# CBD IN FOOD & BEVERAGES

*Government Regulation and Related Issues*

**SupplySide® WEST**
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**Todd Halpern**
Partner
Venable, LLP

thhalpern@venable.com
202.344.4152

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# CANNABIDIOL (CBD)

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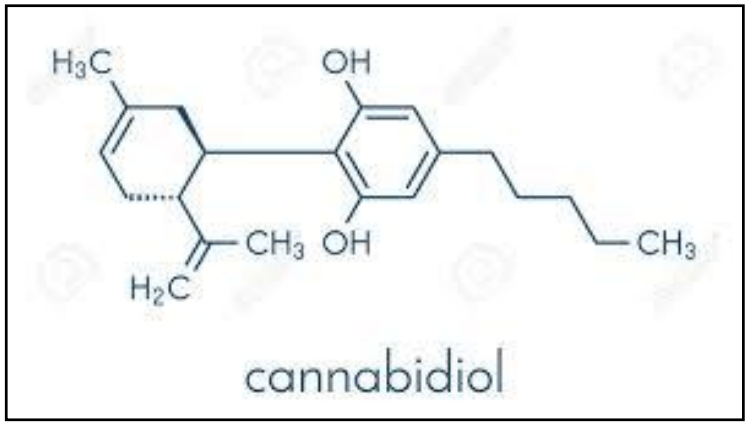
# Cannabidiol (CBD)


- One of more than 100 cannabinoids naturally found in cannabis plants
- Can be extracted from cannabis plants that are "marijuana" or "hemp"
  - *Can also be produced synthetically*
- No evidence that CBD is likely to cause THC-like psychoactive effects

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# REGULATORY OVERVIEW

# Federal

FOOD AND DRUG ADMINISTRATION (FDA)

DEPARTMENT OF AGRICULTURE (USDA)

DRUG ENFORCEMENT ADMINISTRATION (DEA)

FEDERAL TRADE COMMISSION (FTC)

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# State

ATTORNEY GENERAL

DEPARTMENT OF HEALTH

DEPARTMENT OF AGRICULTURE

BOARD OF PHARMACY

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# DRUG ENFORCEMENT ADMINISTRATION (DEA)

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# Controlled Substances Act (DEA)
# Schedule I

Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following hallucinogenic substances, or which contains any of their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation…

(23) Marihuana…

(31) Tetrahydrocannabinols

# Controlled Substances Act (DEA)
# "Marihuana"

"… all parts of the plant *Cannabis sativa L.*, 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. Such term does not include 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."

21 U.S.C. § 802(16)

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# Agriculture Improvement Act of 2018 ("Farm Bill")

Amended CSA Definition of Marijuana to exclude "Hemp":

- 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.

# FOOD AND DRUG ADMINISTRATION (FDA)

# Food, Drug, and Cosmetic Act

*Dietary Supplement - Exclusionary Clause of Definition (21 U.S.C. § 321 (ff)(3)(B))*

- Definition of Dietary Supplement does not include "an article":
  - Approved as a new drug, antibiotic, or licensed biologic; or
  - Authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public; and

  which was not before such approval or investigation…marketed as a dietary supplement or as a food…"

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# Food, Drug, and Cosmetic Act

## *Food – Prohibited Act* *(21 U.S.C. § 331 (ll)(3)(B))*

- Prohibits introduction (or delivery for introduction) into interstate commerce of any food to which has been added an approved drug, a licensed biological product, or a drug/biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, **unless**:
  - Such drug/biological product was marketed in food before approval, licensure, and any substantial clinical investigations have been instituted; or
  - FDA has issued a regulation, pursuant to a notice and comment rulemaking, approving the use of such drug/biological product in the food.

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# FDA Enforcement

Although you market "Everyday Dietary Supplement," "Everyday Plus Dietary Supplement," and "Everyday Advanced Dietary Supplement" as dietary supplements, FDA has concluded based on available evidence that CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(ii) of the Act [21 U.S.C. § 321(ff)(3)(B)(ii)]. Under that provision, if an article (such as CBD) 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 outside the definition of a dietary supplement. There is an exception if the substance was "marketed as" a dietary supplement or as a conventional food before the new drug investigations were authorized; however, based on available evidence, FDA has concluded that this is not the case for CBD.

The existence of substantial clinical investigations regarding CBD has been made public. For example, two such substantial clinical investigations include GW Pharmaceuticals' investigations regarding Sativex and Epidiolex[1] Under FDA's regulations [21 CFR § 312.2], unless a clinical investigation meets the limited criteria in that regulation, an IND is required for all clinical investigations of products that are subject to section 505 of the Act. FDA is not aware of any evidence that would call into question its current conclusion that CBD products are excluded from the dietary supplement definition under section 201(ff)(3)(B)(ii) of the Act, but you may present FDA with any evidence that has bearing on this issue. . 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.

# Risk Factors

1. **Claims**

   Warning letters to CBD manufacturers have included egregious disease claims, e.g., “anti-tumor” and causes “cancer cells to commit suicide”, and “arthritis relief.”

2. **Dosage Form**

   Dietary supplements cannot be marketed as conventional food and must be ingested.

3. **Manufacturing Operations**

   Current Good Manufacturing Practices

4. **Importation**

   FDA review and potential detention at border.

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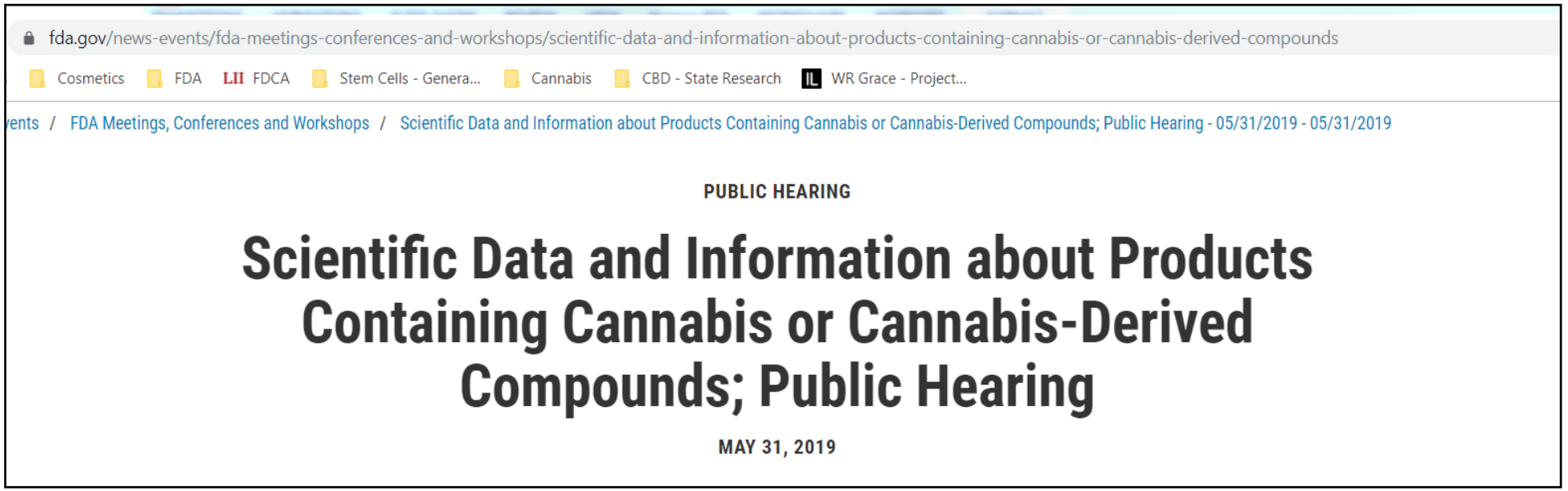
# FDA Actions

- Guidance Document: FDA and Marijuana: Questions and Answers
  - "Can products that contain THC or cannabidiol (CBD) be sold as dietary supplements?"
  - FDA Response: "No." (Citing dietary supplement definition - exclusionary clause)
- FDA Drug Approval: Epidiolex
- June 25, 2018: FDA approved the first CBD-derived drug, Epidiolex, for the treatment of seizures associated with Lennox-Gastaut syndrome and Dravet syndrome.
- FDA Commissioner Gottlieb emphasized the importance of the drug approval process for "other product developers who want to bring forth marijuana-derived products through appropriate drug development programs." See Press Announcement.

# FDA Public Hearing (May 31, 2019)




**Focus:**

- ✓ Health and safety risks
- ✓ Manufacturing and product quality
- ✓ Marketing/labeling/sales

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# LEGISLATION

# Senator Mitch McConnell: Bill Amendment to Compel FDA to Issue CBD Enforcement Discretion Policy

9/23/2019 Senator McConnell Advances Kentucky Hemp Priorities - Press Releases - U.S. Senator Mitch McConnell

Majority Leader
**Mitch McConnell**
U.S. Senator for Kentucky

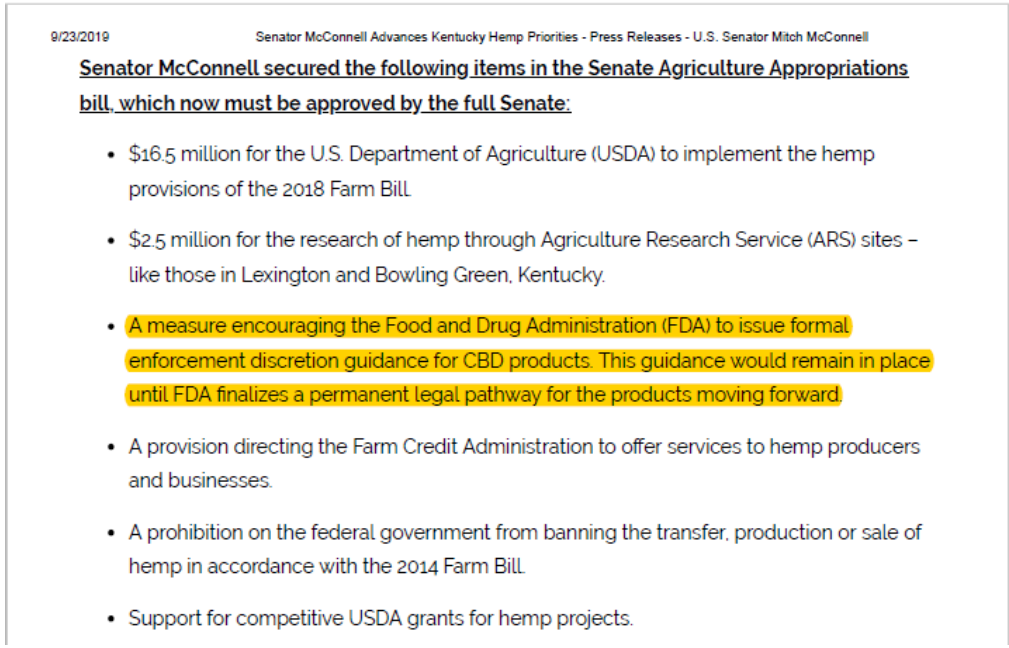
## Press Releases

### Senator McConnell Advances Kentucky Hemp Priorities

**'Hemp farmers, processors and manufacturers are exploring the crop's great potential, and I'm proud to work with them every step of the way'**

September 19, 2019

**WASHINGTON, D.C.** – U.S. Senate Majority Leader Mitch McConnell (R-KY) announced several important provisions in the Senate Agriculture Appropriations bill that will benefit Kentucky's growing hemp industry. Senator McConnell, a senior member of the Senate Appropriations and Agriculture Committees, secured nearly $20 million to implement the hemp provisions in the 2018 Farm Bill as well as to support federal research of hemp.



9/23/2019 Senator McConnell Advances Kentucky Hemp Priorities - Press Releases - U.S. Senator Mitch McConnell

**Senator McConnell secured the following items in the Senate Agriculture Appropriations bill, which now must be approved by the full Senate:**

- $16.5 million for the U.S. Department of Agriculture (USDA) to implement the hemp provisions of the 2018 Farm Bill.
- $2.5 million for the research of hemp through Agriculture Research Service (ARS) sites – like those in Lexington and Bowling Green, Kentucky.
- A measure encouraging the Food and Drug Administration (FDA) to issue formal enforcement discretion guidance for CBD products. This guidance would remain in place until FDA finalizes a permanent legal pathway for the products moving forward.
- A provision directing the Farm Credit Administration to offer services to hemp producers and businesses.
- A prohibition on the federal government from banning the transfer, production or sale of hemp in accordance with the 2014 Farm Bill.
- Support for competitive USDA grants for hemp projects.

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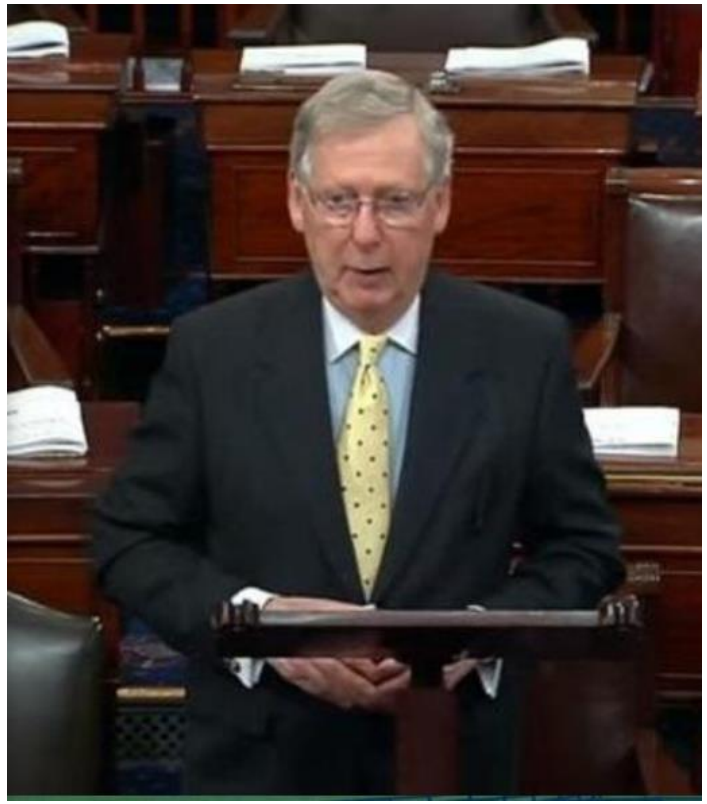
# Senator Mitch McConnell: Bill Amendment to Compel FDA to Issue CBD Enforcement Discretion Policy



As previously mentioned, the Committee provides $2,000,000 for research, policy evaluation, market surveillance, issuance of an enforcement discretion policy, and appropriate regulatory activities with respect to products under the jurisdiction of the Food and Drug Administration which contain cannabidiol (CBD) and meet the definition of hemp, as set forth in section 297A of the Agricultural Marketing Act of 1946 (7 U.S.C. 1639o). Within 90 days, FDA shall provide the Committee with a report regarding the Agency's progress toward obtaining and analyzing data to help determine a policy of enforcement discretion, and the process in which CBD meeting the definition of hemp will be evaluated for use in products. Within 120 days, FDA shall issue a policy of enforcement discretion with regard to certain products containing CBD meeting the definition of hemp as defined by section 297A of the Agricultural Marketing Act of 1964 (7 U.S.C. 1639). Such enforcement discretion shall be in effect until FDA establishes a process for stakeholders to notify FDA for use of CBD in products that include safety studies for intended use per product, and makes a determination about such product. FDA is encouraged to consider existing and ongoing medical research related to CBD that is being undertaken pursuant to an Investigation New Drug (IND) application in the development of a regulatory pathway for CBD in products under the jurisdiction of FDA and to ensure that any future regulatory activity does not discourage the development of new drugs.

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# Questions?

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