

May 10, 2019

Food and Drug Administration - 5630 Fishers Ln, Rm 1061 - Rockville MD 20582

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

To whom it may concern,

I am writing on behalf of the National Organization for the Reform of Marijuana Laws (NORML) to urge the US Food and Drug Administration to move expeditiously in the establishment of regulations specific to the production, manufacturing, marketing, testing, and retail sale of commercially available CBD-infused products.

Passage of the 2018 Farm Bill explicitly included provisions declassifying industrial hemp (cannabis plants possession no more than 0.3 percent THC) and cannabinoids derived from these plants. As a result, commercially produced and marketed products advertised as containing hemp-derived CBD are no longer under the purview of the US Drug Enforcement Administration. Rather, regulation of these products now falls under the authority of the FDA.¹

On multiple occasions, FDA has made clear that – at present – it believes that it is “unlawful under the FD&C Act to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements, regardless of whether the substances are hemp-derived.”² The online document,³ ‘FDA Regulation of Cannabis and Cannabis-Derived Products: Questions and Answers,’ further affirms this opinion.

That said, FDA has also indicated that these new changes in federal law for the first time provide “potential regulatory pathways for products containing cannabis and cannabis-derived compounds.”⁴ FDA has further stated that it “will continue to take steps to make the pathways for the lawful marketing of these products more efficient.”⁵ But, in Congressional testimony in March, the outgoing FDA director acknowledged that regulating these products “is not a straight forward issue,”⁶ and that he expects there to be “a multi-year regulatory process that could take two, three, four years.”⁷

¹ Statement of former FDA Commissioner Scott Gottlieb: “We’re aware of the growing public interest in cannabis and cannabis-derived products, including cannabidiol (CBD). This increasing public interest in these products makes it even more important with the passage of this law for the FDA to clarify its regulatory authority over these products. In short, we treat products containing cannabis or cannabis-derived compounds as we do any other FDA-regulated products – meaning they’re subject to the same authorities and requirements as FDA-regulated products containing any other substance. This is true regardless of the source of the substance, including whether the substance is derived from a plant that is classified as hemp under the Agriculture Improvement Act.” (December 20, 2018).

² Ibid.

³ FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)

⁴ Statement of former FDA Commissioner Scott Gottlieb. Op. Cit.

⁵ Ibid.

⁶ FDA Head Reveals New Details About Agency’s CBD Regulation Plans, February 27, 2019.

⁷ Ibid.

It is NORML's opinion that regulations governing the production, sale, quality, and marketing of these products must take place far more expeditiously in order to protect consumer safety and to prevent confusion in the marketplace.

There exists rapidly growing consumer interest in the use of CBD-infused products. A 2019 Harris poll of over 2,000 Americans found that 86 percent of respondents are familiar with CBD, and just under ten percent say that they consume it "regularly" – typically for purposes of relaxation, anxiety relief, or improved sleep.⁸ Domestic retail sales of CBD products now total over \$1 billion annually and are expected to surpass \$16 billion by 2026.⁹ In recent weeks, several 'Big Box' chains – such as CVS and Walgreens – have announced their interest in selling certain CBD products in their retail stores.

This retail market is far too large to remain unregulated, and this lack of regulation is leading to a variety of problems. First, there exists significant confusion within the marketplace, as well as among state regulators and law enforcement, with regard to whether these products are legal or illegal. NORML is aware of numerous instances where local law enforcement has seized CBD products from shelves, only to refuse to file criminal charges later. In other instances, regulators have called for removing certain CBD products from retailers because of ongoing questions regarding their legal status. In some cases, consumers have been arrested¹⁰ for possessing these products, despite the good faith belief that they were legal.¹¹

In addition, increasing market demand, coupled by an absence of regulatory guidance, has motivated predatory companies to become increasingly pervasive in this space. Often times, these companies market inferior quality products that could potentially put the consumer at risk. To date, these commercially available products are not subject to lab testing to affirm either CBD potency or an absence of adulterants. Consequently, independent testing of CBD-infused products often reveals inconsistencies between the percentage of CBD advertised and the amount actually contained in the product (e.g., here,¹² here,¹³ here,¹⁴ here,¹⁵ and here.¹⁶) Other products have revealed the presence of THC,¹⁷ which may put consumers in jeopardy for legal ramifications – such as arrest or the loss of employment (due to a drug

⁸ [New data show Americans are turning to CBD as a cure-all for the modern condition](#), April 15, 2019

⁹ [Consumer Interest Continues to Rise as CBD Sales Expected to Reach \\$16 Billion By 2026](#), February, 2, 2022.

¹⁰ ["Great-grandmother with CBD oil arrested at Disney World."](#) May 7, 2019.

¹¹ ["CBD arrests flying high at Dallas Fort Worth International Airport"](#), April 26, 2019.

¹² [Testing CBD Label Claim](#), 7 News Boston, May 6, 2019.

¹³ [I-Team Tests CBD Products. But Finds Results Alarming](#), April 11, 2019.

¹⁴ [CBD is in just about everything: Are you getting what you pay for?](#), November 18, 2019.

¹⁵ [NBC 6 Tests CBD Products](#), February, 4, 2019.

¹⁶ [CBD & Hemp Extract Supplements, Lotions, and Balms Review](#), September 5, 2020.

¹⁷ [Bonn-Miller et al., 2017. Labeling accuracy of cannabidiol extracts sold online. JAMA: 1708-1709. See also: Pavlovic et al., 2018. Quality traits of 'cannabidiol oils': cannabinoids content, terpene fingerprint and oxidation stability of European commercially available preparations. Molecules: 1230.](#)

test failure). Still other products have been identified to contain unwanted and potentially dangerous adulterants – such as 5F-ADB (aka ‘Spice’) or DXM¹⁸ – as well as heavy metals and solvents.¹⁹

Finally, no generally accepted ‘best practices’ currently exist governing CBD extraction from hemp. This void has left some to question whether CBD extraction from traditional hemp plants is either safe²⁰ or viable.²¹

Therefore, it is NORML’s position that FDA must move expeditiously to develop and finalize regulations and standards specific to the commercial CBD market. These regulations ought to address:

Product legality: FDA must provide clear guidance to state regulators and law enforcement with regard to the legal status of hemp-derived CBD products available commercially.

Product Quality: FDA must impose regulations with regard to universal standards for lab testing as it pertains to hemp-derived CBD products. Commercial products ought to be tested for CBD content, as well as for the presence of other cannabinoids (e.g. THC), and labeled appropriately. Products must be free of contaminants and heavy metals. The inclusion of any additional chemical compounds or supplements (e.g., melatonin²²) must be included on the product’s label. Companies who provide products at retail who do not meet these standards, or whose products are determined to be mislabeled, ought to face penalties.

Manufacturing Quality: FDA must establish regulations governing the extraction of CBD from hemp and recommending good manufacturing practices.

For years, producers of these products have navigated in a grey area of the law – manufacturing products of variable and sometimes questionable quality and safety. Now it is time for the FDA to craft benchmark safety and quality standards for hemp-derived CBD products in order to increase consumer satisfaction and confidence as this nascent industry transitions and matures into a legal marketplace.

Sincerely,

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¹⁸ Poklis et al. 2019. *The unexpected identification of the cannabimimetic, 5F-ADB, and dextromethorphan in commercially available cannabidiol e-liquids*. Forensic Science International: e25-3-27.

¹⁹ [I-Team Tests CBD Products, But Finds Results Alarming](#), April 11, 2019.

²⁰ [Report: Purity Of So-Called Hemp-Based CBD Oils Questioned](#), October 16, 2014.

²¹ [Alice Mead](#). 2017. *The legal status of cannabis and cannabidiol under US law*. Epilepsy & Behavior: 288-291: “[H]emp varieties are generally poor sources of cannabinoids, including CBD. ... Cannabidiol expression is typically limited to flowering buds and not stalk, fiber, or sterilized seeds; this is true of all cannabis varieties. Traditional hemp is an inefficient source of CBD, requiring many acres to be cultivated to produce significant amounts of CBD extract. Moreover, hemp is considered a “bioaccumulator” or “phytoremediator.” It absorbs heavy metals and other chemical waste from the soil. Accordingly, if large quantities of hemp are being cultivated to produce CBD, it is critically important that the quality of the soil is closely monitored and regulated.”

²² [Janet Burns](#). 2018. “Tests of CBD oils reveal three surprise chemicals, one big problem.”