STATUS REPORT:

Marketing of hemp and cannabidiol (CBD) products in the United States following passage of the 2018 Farm Bill

December 2018

Prepared by the American Herbal Products Association

Disclaimer

The information contained herein is not and should not be considered legal advice. This AHPA publication is not a substitute for the actual laws and regulations that apply to the products and activities that are discussed herein. The information contained herein is not intended to replace or supersede federal or any State laws, regulations or guidance.

This document is specifically relevant to addressing the current legal status of the ingredients identified herein. No other issues related to the manufacture, marketing, or sale of food, dietary ingredients, dietary supplements, cosmetics, or any other class of consumer goods are addressed herein.

While AHPA believes the information herein is accurate, any company that chooses to use this information is advised to discuss all aspects of their application of this information with an attorney or qualified consultant, or with personnel at relevant regulatory agencies.

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Summary points

The 2018 Farm Bill passed by the 115th Congress and signed into law[1] includes numerous provisions inserted from legislation identified as the Hemp Farming Act.[2] The statutory changes established by these provisions have immediate and significant effects on the legal status in the United States of hemp cultivation operations and of products that include any part or derivative of the hemp plant, including cannabidiol (CBD) derived from hemp, and greatly affect the regulatory oversight of hemp and CBD products by U.S. federal agencies.

The purpose of this document is to provide concise and up-to-date information on the status of such operations and products[3] now that this legislation has been adopted as federal law and taking into account other current and relevant laws and regulations.

Of most significance are the following points:

- The U.S. Drug Enforcement Administration (DEA) now has no authority over hemp cultivation or products that contain hemp (including plant parts and derivatives) as an ingredient.
- Cultivation of hemp is now lawful in the United States; certain state-by-state rules apply and each participating State must establish and maintain a hemp "plan" and submit certain reports to the U.S. Department of Agriculture.
- Hemp ingredients, including plant parts and derivatives of any part of the hemp plant, are now lawful under federal law for use in food, dietary supplement, and cosmetics and personal care products. Use of hemp ingredients in such products is, as with any other herbal ingredient, subject to compliance with all relevant regulations (e.g., facility registration; labeling requirements; cGMP regulations; pertinent rules for submission of received serious adverse event reports; safety requirements, including, as applicable, GRAS or NDI regulations; etc.).
- The U.S. Food and Drug Administration (FDA) has taken the position that cannabidiol (CBD) is not allowed as an ingredient in conventional foods or dietary supplements due to provisions of the Federal Food, Drug and Cosmetic Act that generally prohibit, in relevant part, marketing as a dietary supplement or adding to food any article investigated or approved as a new drug. AHPA has been informed, however, that some marketers of CBD products and affiliated legal experts believe that FDA's interpretations of these provisions are inaccurate.

[1] H.R. 2. The Agriculture Improvement Act of 2018.

[2] S. 2667 and H.R. 5485.

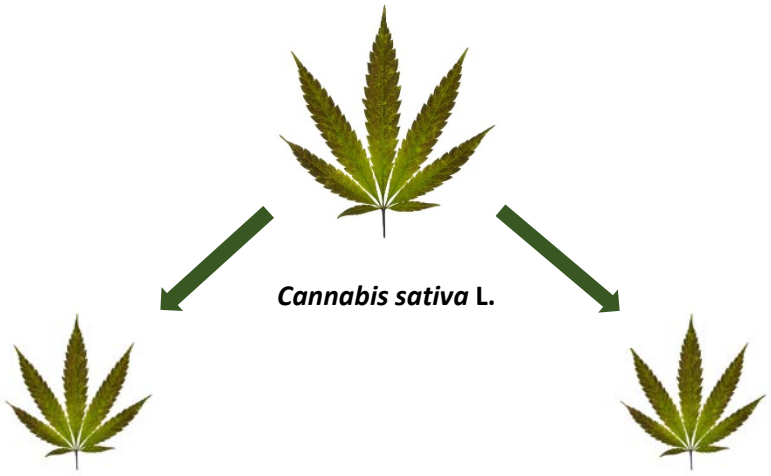
[3] The products addressed herein are limited to conventional foods, dietary supplements, and cosmetics. Hemp-derived products are also available in pulmonary dosage forms such as "vape" pens; such products are not addressed in this document.

- With regard to the last listed point, the Secretary of Health and Human Services has authority to issue regulations overriding both provisions and permitting the marketing as a dietary supplement or addition to food of an article studied or approved as a drug. Recognizing consumer safety as a shared FDA-industry priority, AHPA will encourage FDA to urge the Secretary of Health and Human Services to use this authority and issue a regulation finding that CBD is lawful under the Food, Drug and Cosmetic Act for use as an ingredient in foods and dietary supplements.

Additional details on each of these points and related explanations follow.

What is hemp?

The botanical identified as *Cannabis sativa* L.[4] is inclusive of two legally distinct articles under current U.S. federal laws and regulations.



1) **Hemp** cultivars of *Cannabis sativa* are those in which the level of delta-9 tetrahydrocannabinol (THC) is not more than 0.3 percent on a dry weight basis; it was formerly (and still is under some state and international regulations) referred to as "industrial hemp." The definition of "hemp" under U.S. federal law, as now established in section 297A of the Agricultural Marketing Act of 1946 as amended by the 2018 Farm Bill, also means "any part… and all derivatives" of hemp (e.g., all parts of the hemp plant, extracts, constituents, concentrates, etc.). This definition therefore includes such commercial consumer products as tinctures or extracts of any part of the hemp plant, such as the leaf or flowering top, and cannabidiol (CBD) derived from hemp cultivars; the THC content must remain at not more than 0.3 percent for any such plant part or derivative to still qualify as "hemp."

[4] Some taxonomic references identify up to three distinct species of plants within the *Cannabis* genus. AHPA takes no position on this detail and the information presented is intended to apply to all *Cannabis* spp.

2) **Marijuana** cultivars of *Cannabis sativa* are all those that cannot be categorized as hemp as defined above. All parts and derivatives of any marijuana cultivar of *Cannabis sativa* are included in the definition of "marihuana" under the federal Controlled Substances Act (CSA),[5] with the exception of 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." Marijuana is classified as a Schedule I controlled substance under the CSA. The CSA prohibits the manufacture, distribution, or dispensing of, or possession with intent to manufacture, distribute, or dispense, a Schedule I controlled substance without authorization; for all intents and purposes, marijuana is currently illegal under federal law. Over the past several years, however, numerous individual States have decriminalized or legalized marijuana within their borders for medical use or for any adult use.[6] *Inclusion of this paragraph on marijuana is provided solely to clarify the legal differentiation of the two classes of cultivars of* Cannabis sativa*; this document provides no additional information on marijuana or its legal status federally or in any State or other jurisdiction.*

Post-Farm Bill authority of hemp by the DEA

Of most relevance to the former authority of the U.S. Drug Enforcement Administration (DEA) over hemp is an amendment in the 2018 Farm Bill to the definition of "marihuana" under the CSA to completely remove hemp, including all parts of the plant and all derivatives, from that CSA definition, as follows:

> "The term 'marihuana' does not include … hemp, as defined in section 297A of the Agricultural Marketing Act of 1946." [7]

[5] This definition is found at 21 U.S.C. § 802(16); prior to amendment by the 2018 Farm Bill this section stated as follows: "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. Such term does not include 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."

[6] Summary information on the current status of specific State laws on medical marijuana is available at the website of Americans for Safe Access at https://www.safeaccessnow.org/state_and_federal_law. Summary information on the legal status of both medical and adult use marijuana in individual states is available on the website of the Marijuana Policy Project at https://www.mpp.org/states/ and on the website of NORML at https://norml.org/legal/medical-marijuana-2. All cited webpages accessed December 9, 2018.

[7] The amended definition of "hemp" in the Agricultural Marketing Act of 1946, section 297A, is as follows: "The term 'hemp' means the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all

The 2018 Farm Bill provisions also amended the CSA to revise the Schedule I listing of "Tetrahydrocannabinols" to "except … tetrahydrocannabinols in hemp…."

These changes effectively remove the authority of DEA over hemp cultivation and hemp products, including hemp-derived CBD products.

This Agency still retains jurisdiction over marijuana, however, and all articles that meet the revised definition of marijuana, including, for example, CBD derived from any part of a marijuana cultivar other than the plant parts excluded from that definition (i.e., mature stalk, fiber, seed oil, seed cake, sterilized seed, etc.).[8]

Post-Farm Bill federal regulation of hemp cultivation

The 2018 Farm Bill amends the Agricultural Marketing Act of 1946 with permanent amendments that categorize hemp as an agricultural commodity under the regulatory purview of the U.S. Department of Agriculture (USDA). By recognizing hemp as an agricultural commodity under USDA, production of hemp is assumed to now be eligible for federal programs such as crop insurance, agricultural research grants, and certification of organic production practices under the National Organic Program. Classification as an agricultural commodity also benefits hemp industry access to the financial services needed to support agricultural production of hemp and hemp products.

Other hemp provisions in the 2018 Farm Bill will require that hemp production occur in compliance with "plans" administered by individual States (or Tribal governments) or by USDA. Over a one-year transition period, hemp plans that, among other things, document the existence of procedures for tracking properties where hemp is grown, verifying that the crop is hemp, and enforcing against violations of the law will be submitted to the USDA, but the agency has no authority to reject any plan that conforms to the relevant provisions.

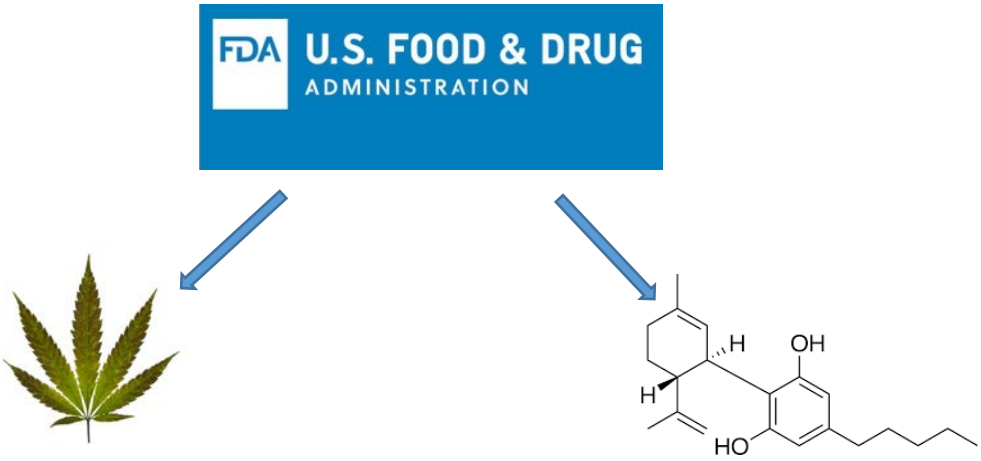
Under federal law as amended by these new hemp provisions, a State or Tribal government with an approved hemp plan will have primary regulatory authority over hemp cultivation within its jurisdictional borders. In addition, it is now clear that the federal CSA does not restrict or limit cultivation of hemp or the use of hemp-derived products or prohibit their marketing for general commercial purposes.

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."

[8] The document does not address DEA's potential legal authority to regulate synthetic CBD (or other synthetic cannabinoids) under other provisions of the CSA.

U.S. Food and Drug Administration (FDA)

The FDA has a role in the governance and oversight of hemp and CBD products[9] when used in articles regulated by the Agency, such as drugs, cosmetics and personal care products, and foods, including dietary supplements.



Hemp **Cannabidiol**

Post-Farm Bill FDA regulation of hemp for food and dietary supplement use

Each of the parts of the hemp plant (including for example the leaf, flowering top or inflorescence, seed, etc.), meets the definition of a dietary ingredient under the Food, Drug & Cosmetic Act (FDCA) at 21 U.S.C. § 321(ff)(1)(C), because it is an "herb or other botanical (except tobacco)," Similarly, any "concentrate, metabolite, constituent, extract or combination" of any part of the hemp plant meets that definition under 21 U.S.C. § 321(ff)(1)(F).

It thus appears that a product that consists of or contains any of the above-described hemp ingredients can be marketed as a dietary supplement in compliance with federal law as long as the THC level does not exceed 0.3% and the product meets all other federal regulations for dietary supplements generally. Note however that a hemp food or dietary supplement product in which the quantitative level of CBD is controlled or declared may be viewed by FDA as subject to certain restriction, as discussed in the next section of this document.

In addition, many conventional food products derived from hemp seeds are currently in the marketplace, ranging from hemp seed oil, "milk" or plant-based beverages, flour, protein

[9] AHPA notes that CBD can be synthetically produced; this discussion is intended to be applicable only to CBD that is derived from hemp as recognized in the 2018 Farm Bill.

powders, and meat substitutes. Prior to passage of the 2018 Farm Bill, these products were generally assumed to be manufactured from imported hemp seed or seed oil; now a domestic hemp seed supply can be established to support U.S. manufacture of these products.

Marketers of hemp-derived foods and dietary supplement products must comply with the FDA regulations applicable to their product category. These include regulations for food facility registration; current good manufacturing practice (cGMPs) regulations; nutrition and allergen labeling and label claim regulations; rules for submission of received serious adverse event reports (applicable to dietary supplement products); safety requirements, including, as applicable, new dietary ingredient (NDI) and food additive regulations (e.g., establishment of ingredients as GRAS, or generally recognized as safe); etc. Information about these regulations and guidance for achieving compliance can be found on the FDA website.[10]

Note also that several States have adopted laws and regulations that define "hemp" or "industrial hemp." Many of these State laws most specifically address hemp cultivation and all were adopted prior to the recent passage of the 2018 Farm Bill. Some may nonetheless have relevance to lawful marketing of foods and supplements that include any part of the hemp plant or articles derived from hemp, so companies manufacturing, marketing or selling such products should be familiar with applicable rules in States in which they do business.[11]

Post-Farm Bill FDA regulation of hemp-derived CBD for food and dietary supplement use

As inferred in the previous section of this document, because CBD is a constituent of hemp, which is "an herb or other botanical," CBD meets the definition of a dietary ingredient under 21 U.S.C. § 321(ff)(1)(F), and should therefore be allowed as an ingredient in a dietary supplement.

FDA has taken the position, however, that CBD may not be sold as a dietary ingredient, citing a provision of the FDCA (21 U.S.C. §321(ff)(3)(B)) that prohibits marketing as an ingredient in a dietary supplement any "article" that has been approved as a new drug or authorized for investigation as a new drug (i.e., as an Investigational New Drug or IND) in conjunction with certain other conditions (e.g., research related to the IND must be "substantial" and have been publicly announced). This provision does not apply if the article was "marketed as" a dietary supplement or conventional food before the date of the drug approval or IND authorization.

[10] See https://www.fda.gov/Food/GuidanceRegulation/default.htm for basic regulatory information for marketers of conventional food products. Similar information for marketers of dietary supplements can be found at https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/DietarySupplements/default.htm. Both accessed December 9, 2018.

[11] Information on the current status of specific State laws on hemp is available at the website of Vote Hemp at https://www.votehemp.com/resources/state-hemp-law/ or the website of the National Conference of State Legislatures at http://www.ncsl.org/research/agriculture-and-rural-development/state-industrial-hemp-statutes.aspx.

FDA has stated its belief that CBD was not so marketed prior to its authorization of IND investigations of CBD-containing drug products.[12] In making pronouncements on this position FDA has specifically cited announcements issued by GW Pharmaceuticals with regard to its *Cannabis*-derived drugs Sativex® ("an investigational new product composed primarily of two cannabinoids: CBD (cannabidiol,) and THC;" press release issued November 26, 2007) and Epidiolex® (identified as "a prescription cannabidiol (CBD) medicine;" press release issued May 7, 2014).

FDA has taken the same position with regard to CBD as an ingredient in conventional food, citing a separate but quite similar section of the FDCA that prohibits the addition of a drug to a food unless the drug was marketed in food before the drug's approval or any substantial clinical investigations involving the drug were instituted (21 U.S.C. § 331(ll)). Again, FDA's position is that based on evidence available to the agency, CBD was not added to food prior to the clinical investigation of a CBD-containing drug, and "FDA has therefore concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food … to which … CBD has been added."

AHPA has been informed that some marketers of CBD and affiliated legal experts believe that FDA's interpretations of these provisions are inaccurate, and arguments can be made that potentially counter FDA's position on CBD as an ingredient in foods and dietary supplements, including but not limited to the following examples:

- A hemp-derived CBD-containing "article" currently being marketed as or in a food or dietary supplement may not be the exact same "article" as either of those cited by FDA as studied under IND authorizations or, in the case of Epidiolex®, approved by the agency.
- Records may exist that indicate the presence in the U.S. market of CBD as a food or dietary supplement ingredient before research on CBD-containing drug products was authorized by FDA or initiated by sponsors.
- In explaining its interpretations of these provisions, FDA references GW press releases regarding planned research but does not provide the specific dates that the agency must use in its analysis: (i) the dates on which GW obtained authorization to conduct substantial clinical investigations of CBD-containing drug products; and (ii) the dates on which GW initiated such investigations. Without understanding the dates used by FDA in its analysis, stakeholders cannot properly evaluate the accuracy of FDA's conclusions.

Whether or not FDA is correct in its assertion that CBD itself is not allowed as an ingredient in foods or dietary supplements, the cited provisions do not prohibit marketing of hemp that contains CBD as a naturally-occurring constituent, nor has the Agency taken a position to the

[12] See "FDA and Marijuana: Questions and Answers," questions 12 through 15, at https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm#legal. Accessed December 9, 2018.

contrary. Thus, hemp food or supplement products should not be required to be free of CBD even under FDA's interpretations of these statutory provisions.[13]

In relation to its expressed opinion that CBD may not be used as a food or dietary supplement ingredient, FDA has since 2015 sent warning letters to numerous marketers of products containing CBD. These warning letters have largely focused on claims that FDA asserted rendered the promoted products to be unapproved new drugs. Most of these letters also cite the Agency's position that CBD cannot lawfully be added to food or marketed as a dietary supplement.

Authority of the Secretary HHS

The same provisions of the FDCA that FDA has cited as the basis for its position that CBD is not allowed as a food or supplement ingredient also provide for a possible solution to this issue.

Under both of 21 U.S.C. § 321(ff)(3)(B) and § 331(ll), the Secretary of Health and Human Services (HHS) has the statutory authority to grant an exception to these provisions by issuing a regulation, after notice and comment, approving the use of the subject article – in the present case CBD – or finding that the subject article would be lawful.

Recognizing consumer safety as a shared priority of FDA and the herbal industry, AHPA will continue to encourage use of this authority and the issuance of a regulation permitting addition of CBD to food and its marketing as a dietary supplement.

Post-Farm Bill FDA regulation of hemp and hemp-derived CBD for cosmetic and personal care use

FDA has not stated a public position regarding the use of hemp or hemp-derived CBD in cosmetic and personal care products. Hemp-derived ingredients such as hemp seed oil have been used for many years in cosmetic and personal care products. Topical products containing CBD ingredients were among those for which FDA has issued warning letters for unapproved new drug claims, among other non-compliances.

Marketers of cosmetics and personal care products that contain hemp or hemp-derived ingredients, including CBD derived from hemp, must comply with the applicable requirements of the FDCA and governing regulations for cosmetic and other personal care products. Such regulations include requirements for packaging and labeling, specifications for ingredients such as color additives, and draft guidance on cosmetic GMPs. FDA also offers voluntary facility

[13] The most relevant precedent to the current situation with CBD may be the actions FDA took starting in 1997 to remove from the market a red yeast rice product called Cholestin® standardized to a specific level of lovastatin, a drug product approved by FDA several years prior. The Agency ultimately prevailed, even as it acknowledged that "food red yeast rice" – that is, the traditional food ingredient – could be sold in or as a food or dietary supplement even if some lovastatin was present. In differentiating between the allowed and unallowed ingredients, FDA noted that the level of lovastatin was deliberately controlled to "consistently … maximize and standardize levels of lovastatin" in the product.

registration and cosmetic ingredient statement programs. Information about these regulations and guidance for achieving compliance can be found on the FDA website.[14]

What's next for hemp and hemp-derived products?

As detailed in prior sections of this document, the status of hemp-derived CBD with respect to its lawful and regulated use in dietary supplement and food products remains in question. A path forward is available through the exception power granted to the HHS Secretary. AHPA has been and will continue to partner with its member companies and other hemp industry associations to advocate for appropriate FDA recognition of hemp-derived CBD ingredients under the current applicable regulations for these product categories.

AHPA intends to update this guidance as new developments impacting the hemp industry arise. Readers can utilize the following resources to access timely information and engage with AHPA staff on issues pertaining to the hemp industry.

AHPA Cannabis Committee webpage:
http://www.ahpa.org/AboutUs/Committees/CannabisCommittee.aspx

Scientific, technical, and analytical inquiries:
science@ahpa.org

General hemp and CBD inquiries:
hemp@ahpa.org

Not a member yet? Join AHPA and network with other hemp industry professionals!
AHPA membership information and applications are available at this webpage:
http://www.ahpa.org/AboutUs/JoinAHPA.aspx

AHPA membership inquiries:
membership@ahpa.org

[14] See https://www.fda.gov/Cosmetics/GuidanceRegulation/default.htm for basic regulatory information for marketers of cosmetics and personal care products. Accessed December 12, 2018.