

HEMP INDUSTRIES ASSOCIATION

thehia.org

*Fighting for Hemp
Since 1994*

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To Federal Drug Administration
via [regulations.gov](https://www.regulations.gov)

Re: The Food and Drug Administration (FDA) Notice: The Food and Drug Administration (FDA) Notice: International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Ocfentanil, Carfentanil, Pregabalin, Tramadol, **Cannabidiol**, Ketamine, and Eleven Other Substances; Request for Comments

To Whom it May Concern:

My name is Colleen Keahey and I am the executive director of the Hemp Industries Association (HIA), which is the oldest and largest 501(c)6 association dedicated to industrial hemp, including 596 members. Industrial hemp is defined in the American Agricultural Act of 2014, Section 7606 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." One-third of the HIA memberships identify in the cannabidiol (CBD) category as business stakeholders, CBD-dominant plant growers and CBD experts and advocates. The following response is submitted on behalf of our association to express that the naturally-occurring chemical CBD does not have the potential for abuse and is beneficial. Also, it is our review that despite the Drug Enforcement Administration's claims, hemp-derived CBD is not a controlled substance which has never been designated as such by an act of Congress.

Cannabidiol (CBD) is one of the naturally-occurring, non-psychoactive and non-intoxicating phytocannabinoids in industrial hemp and ought to be universally accessible to people of all ages with no international restrictions as CBD is not addictive, not harmful, nor does it have the potential for abuse.

Industrial hemp extracts rich in non-psychoactive cannabinoids are valuable ingredients for food and food supplements. Because it is naturally occurring in hemp, CBD has been consumed in one form or another for generations as nutritious food. With the discovery of the Endocannabinoid System (ECS) in the 1990s, it was also discovered that consuming naturally



occurring phytocannabinoids, especially CBD, has shown potential benefits to overall well being in a wide range of applications, improving quality of life through health and wellness.

(Hampson, A. J., Grimaldi, M., Axelrod, J., & Wink, D. (1998): Cannabidiol and (–) Δ9-tetrahydrocannabinol are neuroprotective antioxidants. Proceedings of the National Academy of Sciences, 95(14), 8268-8273.)

These include antioxidative, neuroprotective and anti-inflammatory effects.

(U.S. Patent #6630507 - <http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=/netahtml/PTO/srchnum.htm&r=1&f=G&l=50&s1=6630507.PN.&OS=PN/6630507&RS=PN/6630507>)

For example, CBD is a neuroprotective antioxidant more potent than ascorbate, also known as Vitamin C, or tocopherol, also known as Vitamin E.

(Hampson, A. J., Grimaldi, M., Axelrod, J., & Wink, D. (1998): Cannabidiol and (–) Δ9-tetrahydrocannabinol are neuroprotective antioxidants. Proceedings of the National Academy of Sciences, 95(14), 8268-8273)

Similarly to consuming Vitamin C and Vitamin C-rich foods in order to prevent illnesses like hypoascobemia, also known as scurvy, humans can safely consume phytocannabinoids as a nutritive preventative health measure for immune and neurological health.

The ECS is a group of endogenous cannabinoid receptors located in the mammalian brain and throughout the central and peripheral nervous systems, consisting of neuromodulatory lipids, or endocannabinoids, and their receptors. The ECS is involved in a variety of physiological processes including appetite, pain-sensation, mood, and memory, and in mediating the effects of the phytocannabinoids in cannabis, as they are metabolized similarly to the body's own endocannabinoids. The places where certain cannabinoid receptors are absent in the body are in the medulla oblongata and the brain stem. With the brainstem and medulla oblongata responsible for cardiovascular and respiratory functions, the lack of cannabinoid receptors on the medulla might suggest why there has never been a case of lethal overdose from consuming naturally occurring phytocannabinoids, regardless of the amount consumed or the method of consumption.



(Wolfgang Dostmann, PhD and Karen M. Lounsbury, PhD. The Science of Medical Cannabis. https://www.uvm.edu/medicine/documents/CMS_MedicalCannabis_Handout_060716.pdf)

The last couple of years have seen growing interest in CBD. Cannabidiol not only has a plethora of beneficial health effects, but it also has no relevant side effects, even when it is administered at high doses.

A comprehensive review on the safety and side effects of CBD shows that even very high doses of CBD are safe and well tolerated without significant side effects. In a total of 132 reviewed publications, CBD did not induce catalepsy; it did not affect factors such as heart rate, blood pressure, body temperature, gastrointestinal transit, nor did it alter psychomotor and cognitive functions.

(Bergamaschi, M. M., Queiroz, R. H. C., Zuardi, A. W. & Crippa, J. A. S. (2011): Safety and side effects of cannabidiol, a Cannabis sativa constituent. Current drug safety, 6(4), 237-249. Information on toxicological effects: IVN-MUS LD50: 50 mg/kg; IVN-DOG LD50: >254 mg/kg; IVN-MKY LD50: 212 mg/kg; ORL-MKY TDL: 27 gm/kg; ORL-MUS TDL: 750 mg/kg.)

Because of its inherent physiological safety, CBD is increasingly used as a food supplement and in food supplement compositions, and as an ingredient in cosmetics, thereby generating new investments and creating employment in the cultivation and processing of hemp and hemp-derived products.

In Colorado, one of the states in the U.S. with policy supportive of growing hemp as an agricultural product, manufacturers selling consumable hemp-derived CBD products in Denver are permitted by state law to source hemp from within and outside of Colorado, provided all parts of the hemp plant originate from a cultivator regulated under an "industrial hemp for consumption" program that applies safe consumption criteria.

In April 2017, Denver's Department of Environmental Health (DEH) published guidance regarding cannabidiol (CBD) products manufactured or sold in Denver. At that time, DEH also restricted the sale of hemp-derived CBD products originating from unregulated sources due to consumer safety concerns, including, but not limited to, accurate labeling, and toxin contamination of heavy metals, pesticides, molds, etc. in the concentrated products. However,



hemp-derived CBD manufacturers were still able to pursue approval to sell in Denver by submitting documentation demonstrating evidence of safe and standardized operations.

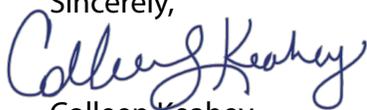
In July, the Colorado Department of Public Health and Environment (CDPHE) announced they will now accept wholesale food manufacturing registration applications for edible CBD product manufacturers. Approved manufacturers will be regulated under the Colorado Wholesale Manufacturing Food Regulations. CDPHE also indicated that hemp sourced from outside of Colorado is considered from an approved source provided all utilized parts of the hemp plant originate from a cultivator operating under a regulated industrial hemp program which applies safe consumption criteria. Since CDPHE's announcement, DEH has followed the same standards set by CDPHE.

(Colorado Department of Public Health and Environment. Update on Requirements for Hemp-Derived CBD Products Sold in Denver, September 1, 2017. https://www.colorado.gov/pacific/sites/default/files/DEHS_MfgFd_IndustrialHempPolicy_FY18.pdf)

With pharmaceutical products having CBD as an active ingredient being developed, the Hemp Industries Association urges the industry to not make any unwarranted health claims when using CBD-rich extracts or tinctures in food and food supplements.

The Hemp Industries Association is strictly opposed to the attempts by a few pharmaceutical companies to make CBD a prescription-only drug. The Hemp Industries Association asks that the FDA not privilege pharmaceutical company priorities at the expense of the U.S. domestic hemp agricultural sector and the cannabinoid nutraceutical industry worldwide in its recommendation to the World Health Organization regarding CBD.

Thank you for your review of this comment in consideration of cannabidiol (CBD).

Sincerely,

Colleen Keahey
Executive Director

