

# HEMP PRODUCTS

and their inclusion in human food and animal feed



## 2018 Farm Bill

The Agriculture Improvement Act of 2018 (or the “2018 Farm Bill”) was signed into law on Dec. 20, 2018. One of the changes included removing hemp from the Controlled Substances Act, which means that cannabis plants and derivatives that contain no more than 0.3 percent THC on a dry weight basis are no longer deemed controlled substances under the federal law.

Congress added a provision allowing hemp and hemp products grown or processed under the USDA Domestic Hemp Production Program to move freely through interstate commerce.

While the Farm Bill opened the door for hemp and hemp products as agricultural commodities, it explicitly preserved the Food and Drug Administration’s (FDA’s) authority to regulate products containing cannabis or cannabis-derived compounds under the Food Drug & Cosmetic (FD&C) Act.

## Epidiolex

Prior to the passage of the Farm Bill, FDA had already approved a purified form of cannabidiol oil, or “CBD oil,” for the treatment of seizures. This drug was branded as Epidiolex.

FDA’s prior approval of Epidiolex has direct consequences on the use of CBD oil in both human food and animal feed.

## CBD in Food and Feed

While evaluating their authority to regulate CBD and hemp derived products, FDA came to the following determination via the FD&C Act:

*Under section 301(II) of the FD&C Act, it is prohibited to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which has been added a substance which is an active ingredient in a drug product that has been approved under 21 U.S.C. § 355 (section 505 of the Act) or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public.*

Because FDA previously approved Epidiolex as a drug, the addition of CBD (Epidiolex’s active ingredient) into human food or animal feed products renders those product “adulterated” according to the FD&C Act.

## Are hemp infused products legal?

GDA adopts the FD&C Act by reference within our regulations, and will not allow GDA licensed establishments to make food or feed products that would be deemed “adulterated,” according to the FD&C Act. FDA is currently examining the issue, and GDA will review our policies accordingly.

## FDA approved hemp seed derived ingredients for use in human food only.

The FD&C Act provides the pathway for manufacturers to create and adopt new food and feed ingredients into their manufacturing processes. This system of approval functions as FDA’s determination that a food additive or ingredient is Generally Recognized as Safe (or “GRAS”).

Prior to their approval of Epidiolex, FDA evaluated and passed certain hemp products for inclusion within their GRAS index of approved ingredients. These products are:

- Hulled Hemp Seeds,
- Hemp Seed Oil, and
- Hemp Seed Protein Powder (powder ground from the seeds).

These three hemp seed-derived products have received a GRAS designation from FDA, and their use in human food is acceptable given they contain only trace amounts of THC and CBD. **These hemp seed-derived products have yet to receive GRAS status for use in animal feed.**

FDA further adds, “These GRAS conclusions do not affect the FDA’s position on the addition of CBD and THC to food. As stated on FDA and Marijuana: Questions and Answers, it is a prohibited act under section 301(II) of the Federal Food, Drug, and Cosmetic Act to introduce into interstate commerce a food to which CBD or THC has been added.”

For more info:

<https://agr.georgia.gov/hemp-program>

