

Using Hemp and Hemp Derivatives in Alcohol Beverages

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Agenda

- Cannabis/marijuana/hemp
- Federal laws
- TTB policies
- Ingredients of interest
- Questions



TTB Disclaimer

- This information is being presented to help the public to understand and comply with the laws and regulations that the Alcohol and Tobacco Tax and Trade Bureau (TTB) administers
- It is not intended to establish any new, or change any existing, definitions, interpretations, standards, or procedures regarding those laws and regulations
- In addition, this presentation may be made obsolete by changes in laws and regulations
- Please consult the applicable laws and regulations for the most current requirements
- TTB defers to other Federal agencies (such as the Drug Enforcement Administration, the U.S. Food and Drug Administration, and the U.S. Department of Agriculture) with regard to their interpretation of the laws and regulations enforced by those agencies



What is TTB's Role with Regard to Hemp?

- [TTB Industry Circular 2019-1](#) was published April 25, 2019, in response to numerous inquiries from industry members about whether they may add hemp ingredients, including CBD, to alcohol beverages
- In setting forth its policy, TTB consulted with other Federal agencies that enforce Federal laws regarding hemp and marijuana, including FDA, DEA, and USDA
- In order to explain TTB's policy, this presentation provides some general background about those other Federal laws. TTB of course defers to those agencies in their interpretations of the laws they enforce



Poll Question: What is the Difference between Marijuana and Hemp?

- A) They are different parts of the cannabis plant
- B) The level of THC content
- C) They are completely different strains of cannabis
- D) It's confusing— please explain!



Cannabis

- Cannabis is a plant of the Cannabaceae family and contains more than eighty biologically active chemical compounds*
- The most commonly known compounds are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD)*
- Parts of the *Cannabis sativa* plant have been controlled under the Controlled Substances Act (CSA) since 1970 under the drug class "Marihuana" (commonly referred to as "marijuana") [21 U.S.C. 802(16)]

* From FDA's webpage: What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD



Marijuana: Controlled Substances Act

- **Statutory Authority:** The “Controlled Substances Act” (CSA), 21 U.S.C. Chapter 13
- **Federal Agency:** Drug Enforcement Administration (DEA)
- **Definition (21 U.S.C. 802 (16)):**
 - (A) Subject to subparagraph (B), the term “marihuana” means 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.
 - (B) The term “marihuana” does not include--
 - (i) hemp, as defined in [section 1639o of Title 7](#); 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.



Hemp: 2018 Farm Bill

- **Statutory Authority:** The Agriculture Improvement Act of 2018 (the 2018 Farm Bill), 7 U.S.C. Chapter 38
- **Federal Agency:** U.S. Department of Agriculture
- **Definition (7 U.S.C. 1639o):**
 - 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
- The law explicitly preserved FDA’s authority to regulate products containing cannabis or cannabis-derived compounds under the Federal Food, Drug and Cosmetic Act (FD&C Act)



Federal Food, Drug, and Cosmetic Act

- **Statutory Authority:** Federal Food, Drug, and Cosmetic Act (FD&C Act) 21 U.S.C. Chapter 9
- **Federal Agency:** U.S. Food and Drug Administration (FDA)
- Among other provisions relating to food safety are the [GRAS provisions](#):
 - Any substance intentionally added to food (including alcohol beverages) is a food additive, and therefore subject to premarket review and approval by FDA, unless the substance is generally recognized as safe (GRAS)
 - Aside from three hemp seed ingredients (hulled hemp seed, hemp seed protein powder, hemp seed oil) no other cannabis-derived ingredients have been the subject of a food additive petition, an evaluated GRAS notification, or have otherwise been approved for use in food by FDA
- [Section 301\(II\)](#) of the FD&C Act: With limited exceptions, it is prohibited to introduce or deliver for introduction into interstate commerce any food to which has been added a substance which is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act, or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public



2000 Hemp Policy

- A report of laboratory analysis (THC content) of the hemp component should be submitted with formula applications
- When drafted, “hemp” referred to the parts of the cannabis plant excluded from the definition of marijuana in the Controlled Substances Act (CSA), 21 U.S.C. Section 802(16) (such as sterilized seeds and seed oil)
- Finished product may not contain a controlled substance (e.g., marijuana)
- TTB regulations require formula approval for alcohol beverages to which certain ingredients have been added, even if the product is sold only intrastate



TTB Industry Circular 2019-1

[TTB Industry Circular 2019-1](#) was published April 25, 2019, in response to numerous inquiries from industry members about whether they may add hemp ingredients, including CBD, to alcohol beverages, after passage of the 2018 Farm Bill

Key provisions:

- It remains TTB policy not to approve any formulas for alcohol beverages that contain ingredients that are controlled substances under the CSA. In determining whether an ingredient is a controlled substance, TTB will continue to consult with the Drug Enforcement Administration (DEA) where appropriate.
- Even if an ingredient derived from cannabis is not a controlled substance because it meets the new definition of “hemp,” TTB continues to consult with the U.S. Food and Drug Administration (FDA), to determine if the use of hemp ingredients would violate the Federal Food, Drug, and Cosmetic Act (FD&C Act). FDA has issued public statements explaining why some “hemp” ingredients are not permitted in food under the FD&C Act, which FDA administers.



FDA Website: “FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)”

- Among other things, the Questions and Answers note that it is unlawful under section 301(l) of the FD&C Act to introduce or deliver for introduction into interstate commerce any food to which CBD or THC has been added
- Ingredients that are derived from parts of the cannabis plant that do not contain THC or CBD might fall outside the scope of section 301(l) of the FD&C Act, and therefore might be able to be added to food
- However, FDA stressed that food companies that wish to use cannabis or cannabis-derived ingredients in their foods are subject to the relevant laws and regulations that govern all food products, including those that relate to the requirements for food additive approval and substantiation of evidence for Generally Recognized as Safe (GRAS) status



TTB Review of Formulas

- TTB will continue to process applications for formulas for alcohol beverages that contain ingredients derived from hemp seeds or hemp seed oil
- After consultation with FDA, TTB announced it will return for correction any applications for formulas containing hemp ingredients (other than ingredients derived from hemp seeds or hemp seed oil)
- Applicants will have the option of resubmitting the formula to TTB upon receipt of a favorable individual determination from FDA on the regulatory status of their ingredients



THC

THC (Tetrahydrocannabinol):

- An active ingredient in cannabis
- Has psychoactive effects; THC is the component that produces the “high” associated with marijuana use
- Controlled substance
 - Listed separately as a Schedule 1 drug in the CSA
- Section 301(ii) of the FD&C Act
 - FDA stated that it is unlawful under the FD&C Act to introduce into interstate commerce any food to which THC has been added



CBD

CBD (Cannabidiol):

- An active ingredient in cannabis
- After enactment of the 2018 Farm Bill, FDA stated that it is unlawful under the FD&C Act to introduce into interstate commerce any food to which CBD has been added (FD&C Act Section 301(l))
 - [See also: FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol \(CBD\)](#)



CBD – FDA Webpage

While noting that there is interest in the potential health effects of CBD, the FDA webpage states as follows:

- It is currently illegal to market CBD by adding it to a food or labeling it as a dietary supplement
- The FDA has seen only limited data about CBD safety and these data point to real risks that need to be considered before taking CBD for any reason
- Some CBD products are being marketed with unproven medical claims and are of unknown quality



Terpenes and Botanical Extracts

- “Terpene” refers to a class of organic chemical compounds that may be sourced from plants or synthesized in a laboratory
- FDA has issued regulations that authorize individual synthetic terpenes for use in food (see, *e.g.*, 21 CFR 182.60)
- Many forms of botanical extracts are authorized for use in food in specific FDA regulations; botanical extracts from cannabis (hemp) are not included in these regulations
- FDA has advised that alcohol beverage industry members interested in using botanical extracts containing mixtures of terpenes sourced from hemp, or any other plant, should consider submitting a GRAS notice



Poll Question: Would hemp leaves be an allowable ingredient in a TTB-approved formula?

- A) Yes
- B) No**
- C) It's complicated- please explain!