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President signs 2018 Farm Bill with hemp reforms – implications for regulatory oversight of hemp-derived products including cannabidiol (CBD)

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On December 20, 2018, President Donald Trump signed the Agricultural Improvement Act of 2018 (the 2018 Farm Bill) into law. The 2018 Farm Bill contains several provisions that change the regulatory framework for the cultivation and production of hemp in the United States and the commercialization of hemp-derived products. Importantly, these provisions redefine "hemp" and amend the Controlled Substances Act (CSA) to exclude hemp, under this revised definition, from the CSA definitions of marijuana and tetrahydrocannabinol (THC). Therefore, hemp, under this revised definition, is not subject to control under the CSA.

It has been widely reported that the 2018 Farm Bill "legalizes" hemp and hemp-derived products such as cannabidiol (CBD). Although the Farm Bill explicitly allows for the sale of hemp-derived products, hemp products will still have to comply with state and U.S. Department of Agriculture (USDA) regulatory programs. The hemp provisions of the 2018 Farm Bill do not alter the Food and Drug Administration's (FDA's) authority over the use of hemp-derived ingredients in FDA-regulated products, including drug products, foods, dietary supplements, and cosmetics. As discussed further below, FDA has consistently taken the position that CBD, whether derived from hemp or marijuana, is prohibited from use as an ingredient in food and dietary supplements under the exclusionary clauses of the Federal Food, Drug, and Cosmetic Act (FFDCA). FDA's regulatory authority over these products would remain unchanged.[1] For these reasons, it is paramount for companies seeking to market FDA-regulated products that contain hemp-derived ingredients to seek advice from their FDA regulatory counsel prior to doing so.

After the Farm Bill was passed, FDA Commissioner Scott Gottlieb issued a public statement reaffirming this position, but also acknowledged FDA has the authority to promulgate a regulation to allow the use of a pharmaceutical ingredient in a food or dietary supplement, and that the agency is currently evaluating whether to pursue such a process. In addition, on the same day the Farm Bill was signed, FDA announced it had completed its review of three generally recognized as safe (GRAS) notifications for hemp seed oil, hulled hemp seed, and hemp seed

[1] CBD also is marketed in topical products as a "cosmetic." It is unclear if FDA would concur CBD may be incorporated into cosmetic ingredients.

protein, and that the agency had no questions regarding the company's conclusion that the use of these ingredients as described in the notices is safe.[2]

The 2018 Farm Bill, by expanding the definition of hemp derivatives that are removed from control under the CSA, shifts the regulatory and enforcement burden for FDA-regulated products from the Drug Enforcement Agency (DEA) to FDA. FDA may face more pressure to use its authority under the FFDCA.

The Farm Bill provides that the cultivation of hemp will be subject to regulation by states, or, if a state does not wish to be the primary regulator of hemp production in its jurisdiction, by the USDA. While this measure will undoubtedly open the market for hemp cultivation and the production of hemp-derived products, significant work remains ahead for both federal and state regulators to establish these programs and promulgate the necessary regulations to monitor and implement these programs. Until these programs are established, the cultivation and production of hemp-derived products may only be performed in accordance with an agricultural pilot program, as established under section 7606 of the Agricultural Act of 2014 (7 U.S.C. 5940). Section 7606 sunsets one year after the USDA establishes its plan under the new subtitle.

New definitions of "hemp" and "marijuana" and classification of "THC" in "hemp"

Section 10113 of the 2018 Farm Bill amends the Agricultural Marketing Act of 1946 by adding a new subtitle on hemp production (Subtitle G – Hemp Production). Under this new subtitle of the Agricultural Marketing Act, hemp will be defined as follows:

- 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.

It remains to be seen how the USDA and/or states will establish tests to measure the THC concentration in hemp to ensure it falls within the new definition of "hemp." It is also not clear how the definition will be applied. For example, if a plant meets the definition of hemp because it contains less than 0.3 percent THC, do all products derived from that plant also meet the "hemp" definition, regardless of those finished products' THC concentration? Or can a product derived from a "hemp" plant be swept back under the CSA because of its THC concentration?

- Under current federal law, the distinction between "hemp" and "marijuana" is based on the definition of "marihuana" in the CSA. The current law defines marijuana as all parts of the Cannabis sativa L. plant and its derivatives, but excludes certain parts of the plant, such as the mature stalks, sterilized seeds, oil from the seeds, and derivatives of the mature stalks. These exempted portions of the plant were considered to be "hemp." Under the new definition of "hemp" in the Agricultural Marketing Act, the distinction between marijuana and hemp will be based solely on the delta-9 tetrahydrocannabinol (THC) concentration of any part of the Cannabis sativa L. plant rather than the part of the plant.

Section 12619 of the 2018 Farm Bill makes conforming changes to the CSA. Specifically, the law would revise the definition of marijuana to state:

- (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 297A of the Agricultural Marketing Act of 1946; or

[2] *See* FDA Constituent Update, FDA Responds to Three GRAS Notices for Hemp Seed-Derived Ingredients for Use in Human Food, *available here*.

- (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.

The law would also amend the CSA's Schedule I definition of THC, to explicitly exclude THC in hemp from control under Schedule I, as newly defined by the Agricultural Marketing Act. In doing so, Congress has legislatively codified the 9th Circuit holdings in the Hemp Industries Association cases decided in the early 2000s. In *Hemp Industries Association v. DEA*, 357 F.3d 1012 (9th Cir. 2004), the court held invalid and permanently enjoined enforcement of a DEA regulation clarifying "tetrahydrocannabinoids naturally contained in a plant of the genus Cannabis plant" are controlled as THC. This decision followed the court's invalidation, a year earlier, of DEA's identical interpretive rule on a similar basis. DEA recently clarified that it follows the 9th Circuit's decisions in all jurisdictions; however, some questions remained about the scope of DEA's regulation. The 2018 Farm Bill now makes clear that THC in hemp is not a Schedule I controlled substance under the definition of THC.

In addition to establishing a new definition for hemp, this new subtitle establishes a system whereby a state that wants to have primary regulatory authority over the production of hemp has to submit a plan to monitor and regulate the production of hemp to USDA for approval. If a state does not establish a plan or have a plan approved by USDA, the production of hemp in that state will be subject to a plan established by USDA. A state may still impose (or continue to impose) restrictions on hemp that are more stringent than the federal law, as the 2018 Farm Bill contains an express "anti-preemption" provision that provides the law does not preempt or limit state law regulating the production of hemp that is more stringent than federal law. Some states, such as California and Washington, have determined that CBD derived from hemp may not be lawfully used as a food or dietary supplement ingredient under state law. However, the 2018 Farm Bill forbids states from prohibiting the transportation or shipment of hemp or hemp products produced in accordance with the new subtitle, through the state (or Indian Tribe).

USDA is directed to promulgate regulations and guidelines to implement this subtitle "as expeditiously as practicable." Both state and USDA plans to regulate hemp must address issues such as procedures for testing THC levels of hemp, destruction of violative plants and products derived from those plants, inspections, and maintaining records of land used to plant hemp. Until these programs are established, the cultivation and production of hemp-derived products may only be performed in accordance with an agricultural pilot program, as established under section 7606 of the Agricultural Act of 2014 (7 U.S.C. 5940). Thus, there will be a period of time where a product may meet the definition of hemp under the Farm Bill and be excluded from control under the CSA, but will not have been produced in accordance with an approved state or tribunal plan, or with a USDA license. In such instances, production may only occur under an agricultural pilot program and these programs prohibit the sale of hemp for general commercial activity.[3]

Implications for use of hemp-derived ingredients in FDA-regulated products

The 2018 Farm Bill does not change the fact that the use of hemp-derived ingredients, including hemp extracts containing CBD, in products subject to FDA's authority under the FFDCA (e.g., foods, dietary supplements, and drugs).

[3] As we previously reported, in August 2016, the U.S. Department of Agriculture (USDA), in concurrence with FDA and DEA, issued a statement of principles (Joint Statement), to resolve open questions regarding the application of federal law to activities associated with industrial hemp following the passage of Agricultural Act of 2014 (2014 Farm Bill). The Joint Statement clarified that industrial hemp may be sold in a state (or among states) with an agricultural pilot program, and by institutions of higher education or State departments of agriculture for purposes of marketing research, but industrial hemp may not be sold for the purpose of general commercial activity.

The DEA/USDA/FDA Joint Statement is based on Section 7606 of the 2014 Farm Bill. The 2018 Farm Bill establishes an entirely separate framework for cultivating hemp (in accordance with a state plan approved by USDA, or in a state that does not seek approval of a plan, a USDA plan), that is not limited to research or commercial restrictions. As set forth above, section 7606 sunsets one year after the USDA establishes that plan.

FDA has consistently taken the position that CBD, whether derived from hemp or marijuana, is prohibited from use as an ingredient in food and dietary supplements. FDA's position was not based on whether CBD was controlled under the CSA, but rather stems from clauses in the FFDCA, known as the exclusionary clauses, which provide that a substance that has been approved and/or has been subject to substantial clinical investigations as a drug may not be used in a food or dietary supplement, unless the substance was first marketed in food or a dietary supplement prior to FDA issuance of the investigational new drug (IND). FDA has approved a new drug that contains CBD as an active ingredient and has asserted that companies did not market CBD as a food or dietary supplement prior to the FDA authorization of the IND. In FDA's view, the exclusionary clauses bar the marketing of CBD as a food or dietary supplement ingredient. The Farm Bill makes clear nothing in the bill alters the authority under the FFDCA. Any company interested in marketing CBD as a food or dietary supplement should consult with legal counsel to assess the exclusionary clauses and the FDA interpretation of those clauses.

Commissioner Gottlieb's statement explained that the Farm Bill does not alter FDA's authority to regulate cannabis and cannabis-derived compounds under the FFDCA and that FDA continues to view the exclusionary clause as prohibiting the use of CBD in a food or dietary supplement whether derived from marijuana or hemp.[4] He reiterated the agency's concern about the number of products that purport to contain CBD or other cannabis-derived compound bearing drug claims that are not approved by FDA and that FDA will continue to warn consumers and take enforcement actions when products could pose risks to consumers. At the same time, FDA acknowledged the growing public interest in cannabis and cannabis-derived products, and committed to better define its public health obligations in this area. In particular, FDA recognized that it does have authority to issue a regulation to allow the use of a pharmaceutical ingredient in a food or dietary supplement, and is currently taking steps to evaluate whether to pursue such a process. Commissioner Gottlieb also announced that FDA will hold a public meeting in the near future on these products.

[4] See statement from FDA Commissioner Scott Gottlieb, M.D., on signing of the Agricultural Improvement Act and the agency's regulation of products containing cannabis and cannabis-derived compounds, *available here*.

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