilogram of body weight per day. The average American man weighs approximately 88.8 kg, while the average American female weighs approximately 76.4 kg.<sup>14</sup> This means that in order to realize the Agency’s concerns regarding liver injury, the average American male requires a *daily* consumption of **1,776 mg of CBD**, while the average American female must consume **1,528 mg of CBD**. This level of CBD consumption is staggering when compared to the hemp extract products currently on the market—most of which (if not all) have serving sizes that are orders of magnitude lower than this 20mg/kg threshold.

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<sup>12</sup> Ethan B. Russo, *The Case for the Entourage Effect and Conventional Breeding of Clinical Cannabis: No “Strain,” No Gain*, FRONTIERS IN PLANT SCIENCE (Jan. 9, 2019), <https://www.frontiersin.org/articles/10.3389/fpls.2018.01969/full>.

<sup>13</sup> See H.R. 2, 115th Cong. § 10111 (2018).

<sup>14</sup> *Anthropometric reference data for children and adults: United States, 2011–2014*, U.S. DEP’T. OF HEALTH AND HUMAN SERVICES (Aug. 2016), [https://www.cdc.gov/nchs/data/series/sr\\_03/sr03\\_039.pdf](https://www.cdc.gov/nchs/data/series/sr_03/sr03_039.pdf).

As a molecule, CBD has a remarkable safety profile. The World Health Organization Expert Committee on Drug Dependence (“ECDD”) recently published an extensive scientific review of CBD.<sup>15</sup> Conclusions include “[t]here are no case reports of abuse or dependence relating to the use of pure CBD,” and “no public health problems (e.g., driving under the influence of drugs cases, comorbidities) have been associated with the use of pure CBD.”<sup>16</sup> The ECDD report also states that “CBD is generally well tolerated with a good safety profile.”<sup>17</sup> Similarly, in a memo from the Department of Health and Human Services (“HHS”) to the Acting Administrator of the Drug Enforcement Agency regarding the scheduling of CBD, HHS concluded that based on the scheduling criteria set forth in the CSA, CBD should be removed from the schedules of controlled substances because of its low potential for abuse.<sup>18</sup> The memo also states that the only reason that CBD should be placed in Schedule V is because it was required under international treaties.<sup>19</sup> The memo makes clear that HHS believes CBD is safe with a low potential for abuse and does not appear to produce physical dependence.

In addition, Vote Hemp has received information provided by the Realm of Caring, an independent non-profit that has been documenting consumers of hemp products and their experiences with hemp products for seven years. Since the inception of their call center in 2015, Realm of Caring has had over 284,000 touch points with consumers of hemp products. These touchpoints record only sixty-nine suspected adverse events potentially associated with the consumption of hemp products. This represents 0.12% of the registered individuals in their database. According to Realm of Caring, the most common reaction reported during a suspected adverse event was an increase in symptoms that were reported as already present and as not necessarily requiring medical intervention.

### **Request for prompt FDA action.**

To fully realize Congressional intent to allow access to products that contain hemp-derived CBD, and to further Vote Hemp and FDA’s shared goal of ensuring safe and well-manufactured dietary supplements and foods, Vote Hemp joins the American Herbal Products Association in requesting that FDA promptly take one of the two following actions.

FDA should use its authority under the FD&C Act to issue an Interim Final Rule with an accelerated effective date – permitting CBD as a lawful ingredient in dietary supplements and foods. Of course, this regulation would still require compliance with all other applicable federal regulations for these product categories, such as food facility registration, compliance with

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<sup>15</sup> *Cannabidiol (CBD) Critical Review Report*, WORLD HEALTH ORGANIZATION, EXPERT COMMITTEE ON DRUG DEPENDENCE (June 4–7, 2018), <https://www.who.int/medicines/access/controlled-substances/CannabidiolCriticalReview.pdf>.

<sup>16</sup> *Id.*

<sup>17</sup> *Id.*

<sup>18</sup> Letter from Brett P. Giroir, M.D., Assistant Secretary for Health to Robert W. Patterson, Acting Administrator, Drug Enforcement Admin. (May 16, 2018), <https://hempindustrydaily.com/wp-content/uploads/2018/10/DHS-DEA-letter-2018-0014-0002.pdf>

<sup>19</sup> *Id.*

current Good Manufacturing Practices, reporting of serious adverse events, submission of New Dietary Ingredient Notifications, and labeling for nutritional content and presence of major food allergens. Such a regulation would allow FDA to take the same enforcement action that it currently applies to the existing dietary supplement industry.

Vote Hemp acknowledges that issuance of such a regulation may be conditional upon reasonable restrictions on these products, such as limitations on daily recommended CBD consumption, serving sizes for CBD, special labeling requirements, etc., in addition to compliance with all other applicable federal regulations. The availability of a clear federal regulatory pathway, albeit with reasonable restrictions, would provide certainty to the industry and alleviate the state-by-state regulatory confusion that is rampant and growing daily. FDA issuance of an Interim Final Rule would help to ensure uniform federal standards are applied to hemp-derived foods and dietary supplements, including those with CBD. The need for prompt action by FDA is magnified because the USDA is currently promulgating regulations for hemp cultivation and is expected to complete those within the next few months. These USDA regulations will inevitably result in the increased cultivation of hemp for CBD production.

Alternately, and especially if FDA cannot issue this requested regulation promptly, FDA should issue guidance to state the Agency's intent to exercise formal enforcement discretion with respect to the provisions of the FD&C Act on which FDA bases its position that CBD-containing supplements and foods are unlawful. While the Agency has not announced a formal policy of enforcement discretion for these products, the Agency's limited enforcement actions taken against CBD products on the market (e.g., issuance of eight warning letters for products with perceived unlawful claims of treating diseases since 2017, etc.) is being perceived as either a *de facto* policy of enforcement discretion, or as FDA not regulating these products at all. As stated above, Vote Hemp supports conditioning this exercise of enforcement discretion on full compliance with all other regulations applicable to these product categories and in combination with reasonable restrictions on product use.

In conclusion, through the actions described above, FDA can fulfill its commitment to establish a sound, science-based policy on hemp products, including those containing CBD, while simultaneously ensuring that the public has access to safe hemp-derived CBD products.