

## **Alert** | Food, Beverage & Agribusiness



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### **The New Law Regarding the Regulation of Hemp and CBD**

The enactment of the [Agriculture Improvement Act of 2018](#) (commonly referred to as the 2018 Farm Bill) on Dec. 20, 2018, immediately, dramatically, and favorably changed the legal landscape in the United States with respect to the manufacturing, distribution, and sale of hemp and hemp derivatives, including cannabidiol (CBD).

The 2018 Farm Bill distinguishes hemp from marijuana by defining “hemp” as the *Cannabis sativa L.* plant, or any part of the plant, and extracts of it, that contain no more than 0.3 percent Tetrahydrocannabinol (THC), as calculated on a dry weight basis. Furthermore, the 2018 Farm Bill exempts “hemp” from the definition of “marijuana” as a Schedule 1 controlled substance as defined in 21 USC § 802(16) of the Controlled Substances Act (CSA), and expressly permits the interstate sale and transportation of hemp products. Now, hemp that contains 0.3 percent or less of THC is legal to grow and cultivate in the United States, thereby eliminating a significant roadblock to companies’ ability to manufacture, distribute, and sell CBD-containing products. The enactment of the 2018 Farm Bill is also expected to have a significant positive impact on the involvement of financial institutions, such as banks and payment processors, with companies in the hemp and CBD industries.

CBD, as an ingredient in food and dietary supplements, will continue to be regulated by the Food and Drug Administration. The 2018 Farm Bill specifically declares that its provisions have no bearing on the regulation of products, including those with hemp, by the FDA. FDA Commissioner Scott Gottlieb publicly acknowledged the effect and impact of the new law and commented that “the FDA will regulate CBD-

containing products as we do other FDA-regulated products. This means that products containing hemp or CBD must still be labeled and sold in compliance with the laws and regulations pertaining to food, beverages, and dietary supplement products.”

The FDA’s current position on the regulatory status of CBD for use in food, beverages, and dietary supplements is that CBD is not a legally permissible ingredient due to a provision of the Federal Food, Drug and Cosmetic Act (FDCA) that excludes any ingredient that was authorized for investigation as a possible new drug before being used as or in a dietary supplement or food – this provision is often referred to as the “Exclusionary Clause,” the “Exclusionary Provision,” or “the IND Provision.” The FDA has indicated in warning letters that it presumes the Exclusionary Provision applies to CBD. However, this position has not been formally stated in any guidance or other proceeding that would be open to public comment. Nor has the issue been tested in litigation. There are several reasons a court could cite as a basis for not applying the Exclusionary Provision to CBD, including evidence of prior sales of CBD before it was first authorized for study in clinical trials as a new drug, the percentage of CBD in the ingredient and its molecular structure as compared to the ingredient (article) that was investigated as a new drug, and the nature of the investigations, which are required to have been “substantial.”

Notwithstanding the FDA’s public statements about the Exclusionary Provision’s applicability, there are reasons to be cautiously optimistic that it may eventually take a different formal, final position. In responding to President Trump’s signing of the 2018 Farm Bill, FDA Commissioner Gottlieb noted that the FDCA provided the Secretary of Health and Human Services with authority to take action and exempt an ingredient from the Exclusionary Clause.

The full repercussions and effect of the 2018 Farm Bill and the regulation of CBD and hemp by the FDA and state agencies will be a fluid, constantly changing landscape throughout 2019 and beyond. The enforcement action, if any, the FDA takes with respect to the application to CBD of the Exclusionary Provision will be closely monitored by Greenberg Traurig lawyers. We are well-positioned to assist companies with compliance issues in this rapidly expanding area of commercial activity.

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