



HEMP and CBD REGULATORY FACT SHEET

Terminology

<i>Cannabis</i>	any part of the plant <i>Cannabis sativa</i> L as a federal designation, many states and countries refer to marijuana as cannabis; includes both hemp and marijuana
<i>Marijuana</i>	cannabis with THC content above 0.3%
<i>Hemp</i>	cannabis with THC content less than 0.3%
<i>Industrial Hemp</i>	Hemp grown for fiber; non-food uses only
<i>Cannabinoids</i>	related compounds (100+) in the cannabis plant, including CBD and THC; primarily in the flowering tops; absent in seeds
<i>CBD</i> <i>(Cannabidiol)</i>	the active therapeutic substance of Epidiolex (FDA-approved pediatric epileptic drug)
<i>THC</i> <i>(Tetrahydrocannabinol)</i>	the cannabinoid responsible for psychotropic effects

Lawful Food and Dietary Supplement Ingredients

1. Ingredients prohibited as Class I Controlled Substances

- Any part of the Cannabis plant, including all derivatives, extracts, cannabinoids, isomers, and salts with a THC concentration MORE than 0.3 percent on a dry weight basis.

2. Ingredients NOT prohibited as Class I Controlled Substances

- Any part of the Cannabis plant, including all derivatives, extracts, cannabinoids, isomers, and salts with a THC concentration LESS than 0.3 percent on a dry weight basis.
- Sterilized Cannabis seed, and substances derived from seeds.
- Mature Cannabis stalks, and fiber produced from stalks.

3. Substances that can be used as conventional food ingredients

- Hemp-derived substances that have Generally Recognized as Safe (GRAS) food ingredient uses.
- FDA has issued *No Objection* letters on three hemp seed GRAS notifications – Hemp Seed Protein (GRN 771), Dehulled Hemp Seed (GRN 765) and Hemp Seed Oil (GRN 778).
- There is a history of self-determined GRAS hemp seed-derived substances (e.g., hemp seed protein, hemp seed oil) being marketed as food ingredients in the U.S.

4. Substances that can be used as dietary supplement ingredients

- Hemp-derived substances (other than CBD – see #5 below).
- No hemp-derived substance has a history of dietary ingredient use pre-dating October 1994; therefore, all hemp-derived dietary ingredients are *New Dietary Ingredients* (NDIs). Manufacturers of NDI-containing dietary supplements must submit an NDI safety Notification to FDA at least 75-days prior to first marketing the NDI-containing dietary supplement.
- A hemp seed derived NDI that is currently in the human diet as a lawful food ingredient is exempt from the NDI notification requirement.

5. CBD is a prohibited food and dietary supplement ingredient.

- CBD is the active ingredient in an FDA-approved drug and was the subject of substantial clinical investigations before being marketed as food or dietary supplements. Under the FD&C Act it is illegal to introduce drug ingredients, like CBD, into the food supply, or to market them as dietary supplements.
- The 12/20/2018 FDA Commissioner statement on the 2018 Farm Bill specifically highlighted that it is unlawful under the FD&C Act to market a food or dietary supplement containing added CBD (see below).
- It is not yet clear whether FDA will make a distinction between added CBD and native CBD in a hemp product.
- It is clear that FDA will object to any food or dietary supplement product that (1) identifies as being CBD, or (2) calls out its CBD content, or (3) has been processed to increase CBD content, or (4) is derived from a hemp strain specifically bred or selected for its greater CBD content, or (5) makes any claims about CBD effects.
- Some manufacturers assert that processing of hemp to extract all the native cannabinoid compounds without proportionally increasing CBD content of the cannabinoid extract does not constitute an added CBD ingredient; and thus, such cannabinoid extracts are different from the FDA approved active drug ingredient CBD. Typically, the manufacturers identify these hemp-derived extracts as *Full Spectrum Cannabinoid Extracts*.

- FDA has yet to take a position as to whether Full Spectrum Cannabinoid Extracts confer a safe harbor from the prohibition of added CBD ingredients in food and dietary supplements. If FDA comes to view the use of *Full Spectrum Cannabinoid Extracts* as a maneuver to circumvent drug regulations, FDA is likely to act to prohibit use of such ingredients in food and dietary supplements.

Agriculture Improvement Act of 2018 (the 2018 Farm Bill)

The 2018 Farm Bill includes several items that provide for new marketing opportunities for hemp by moving it out of Drug Enforcement Agency jurisdiction. With respect to hemp, the 2018 Farm Bill did the following:

- Created a definition for *hemp*; and excluded hemp from the Controlled Substances Act from the definition of marijuana. The result is that hemp is not a controlled substance.
- Established a system for state government regulation and monitoring of hemp cultivation.
- The 2018 Farm Bill provisions to legalize hemp production explicitly do nothing to affect or modify the FDA authority to regulate food and drugs under the Food, Drug, and Cosmetic Act (i.e., the 2018 Farm Bill did not legalize use of CBD as a food or dietary supplement ingredient).

The following is a quote from the Statement from FDA Commissioner Scott Gottlieb, M.D., on the Agriculture Improvement Act and the agency's regulation of products containing cannabis and cannabis-derived compounds

..... Additionally, it's unlawful under the FD&C Act to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements, regardless of whether the substances are hemp-derived. This is because both CBD and THC are active ingredients in FDA-approved drugs and were the subject of substantial clinical investigations before they were marketed as foods or dietary supplements. Under the FD&C Act, it's illegal to introduce drug ingredients like these into the food supply, or to market them as dietary supplements. This is a requirement that we apply across the board to food products that contain substances that are active ingredients in any drug (December 20, 2018)

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