CBD Update

September 10, 2021

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Cannabis sativa

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Cannabis Sativa

- Hemp and marijuana come from the same plant
- Distinction used to be parts of the plant
- Now, typically the main distinction is the level of THC with the dividing line .3% THC
  - Terpenes
  - Cannabinoids
    - CBD
    - CBN
    - CNC
    - THC

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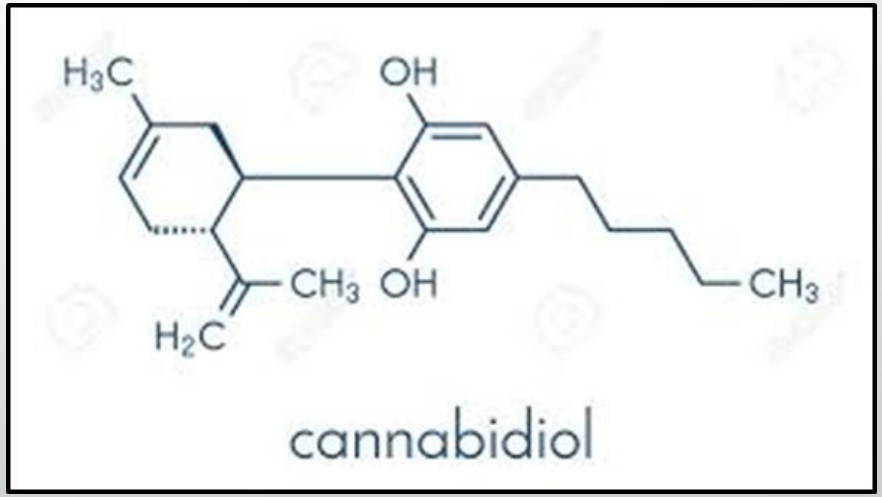
Cannabidiol (CBD)

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



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REGULATORY OVERVIEW

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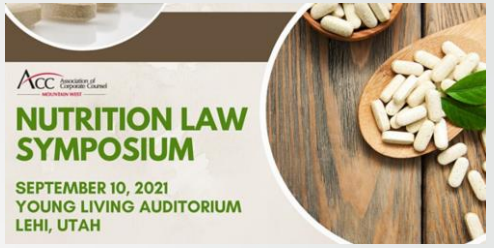
Federal Agencies



DEA
U.S. DRUG ENFORCEMENT ADMINISTRATION

USDA United States Department of Agriculture

Federal Trade Commission
Protecting America's Consumers

FDA

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Drug Enforcement Agency (DEA)

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DEA Enforcement

- DEA enforces the Federal Controlled Substances Act
- 21 uSC 812 lists the substances that are Schedule I controlled substances as follows:

  "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…

DEA Enforcement

"… 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 USC 802(16)

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2018 FARM BILL

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

- 2018 Farm Bill, among other things, defines "hemp" as:

  "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"

- Key difference is that the plant part doesn't matter – the distinction is the level of THC

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US Dept. of Ag. (USDA)

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USDA Regulation

- Pursuant to the 2018 Farm Bill, USDA must submit state and tribal land hemp programs for approval
- USDA announced Interim Rule on October 29, 2019 entitled "Establishment of a Domestic Hemp Production Program" – immediately in effect
- Farmers must be authorized under a state or tribal hemp program
- 2018 Farm Bill prohibits interference with interstate transports of legal hemp; USDA issued legal memo reaffirming this

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Federal Trade Commission (FTC)

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FTC Enforcement

- FTC regulates all advertising under the Truth in Advertising Laws
- All advertising must be:
  - Truthful and not misleading
  - Not unfair
  - Substantiated
- FTC has issued joint warning letters with the FDA to companies selling products with CBD and hemp, asserting companies did not have substantiation for claims

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Food and Drug Administration (FDA)

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FDA Regulation

- The FDA enforces the Federal Food, Drug and Cosmetic Act
- There is currently no law or regulation that specifically address the use of hemp and/or CBD in FDA-regulated products
- FDA has taken the position that CBD is excluded from use in a food, beverage, or supplement due to certain provisions of the Food, Drug, and Cosmetic Act

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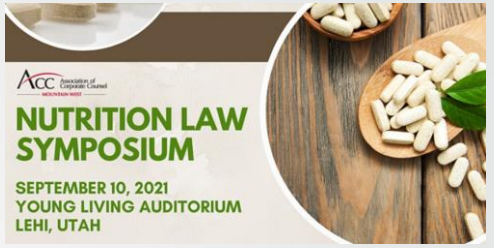
FDA Regulation

- Dietary Supplement Exclusionary Clause in 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…."

FDA Regulation

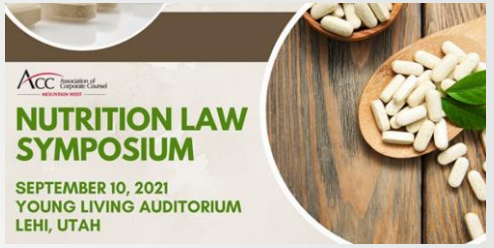


- Food Exclusionary Clause in Prohibited Acts (21 U.S.C. § 331 (ll)(3)(B))
- Prohibits introduction (or delivery for introduction) into interstate commerce of any food to which has been added an approved drug, a licensed biological product, or a drug/biological product for which substantial clinical 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

FDA Enforcement

- FDA has issued 30-35 warning letters to companies selling products with hemp and/or CBD
- In almost every case, the company was making express disease claims in addition to using CBD and/or hemp
- An example of the language from such letters is the following:

> 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.



FDA Enforcement

- **Claims**

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

- **Safety**
- **Manufacturing Operations**

  Current Good Manufacturing Practices

- **Importation**

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FDA Regulation and Enforcement

- Guidance Document: FDA and Marijuana: Questions and Answers
- May 31, 2019 Hearing
- FDA Task Force
- 2019 guidance regarding Pregnancy and Breast Feeding with CBD was last guidance from FDA

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Supplement vs. Food/Beverage

- What is the right way to sell products with CBD and hemp? Supplement or food/beverage?
- Factors to consider
  - Ingredients
  - Manufacturing
  - Labeling
  - Claims
  - Location on Shelf

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Dietary Supplements

- Ingredients must be dietary ingredients
  - Vitamin
  - Mineral
  - Amino acid
  - Herb or other botanical
  - Extractive, constituent, or metabolite of one of the above
  - Dietary substance used to increase the total dietary intake
- Must notify FDA of New Dietary Ingredients (NDIs)
- Manufactured pursuant to dietary supplement GMPs (21 CFR Part 111)
- May not be represented for use as a conventional food/beverage

Dietary Supplements

- Supplement Facts Panel
  - Only nutrients in amounts above zero
  - Declare the plant parts of any botanical ingredient
  - All dietary ingredients declared in the Supplement
- Dietary Supplement Disclaimer

***These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.**

Supplement Facts

Serving Size 1 tsp (3g) (makes 8 fl oz prepared)
Servings Per Container 24

	Amount Per Teaspoon	% Daily Value
Calories	10	
Total Carbohydrate	2 g	<1%*
Total Sugars	2 g	†
Includes 2g Added Sugars		4%*
Proprietary Blend	0.7 g	
German Chamomile (flower)		†
Hyssop (leaf)		†

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily Value not established.

Other ingredients: Fructose, lactose, starch, and stearic acid.

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Conventional Food / Beverages

- Ingredients must be approved food additives or GRAS
  - Food additive or GRAS by regulation
  - GRAS by common use in food prior to January 1, 1958
  - Self-affirmed GRAS
- RACC / serving size for liquids must be 8 or 12 fl oz
- No RACC / serving size for tablets or drops (tinctures)
- Manufactured pursuant to FSMA (21 CFR Part 117)

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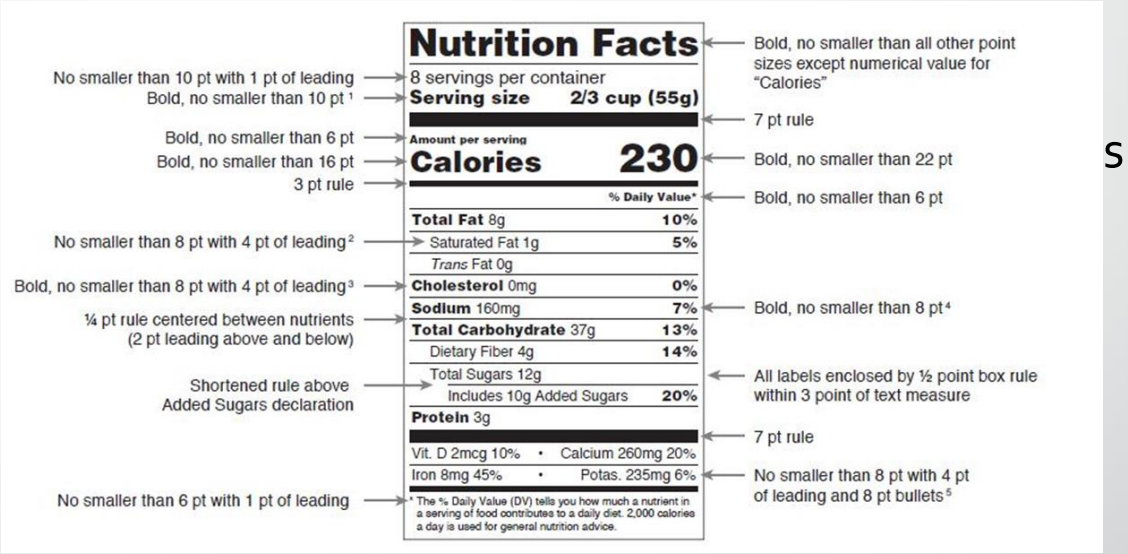
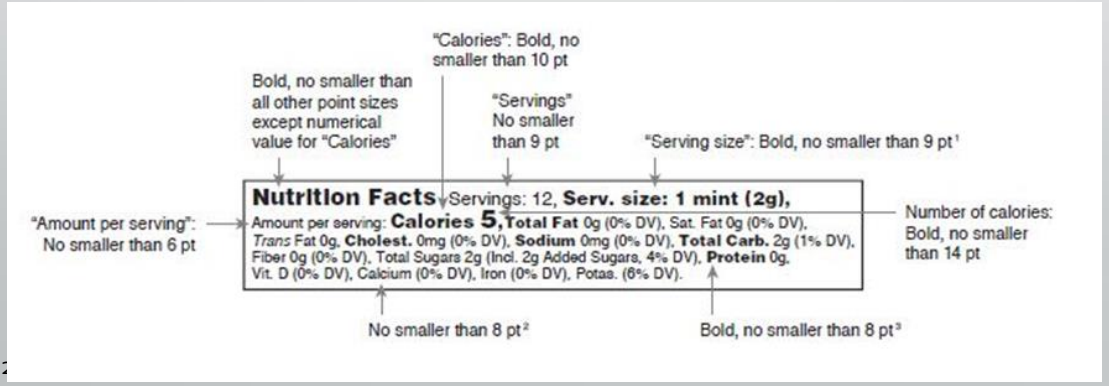
Conventional Food / Beverages

- Nutrition Facts Panel
  - Calories, Total Fat, Sodium, Total required
  - New NFP by January 1, 2020 or depending on total
- Modified panels for small and intermediate packages





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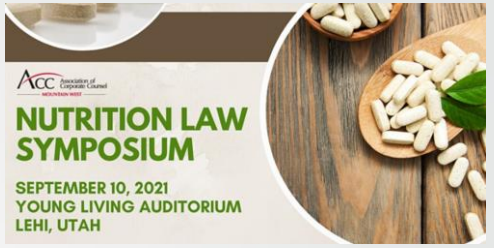
Topicals

- Topicals may only be sold as cosmetics or drugs
- Cosmetics may only be sold to:
  - Cleanse
  - Beautify
  - Promote attractiveness
  - Alter the appearance of the skin
- Claims to treat anxiety and stress, sleep, pain and inflammation, make topical products drugs
- OTC drugs have specified active ingredients; declaring ingredients as inactives doesn't make them inactive if they are promoted for benefits. FDA issued March 2021 warning letters on this subject



Litigation Risks

- Disease claims
- "All Natural"
- "Rich in" and "High in" claims, such as
- "THC free" claims
- No positive drug tests claims
- Testing to levels declared on labels
- FOP label claims
  - CBD or hemp
  - "Per container" or "per serving"

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QUESTIONS AND ANSWERS

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