

# U.S. LEGAL & REGULATORY STATUS OF HEMP-DERIVED CBD EXPLAINED



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1995 ~ Upstate NY



2019 ~ Upstate NY





# 2014 FARM BILL AT-A-GLANCE

## Agricultural Pilot Program



***THIS WILL BE REPEALED AS OF 11/1/20***

# §7606 OF THE 2014 FARM BILL

## “Legitimacy of Industrial Hemp Research” (7 U.S.C. 5940)

|   |  |
|---|--|
| 698   | 699  |
| 1 SEC. 7606. LEGITIMACY OF INDUSTRIAL HEMP RESEARCH.        | 1 (B) in a manner that—                                    |
| 2 (a) IN GENERAL.—Notwithstanding the Controlled            | 2 (i) ensures that only institutions of                    |
| 3 Substances Act (21 U.S.C. 801 et seq.), the Safe and      | 3 higher education and State departments of                |
| 4 Drug-Free Schools and Communities Act (20 U.S.C. 7101     | 4 agriculture are used to grow or cultivate                |
| 5 et seq.), chapter 81 of title 41, United States Code, or  | 5 industrial hemp;   |
| 6 any other Federal law, an institution of higher education | 6 (ii) requires that sites used for grow-                  |
| 7 (as defined in section 101 of the Higher Education Act    | 7 ing or cultivating industrial hemp in a                  |
| 8 of 1965 (20 U.S.C. 1001)) or a State department of agri-  | 8 State be certified by, and registered with,              |
| 9 culture may grow or cultivate industrial hemp if—         | 9 the State department of agriculture; and                 |
| 10 (1) the industrial hemp is grown or cultivated           | 10 (iii) authorizes State departments of                   |
| 11 for purposes of research conducted under an agricul-     | 11 agriculture to promulgate regulations to                |
| 12 tural pilot program or other agricultural or academic    | 12 carry out the pilot program in the States               |
| 13 research; and  | 13 in accordance with the purposes of this                 |
| 14 (2) the growing or cultivating of industrial             | 14 section.  |
| 15 hemp is allowed under the laws of the State in which     | 15 (2) INDUSTRIAL HEMP.—The term “industrial               |
| 16 such institution of higher education or State depart-    | 16 hemp” means the plant <i>Cannabis sativa L.</i> and any |
| 17 ment of agriculture is located and such research oc-     | 17 part of such plant, whether growing or not, with a      |
| 18 curs.  | 18 delta-9 tetrahydrocannabinol concentration of not       |
| 19 (b) DEFINITIONS.—In this section:                        | 19 more than 0.3 percent on a dry weight basis.            |
| 20 (1) AGRICULTURAL PILOT PROGRAM.—The                      | 20 (3) STATE DEPARTMENT OF AGRICULTURE.—                   |
| 21 term “agricultural pilot program” means a pilot pro-     | 21 The term “State department of agriculture” means        |
| 22 gram to study the growth, cultivation, or marketing      | 22 the agency, commission, or department of a State        |
| 23 of industrial hemp—                                      | 23 government responsible for agriculture within the       |
| 24 (A) in States that permit the growth or                  | 24 State.  |
| 25 cultivation of industrial hemp under the laws of         |  |
| 26 the State; and   |  |

**Agricultural Act of 2014  
Signed into Law  
on Feb. 7, 2014**

**Gives broad authority  
to State Depts. of Ag.  
& Institutions of  
Higher Learning in  
States that permit the  
growth or cultivation of  
industrial hemp**



*THIS WILL BE REPEALED AS OF 11/1/20*

# §7606 OF THE FEDERAL FARM BILL

## Key Definitions

(1) AGRICULTURAL PILOT PROGRAM.—The term “agricultural pilot program” means a pilot program to study the growth, cultivation, or marketing of industrial hemp—

Includes “marketing” research, successfully interpreted in other states as “commerce”

(2) INDUSTRIAL HEMP.—The term “industrial hemp” means 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.

Historical distinction from marijuana; and no carve-out for “resins extracted therefrom” (unlike in the CSA!)





# 2018 FARM BILL AT-A-GLANCE

## Agricultural Commodity



# CONTROLLED SUBSTANCES ACT OF 1970

## *AMENDED* DEFINITION OF “MARIHUANA” (CIRCA 1/1/19)

21 U.S.C. §802(16)

(16)(A) Subject to subparagraph (B), the term “marihuana” means all parts of the plant *Cannabis sativa* L.[sic], 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.

(B) The term ‘marihuana’ does not include

- (i) hemp, as defined in section 297A of the Agricultural Marketing Act of 1946; or
- (ii) 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.

CONTROLLED SUBSTANCES ACT OF 1970  
*AMENDED* DEFINITION OF “TETRAHYDROCANNABINOLS”  
(CIRCA 1/1/19)

21 U.S.C. §812(c)(17)

(17) Tetrahydrocannabinols, except for tetrahydrocannabinols in hemp (section 297A of the Agricultural Marketing Act of 1946)



# NOW “HEMP” IS DEFINED IN §297A OF THE AGRICULTURAL MARKETING ACT OF 1946 (7 U.S.C. 1639)

(1) HEMP.—The term ‘hemp’ means the plant *Cannabis sativa* L. and any part of that plant, **including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers,** whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

# CERTAIN ADDITIONAL 2018 FARM BILL PROVISIONS

- Includes the Tribes (which were not specifically included in §7606 of the 2014 Farm Bill) defined as “Indian Tribes”
- Nothing in the act prohibits the interstate commerce of hemp, nor can States or Tribes prohibit the transportation of hemp or hemp products through their territory.

*USDA's Office of the General Counsel's 5/28/19 Legal Opinion on Certain Provisions of the Agriculture Improvement Act of 2018 Re Hemp: Applies to both 2014 & 2018 Farm Bills*

- Nothing in affects the FDA's authority under the FD&C Act or Public Health Service Act

<https://www.ams.usda.gov/sites/default/files/HempExecSumandLegalOpinion.pdf>



# HEMP-DERIVED CBD

## LET'S TALK ABOUT THE FDA!





# THE FDA'S *CANNABIS* AND *CANNABIS-DERIVED* PRODUCTS FAQ

## 9. Can THC or CBD products be sold as dietary supplements?

**ANSWER:** No. Based on available evidence, FDA has concluded that THC and CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B) of the FD&C Act [21 U.S.C. § 321(ff)(3)(B)]. Under that provision, if a substance (such as THC or CBD) is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. § 355], or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are excluded from the definition of a dietary supplement. FDA considers a substance to be “authorized for investigation as a new drug” if it is the subject of an Investigational New Drug application (IND) that has gone into effect. ...

<https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd>



# THE FDA'S *CANNABIS* AND *CANNABIS*-DERIVED PRODUCTS FAQ, CON'T.

## 9. Can THC or CBD products be sold as dietary supplements?

**ANSWER, con't.:** There is an exception to section 201(ff)(3)(B) if the substance was “marketed as” a dietary supplement or as a conventional food before the drug was approved or before the new drug investigations were authorized, as applicable. However, based on available evidence, FDA has concluded that this is not the case for THC or CBD.

...

# THE FDA'S *CANNABIS* AND *CANNABIS*-DERIVED PRODUCTS FAQ, CON'T.

10. Is it legal, in interstate commerce, to sell a food (including any animal food or feed) to which THC or CBD has been added?

- **ANSWER:** No. ...



# THE FDA'S *CANNABIS* AND *CANNABIS-DERIVED* PRODUCTS FAQ, CON'T.

14. Will FDA take action against cannabis or cannabis-related products that are in violation of the FD&C Act?

- **ANSWER:** The FDA has sent warning letters in the past to companies illegally selling CBD products that claimed to prevent, diagnose, treat, or cure serious diseases, such as cancer. Some of these products were in further violation of the FD&C Act because they were marketed as dietary supplements or because they involved the addition of CBD to food.

When a product is in violation of the FD&C Act, FDA considers many factors in deciding whether or not to initiate an enforcement action. Those factors include, among other things, agency resources and the threat to the public health. FDA also may consult with its federal and state partners in making decisions about whether to initiate a federal enforcement action.

<https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd>



# THE FDA HAS ISSUED 53 WARNING LETTERS SINCE FEBRUARY OF 2015

- Misbranded / Misleading / Unapproved New Drug / Dietary Supplement / Labeling / Adulterated / Cannabidiol / Unapproved New Animal Drug
  - ✓ COVID-19, Opioid Addiction
- cGMP Violations
- (Circa 2019) Co-Authored with the Federal Trade Commission, Division of Advertising Practices



<https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products>

# THE FDA'S GUIDANCE IS GUIDANCE IT'S *NOT* THE LAW

In the primary industry coalition's informed opinion, the FDA's guidance stating that CBD may not be marketed as a dietary supplement or food is inaccurate, has never been determined by the courts to be valid, and is neither final nor legally binding. Neither the FDA statements (Press Release or Congressional testimony or otherwise), nor its "Questions & Answers" Page, nor the mere 53 Warning Letters issued by the FDA since February 2015 are final agency actions or determinations.



# FDA'S REQUEST FOR PUBLIC COMMENTS

## Scientific Data and Information About Products Containing *Cannabis* or *Cannabis*-Derived Compounds

2/27/19 FDA Testimony before a Congressional Committee on 2/27/19:

- *“We heard Congress loud and clear...Congress wants there to be a pathway for CBD to be available.”*

2/26/20 FDA Commissioner's Address to the Nat'l Association of State Depts. of Ag (NASDA):

- *“People are using these [CBD] products. We're not going to be able to say, ‘You can't use these products,’ because . . . even if you did, it's a fools' game to even try to approach that. But what do we need to do? We need to fill the information gaps.”*

That rulemaking procedure commenced on 4/3/19 and originally ended on 7/16/19 with a public hearing on 5/31/19. On 3/11/20, the FDA extended this public comment period indefinitely. The entirety of the process could take two to three to five years. There are also Congressional legislative fixes available to us.

In the meantime, we do not foresee enforcement actions against compliant companies.

<https://www.federalregister.gov/documents/2020/03/11/2020-04919/scientific-data-and-information-about-products-containing-cannabis-or-cannabis-derived-compounds>



# QUESTIONS FDA WANTS ANSWERED ~ SHARED RESPONSIBILITY

1. What happens if you use CBD daily for sustained periods of time?
2. What level of intake triggers the known risks associated with CBD?
3. How do different methods of exposure affect intake (*e.g.*, oral consumption, topical, smoking or vaping)?
4. What is the effect of CBD on the developing brain (such as children who take CBD)?
5. What are the effects of CBD on an unborn child or breastfed newborn?
6. How does CBD interact with herbs and botanicals?
7. Does CBD cause male reproductive toxicity in humans, as has been reported in studies of animals?
8. Are there differing safety concerns for use in certain animal species, breeds, or classes?
9. Are any residues formed in edible tissues of food producing animals?

# WHO EXPERT COMMITTEE ON DRUG DEPENDENCE REPORTS: SAFE!

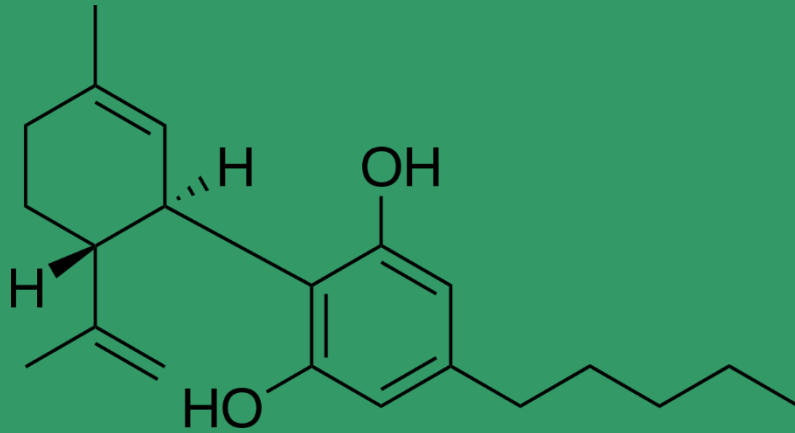
## According to the World Health Organization's June 2018 Critical Review:

- CBD is generally well tolerated with a good safety profile
- In humans, CBD exhibits no effects indicative of any abuse or dependency potential
- To date there is no evidence of recreational use of CBD or any public health-related problems associated with the use of pure CBD





# OVERVIEW OF THE REGULATORY LANDSCAPE OF HEMP-DERIVED CBD ACROSS THE STATES



In General:

- Dotted green lights across the U.S. w/ Intrastate contradictions as to legal status
- Federally legal, but still not legal in all 50 states
- Varying testing and labeling laws/regs
- Varying allowable THC concentrations
- Varying product registration laws/regs
- Varying licensing & registration laws/regs



# HOW CAN YOU HELP?

Become a Hemp Supporter!

Go to [www.HempSupporter.com](http://www.HempSupporter.com) and sign up for the U.S. Hemp Roundtable's Calls to Action and updates by clicking the "Join" button in the upper right-hand corner.

Become a member ~ we're leading the way forward!

*Join Today!*  
U.S. Hemp  
Roundtable



# REFERENCE MATERIALS IN THE DIGITAL SWAG BAG



- This Presentation
- Hemp Ace International Memo Re FDA Warning Letters
- 2014 Farm Bill Hemp Provisions  
(Agricultural Act of 2014)
- 2018 Farm Bill Hemp Provisions  
(Agriculture Improvement Act of 2018)
- June 2018 World Health Organization's  
Cannabidiol (CBD) Critical Review Report
- May 2019 USDA General Counsel's Legal Opinion Re  
Certain 2018 Farm Bill Hemp Provisions
- March 2020 FDA CBD Report to Congressional  
Appropriations Committees
- July 2020 FDA CBD Report to Congressional  
Appropriations Committees

THANK YOU FOR LISTENING  
AND ENJOY THE REST OF THE TRADE SHOW!

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