AIMED ALLIANCE

July 15, 2019

Beth Fritsch
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 32
Silver Spring, MD 20993-002

Re: Scientific Data and Information about Products Containing Cannabis or Cannabis-Derived Compounds; Public Hearing; Request for Comments - Docket No. FDA-2019-N-1482

Dear Ms. Fritsch:

Aimed Alliance is a 501(c)(3) non-profit organization that seeks to protect and enhance the rights of health care consumers and providers. Thank you for the opportunity to provide information to the U.S. Food and Drug Administration (FDA) regarding the regulatory oversight of hemp-derived cannabidiol (CBD) products.

We recommend that the FDA consider manufacturing, testing, and labeling standards for hemp-derived CBD products to reduce confusion around and increase confidence in the safety and quality of such products.

I. The Current Market for CBD Products

The market for CBD products has grown exponentially, with some projecting it to reach $16.3 billion by 2026.[1] While the exact number of adults who currently use CBD is unknown, self-reported survey data indicate that about seven percent of all adult Americans, or about 22 million people, use CBD as a "supplement."[2] Other reports have found that as many as 26 percent of Americans have tried CBD at least once in the past two years, with 40 percent of U.S. adults interested in trying CBD.[3] These widely-available CBD products are used for various reasons, including potential health benefits, lifestyle improvement, and relaxation.[4] While these products are readily-available to consumers, there is general uncertainty and consumer confusion about the health benefits of CBD, especially now that hemp has been exempted from the Controlled Substances Act.[5]

Without the FDA taking action to regulate CBD products, consumers cannot have confidence in the safety, quality, and purity of the products they are purchasing. Moreover, while states have taken the lead in establishing laboratory testing standards for cannabis, a national

[1] https://www.cannabisbusinesstimes.com/article/cbd-market-to-reach-16-billion-by-2026/
[2] https://www.cowen.com/reports/cowen-collective-view-of-cbd/;
[3] https://www.consumerreports.org/cbd/cbd-goes-mainstream/; https://www.highyieldinsights.com/commerce/digital-download/5cad5654e79c706091dc5649?oid=5d0cddff67fe4e000162fd3e
[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6043845/; https://www.nytimes.com/interactive/2019/05/14/magazine/cbd-cannabis-cure.html
[5] https://www.congress.gov/bill/115th-congress/house-bill/2/text

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standard has not yet been adopted.[6] This patchwork of manufacturing standards leaves consumers in some states with greater certainty about the safety, quality, and purity of cannabis-derived products that they purchase, while others are left in the dark. Without strong and consistent manufacturing standards, consumers will be susceptible to deception and fraud, as some CBD products make unsubstantiated therapeutic claims, lack the advertised ingredients, and have inconsistent potencies.[7] Until national standards are adopted to ensure that these products are properly manufactured and labeled, consumers are at risk. This environment is ripe for FDA intervention and regulatory clarity.

II. Health and Safety Risks

The FDA should consider certain potential safety concerns when regulating and monitoring non-prescription CBD products.

A. Purity

Typically, consumers cannot readily determine the purity of non-prescription CBD products.[8] According to recent reports, some consumers have been harmed because the products they used contained additional undisclosed ingredients not listed in the product's label, and other adulterants.[9] For example, some products contain elevated levels of tetrahydrocannabinol (THC), which could cost consumers their job or their family (depending on their circumstances),[10] and others contain toxic chemicals.[11]

Purity issues may arise because CBD is an organic product that is grown from soil. In addition to the cannabis plant's tendency to absorb nutrients and heavy metals from the soil it is grown in,[12] which can later appear in laboratory testing after the plant has been harvested, manufacturing processes have not been standardized to ensure that the final product is unadulterated.[13] This can be further complicated by growers who often use pesticides to ward off insects while the plant is growing.[14] Best practices do not currently exist regarding the growth and harvest of the cannabis plant, as well as the extraction and filtration of CBD itself. For consumers to have confidence in these products, manufacturers must be held to higher production standards, and rigorous testing must be required of all such products to validate their contents. To enable these manufacturing standards to be established, the FDA should publish guidance regarding methods to ensure purity of CBD products.

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[6] https://www.leafly.com/news/industry/leaflys-state-by-state-guide-to-cannabis-testing-regulations
[7] https://www.cbs58.com/news/cbd-test-shocking-results
[8] https://jamanetwork.com/journals/jama/fullarticle/2661569
[9] https://jamanetwork.com/journals/jama/fullarticle/2661569
[10] https://www.thedailybeast.com/parents-treating-kids-with-cannabinoid-oil-could-lose-them; https://www.abcactionnews.com/news/national/can-using-cbd-products-cost-someone-their-job-heres-what-you-need-to-know
[11] https://www.inquirer.com/philly/business/cannabis/toxic-chemicals-found-in-popular-cbd-products-20181115.html-2
[12] https://www.omicsonline.org/open-access/marijuana-toxicity-heavy-metal-exposure-through-statesponsored-access-to-la-fee-verte-2167-7689-1000202-99945.html
[13] https://www.baltimoresun.com/opinion/op-ed/bs-ed-op-0607-cbd-regulation-20190606-story.html
[14] https://www.karger.com/Article/FullText/489287

B. Potency

Non-prescription CBD products have contained inconsistent potencies. Without knowing the exact levels of CBD in a product, consumers cannot determine an appropriate dose.[15] If consumers take too high a dose of CBD, they can experience negative side effects, including anxiety and depression, nausea, vomiting, and diarrhea.[16] Furthermore, even if a consumer can establish an appropriate dose for one specific product, that dose likely will not translate to other similar products because the contents and CBD levels of these products are unverified. Two seemingly identical products could contain drastically different levels of CBD.[17] Therefore, the FDA should publish guidance to ensure standardized potency of CBD products.

C. Therapeutic Claims

Unsubstantiated medical claims regarding non-prescription CBD products are also problematic for consumers because consumers may not be aware that such claims are unlawful and often untrue.[18] These types of claims are misleading to consumers and may induce them to stop taking a safe and effective treatment that they are currently stable on. This could lead to disease progression or relapse, depending on the condition that the consumer is seeking to address. The FDA should also explore the potential for drug-drug interactions to protect consumers from unanticipated side effects and contraindications.[19]

D. Vulnerable Populations

In certain populations, CBD could pose heightened risks. For example, edible products that contain CBD, such as gummy bears and jellybeans, could be attractive to children. Yet, they may not understand that these products contain CBD and possibly THC. Unintentionally high doses, a lack of standardized purity, and uncertainty about the levels of CBD that could be safe for children to consume could result in adverse events. Additionally, the effects of CBD on pregnant women are unknown, and more research needs to be done to determine how CBD consumption during pregnancy can affect both the mother and the fetus.

E. Routes of Administration

There are several ways to consume CBD, including topical application and oral consumption. Some methods of administration may impact consumers differently than others; however, data on such differences is currently lacking. For example, when a chemical is inhaled as a vapor instead of consumed orally as food, the chemical is more quickly absorbed by the body. Because some vaporizers have been shown to leech heavy metals like chromium and nickel into the vapor that users inhale, this route of administration could cause the body to absorb heavy

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[15] https://www.nbcnews.com/know-your-value/feature/dr-madelyn-fernstrom-4-things-you-must-know-trying-cbd-ncna1000021

[16] https://potguide.com/pot-guide-marijuana-news/article/can-you-overdose-on-cbd/

[17] https://www.nbcmiami.com/investigations/505335101.html

[18] https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-committed-sound-science-based-policy-cbd

[19] https://www.vice.com/en_us/article/a3b47k/this-is-how-cbd-could-interact-with-prescription-meds

metals like these more readily,[20] which could be dangerous to consumers' health. Furthermore, given that some CBD products are adulterated, vaporization could result in consumers being exposed to other types of toxins that are even more harmful.[21] Studies regarding the long-term use of CBD products will be needed to determine the routes of administration that are safest for consumers.

III. Manufacturing and Product Quality

The FDA should consider issuing standards to address safety concerns that can arise during the manufacturing process of CBD products. Because cannabis is an organic plant that is consumed, each stage of its growth and each stage of the manufacturing process can introduce foreign substances that could harm consumers. For example, the cannabis plant can absorb heavy metals from the soil while it is growing.[22] Growers also commonly use pesticides, which can turn up in the final product, and the plant matter is susceptible to mold while it is being dried, cured, and stored.[23] The process of creating a product like CBD oil adds several more opportunities for foreign matter to be introduced into the product. For example, when a solvent such as isopropyl alcohol, butane, or petroleum-ether is used to extract CBD from the plant matter, it is possible for the final product to contain residual solvent that could be harmful if ingested.[24] After CBD is extracted from the plant and concentrated into an oil, manufacturers can add other ingredients to the oil to adjust properties such as color, viscosity, taste, and shelf-life stability.[25] To address these issues, the FDA could require licensure of hemp growers to ensure that CBD products are sourced from credible growers who are knowledgeable about the complexities of growing hemp for human consumption and are following best practices for manufacturing.

Additionally, the FDA could enact strong production standards that require products to undergo individual or batch-wide laboratory analysis to verify the products' ingredients before they can be sold to consumers. Several independent groups have promulgated laboratory testing standards,[26] but to enhance consumer confidence in these products, the FDA should enact a national laboratory testing standard.

IV. Marketing / Labeling / Sales

The FDA should require manufacturers to inform consumers about certain risks associated with CBD products, including through marketing efforts and labeling.

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[20] https://www.vice.com/en_us/article/zmk55a/everything-we-know-about-the-health-risks-of-vaping-cbd
[21] https://www.vice.com/en_us/article/zmk55a/everything-we-know-about-the-health-risks-of-vaping-cbd
[22] https://www.omicsonline.org/open-access/marijuana-toxicity-heavy-metal-exposure-through-statesponsored-access-to-la-fee-verte-2167-7689-1000202-99945.html
[23] https://wjla.com/features/7-on-your-side/the-risk-of-contaminants-and-false-labeling-in-the-exploding-cbd-industry
[24] https://www.analyticalcannabis.com/articles/residual-solvent-analysis-ensuring-the-safety-of-cannabis-extracts-289021
[25] https://www.karger.com/Article/FullText/489287
[26] http://cannabissafetyinstitute.org/wp-content/uploads/2015/01/Standards-for-Cannabis-Testing-Laboratories.pdf; https://www.a2la.org/accreditation/cannabis-testing; https://www.anab.org/lab-related-accreditation/cannabis-testing

A. Recommended Marketing and Labeling Language

Manufacturers who market non-prescription CBD products to consumers should be required to include statements on product labels and in their marketing materials and advertisements that explicitly state that the product is not intended to treat any medical condition, that the health effects of the product have not been studied, that the FDA has not granted approval of the product for the treatment of any condition, and that consumers should not replace a treatment they are currently taking without first consulting with their doctor. Additionally, consumers should be cautioned that trace amounts of THC could appear in the product, even if it is marketed specifically as a CBD product. The product's labeling information should also include explicit language that states "this product is not FDA-approved and is not intended to treat any medical condition." These disclosures are intended to prevent consumers from discontinuing current, effective treatment without consulting their health care practitioner; prevent the occurrence of harmful drug-drug interactions; and help consumers understand the difference between these products and prescription medications.

Pediatric populations are at heightened risk of unintentionally consuming a CBD product because they are often marketed as candies and baked goods, which are attractive to children. As such, these products should bear a warning that children should only consume the product under adult supervision and after consultation with a pediatrician. The warning should additionally mention that the effects of CBD in children are unknown. A similar warning should apply to pregnant women, as these products should only be consumed after consultation with an OB/GYN. Additionally, the warning should state that the effects of CBD on pregnant women and unborn fetuses are unknown.

B. State Laws and Legislation

Several states have introduced legislation or passed laws that would require manufacturers of CBD products to update their labeling with helpful safety information. Some effective examples including the following:

- LA Act No. 164 (2019): approves the production of industrial hemp and requires that CBD products be sourced from a licensed hemp grower and have the following words printed clearly on the label: "This product has not been evaluated by the Food and Drug Administration and is not intended to diagnose, treat, cure, or prevent any disease." Additionally, the law prohibits medical claims and requires the inclusion of a scannable code on the product that contains a certificate of laboratory analysis.[27]

- ME LD 1749 (2019): requires a person who manufactures or sells CBD products to be licensed. Requires CBD products to bear a label that states that the product has not been evaluated for safety.[28]

[27] https://www.billtrack50.com/BillDetail/1111316
[28] http://www.mainelegislature.org/legis/bills/getPDF.asp?paper=SP0585&item=5&snum=129

- HI Rev. Stat. § 141 (2017): requires hemp growers to be licensed and requires them to report to the Hawaii Department of Agriculture. Requires testing and sampling of hemp to ensure that THC levels are below 0.3%.[29]

- WA Rev. Code § 69.50.326 (2018): prohibits CBD products from containing over 0.3% THC on a dry weight basis. Requires licensure for the growth, manufacture, and sale of CBD products. Requires CBD products to be traceable through a database. Requires CBD products to undergo laboratory testing before they may be sold to consumers. Requires supplemental product testing for toxins and contaminants.[30]

C. Other Considerations

Currently, states have varying laws on whether the use of CBD products is legal and under what circumstances.[31] Yet, upon the passage of the Farm Bill, many news outlets proclaimed that CBD products were legal, creating widespread confusion.[32] To decrease such confusion and protect consumers from violating state laws, we encourage the FDA to require CBD manufacturers to include a warning on product labels and in marketing materials, including on their website, that the product may not be legal in all states and that transporting products across state lines could be illegal under federal law.

V. Conclusion

For the reasons above, we urge the FDA to issue manufacturing, testing, and labeling requirements for hemp-derived CBD products. Thank you for the opportunity to comment on this issue. If you have any questions or comments, you can contact me at jwylam@aimedalliance.org.

Sincerely,

John A. Wylam, Esq.
Staff Attorney

[29] https://hdoa.hawaii.gov/wp-content/uploads/2018/10/Industrial-Hemp-HRS-141.pdf
[30] http://lawfilesext.leg.wa.gov/biennium/2017-18/Pdf/Bills/Session%20Laws/House/2334-S2.SL.pdf#page=1
[31] https://www.pbs.org/newshour/science/is-cbd-legal-heres-what-you-need-to-know-according-to-science
[32] https://www.nytimes.com/2019/05/06/us/cbd-cannabis-marijuana-hemp.html