COMPLIANCE ALERT

NOVEMBER 15, 2023

FEDERAL LAWS REGULATE SALE OF CBD PRODUCTS

The purpose of this compliance alert is to raise awareness about state and federal law restrictions on sale of CBD products and about potential risks related to the sale of CBD products on UC Campuses.

SUMMARY

Federal and California law differ when it comes to the sale of products containing cannabidiol (CBD), and the laws are changing rapidly. The University of California must comply with both federal and state law regarding the sale of CBD on UC campuses. In cases where Federal law is more restrictive than state law, the University must follow Federal law.

Although California STATE law was amended in 2021 to legalize the sale in California of certain food, beverages, and dietary supplements containing industrial hemp (including hemp-derived CBD¹), the federal Food and Drug Administration (FDA), which has legal authority to regulate such products, continues to PROHIBIT sale of such products.

Under federal law, it is impermissible to distribute food, beverages, or dietary supplements that contain any form of CBD. It is permissible for cosmetics to contain certain types of CBD under certain circumstances, but the details can be complicated. The following summarizes the present state of the federal law. Campus units interested in selling any product that contains CBD should work closely with their campus counsel to assess potential risks associated with legal compliance.

KEY TAKEAWAYS:

Federal Law Applies:

- Under FDA regulations, CBD products offered for sale may not:
 - 1. Be intended for human consumption; and/or
 - 2. Make health claims
- Under the Controlled Substances Act (CSA), it is illegal to distribute a product containing marijuana or marijuana derivatives without a Schedule I DEA registration (regardless of whether the product makes health claims or is intended for human consumption).
 - While "hemp" (including products containing hemp-derived CBD) is excluded from the CSA definition of marijuana, this exclusion applies

¹ Sale of such products was legalized (and regulated) pursuant to Assembly Bill 45 (approved by Governor Newsom 10/26/21), available at <u>https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=202120220AB45</u>. State law requires sale of such products to comply with state regulations, which include a number of restrictions that will not be detailed here (but which include a ban on products containing cannabinoids that were chemically synthesized rather than being derived from hemp, restrictions pertaining to labeling and a ban on sale of alcohol that contains hemp – which would include alcohol containing hemp-derived CBD.).

only in cases where the product contains $\leq 0.3\%$ delta 9 THC and otherwise qualifies as "hemp" under the 2018 Farm Bill²

It can be difficult to ascertain whether the CBD in particular products qualify as hemp under the 2018 Farm Bill. If a campus is uncertain whether a CBD product qualifies as a hemp, there is a risk that sale of such products would be illegal under the CSA.

It is advisable to consult with your Campus Counsel and Senior Leadership prior to making any decisions about the sale of CBD products on UC Campuses.

THE FEDERAL REGULATORY FRAMEWORK

The passage of the 2018 federal Agricultural Improvement Act (known as the 2018 Farm Bill) has led to the misperception that all products containing CBD may be legally sold without issue. While the 2018 Farm Bill removed "hemp" from the list of Schedule I substances under the federal Controlled Substances Act(CSA)³, not all CBD qualifies as "hemp." In addition, FDA regulations still restrict sale of certain CBD products, regardless of whether they qualify as "hemp," and there are other federal laws that apply as well.

Key federal laws governing the legality of CBD product sales include:

THE 2018 FARM BILL

The Farm Bill legalized the cultivation of hemp and excluded hemp and its extracts from the definition of marijuana and from control as a Schedule I drug under the Controlled Substances Act. CBD is considered a hemp extract when derived from a Cannabis plant containing $\leq 0.3\%$ delta-9-tetrahydrocannabinol (THC)⁴.

The Farm Bill specifically preserved the U.S. Food and Drug Administration's (FDA) authority to regulate CBD when used in, or as, cosmetics, dietary supplements, foods, or drugs.

CONTROLLED SUBSTANCES ACT (CSA)

The federal Drug Enforcement Agency (DEA) issued an Interim Final Rule⁵ in 2020 that specifies that CBD derived from hemp (as defined in the 2018 Farm Bill), and that contains no more than 0.3% delta-9-THC, is no longer legally defined as marijuana or as a marijuana extract under the federal Controlled Substances Act. Therefore, such CBD is not a prohibited controlled substance.

However, the Interim Final Rule does not consider **all** CBD as exempted from the definition of marijuana or marijuana extract since not all CBD products qualify as "hemp" or hemp extracts:

CBD does <u>not</u> qualify as "hemp" (and therefore, remains a Schedule I controlled substance under the CSA) if it contains > 0.3% delta-9 THC, or if it was synthetically derived. Similarly, if it was derived from a cannabis plant containing > 0.3% delta-9 THC, it may not qualify as hemp.

² As amended pursuant to the 2018 Farm Bill, the Controlled Substance Act now defines hemp as "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." 7 U.S.C. 16390.

³ Section 12619 of the 2018 Farm Bill.

⁴ Section 10113 2018 Farm Bill (amending 7 U.S.C. 1621 et seq.)

⁵ Federal Register /Vol. 85, No. 163 / Friday, August 21, 2020 /Rules, and Regulations

FOOD, DRUG AND COSMETICS ACT (AND ASSOCIATED FDA REGULATIONS)

FDA has posted useful guidance regarding its regulation of cannabis-derived products pursuant to the Food, Drug, and Cosmetics Act⁶, which clarifies that the FDA regulates CBD in the following ways:

• Cosmetics⁷:

Retailers may sell cosmetic products containing CBD if:

- (1) the CBD meets the Controlled Substance Act's definition of "hemp," including that it contains not more than 0.3% THC);
- (2) it is topical (not intended for consumption); and
- (3) it does not make any health claims (e.g., relieves symptoms of arthritis).

• Dietary Supplements:

Products containing CBD may not be sold or distributed as dietary supplements.

• Food/Drink:

Food and beverage products (including food for animals) containing CBD are NOT legal. Only hemp seeds, hemp protein powder, and hemp seed oil are considered Generally Recognized as Safe (GRAS) by the FDA and may be legally sold for consumption.⁸

• Drugs:

Epidiolex is the only approved drug containing purified CBD. Other purified CBD products that make health claims are currently NOT legal.

In January 2023, FDA announced that after careful review, it concluded that a new regulatory pathway for CBD is needed to balance individuals' desire for access to CBD products with the regulatory oversight needed to manage risks. FDA's announcement noted that the use of CBD raises various safety concerns, and that given available evidence, is not apparent how CBD products could meet safety standards for dietary supplements or food additives. Nonetheless, the agency said it is prepared to work with Congress on this matter.⁹ **Thus, there may be forthcoming changes to the regulations, but until that time, the restrictions discussed above apply**.

DRUG FREE SCHOOLS AND COMMUNITIES ACT (DFSCA) & DRUG FREE WORKPLACE ACT (DFWA)

The DFSCA and DFWA both condition the University of California's receipt of federal funding on the university's implementation of programs and policies that prohibit the possession, use, or **distribution** of any illegal drug – including marijuana – by students or employees.^{10,11} Failure to comply with these federal laws could put UC's federal funding at risk. Since it is difficult to determine whether a particular CBD product meets the federal definitions of "hemp" rather than marijuana (under both the 2018 Farm Bill and the Controlled Substances Act), offices who may

⁶See: FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD),posted at:

https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-<u>cbd#fdacomm</u> (Last accessed7/27/23). ⁷ Cosmetics are defined as, "(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise

⁷ Cosmetics are defined as, "(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap." [21 U.S. Code § 321(i).]

⁸ FDA Constituent Update: December 20, 2018

⁹ See: FDA Concludes that Existing Regulatory Frameworks for Food s and Supplements Are Not Appropriate for Cannabidiol, Will Work With Congress On a New Way Forward, posted 1/26/23 at: <u>https://www.fda.gov/news-events/press-announcements/fda-concludes-existing-regulatory-frameworks-foods-and-supplements-are-not-appropriate-cannabidiol</u>.

¹⁰ Title 34 C.F.R, Subtitle A, Part 86

¹¹ 41 U.S. Code § 8102

be deciding whether to sell CBD products on campus should use caution as doing so may violate the DFSCA and DFWA (as well as the other laws discussed above).

ENFORCEMENT ACTIONS

Thus far, enforcement action has been limited. Actions by the FDA¹² and the Federal Trade Commission¹³ have been directed solely toward the manufacturers of CBD products rather than toward retailers. Nevertheless, sales of CBD food/drink, dietary supplements, and cosmetics that are either non-topical and/or make claims about health and/or that contain CBD that does not meet the CSA definition of "hemp" are not legal under federal law.

CONSIDERATIONS

The law around CBD is complicated.

This guidance is being provided in response to campus inquiries about the legal status/risks re: sale of CBD products on campus. While this is not an area where there is thought to be a high degree of enforcement risk, this guidance is meant to inform campus units about applicable laws, and to equip them to assess potential compliance concerns as they make decisions about products sold in campus stores.

The following offices should review this guidance carefully and coordinate with their campus counsel on the issue of allowing the sale of any CBD products on campus:

- Procurement Offices
- Campus Bookstores
- Housing and Dining Services
- Any other department/unit purchasing goods for sale on UC Campuses

If you have additional questions about this compliance alert, contact Jennifer Lofthus, General Compliance Manager, at <u>jenny.lofthus@ucop.edu</u>. For legal questions, please contact Ellen Auriti, Senior Principal Counsel, at <u>Ellen.Auriti@ucop.edu</u>.

¹² See, <u>FDA Warning Letters and Test Results for Cannabidiol-Related Products</u>

¹³ FTC Press Release December 17, 2020: One thing marketers of CBD products need to know right now; FTC Press Release May 17, 2021: FTC Announces Latest Enforcement Action Halting Deceptive CBD Product Marketing