VIA ELECTRONIC DELIVERY

Tuesday, July 16, 2019

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Public Comments Submission (Docket FDA-2019-N-1482) Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds

Dear Sir/Madam:

The undersigned organizations write to provide comments in response to the U.S. Food and Drug Administration's (FDA) request for comments on Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds dated April 3, 2019. In addition, several organizations have submitted separate comments that address certain issues in further detail.

As the market for cannabidiol (CBD)-based products increases exponentially in the United States – a market expected to exceed $20 billion by 2024[1,2] – so does the need for concurrent, proactive and responsive interventions by the FDA to protect and promote public health and consumer safety. Recognizing that the industry projects significant growth over the next several years, we must ensure a regulatory environment that is both effective and responsive to market shifts, new entrants and the inherent risks from abuses from bad actors.

Substances – be it prescription drugs, dietary supplements, or foods – derived from cannabis must, at a minimum, be subject to the same regulations and enforcement as any other substance marketed and sold to consumers, especially vulnerable populations. While the only FDA-approved CBD-based treatment has demonstrated therapeutic benefits for specific indications, substantial evidence should be required to determine safety for any marketed product. Safety risks associated with CBD have been identified, including the potential for drug-induced liver injury and other drug-drug interactions. Furthermore, the prevalence of unsubstantiated therapeutic claims for CBD products may lead consumers to reject other evidence-based treatment options.

Poor quality, misbranded, fraudulent, adulterated or contaminated CBD-based products place patients and consumers at risk. Consumers, healthcare providers, patients and caregivers should be able to rely on existing regulatory schema and expect that CBD-derived products available for purchase are manufactured in accordance with current good manufacturing practices and safe for use as directed.

As the FDA deliberates on how to regulate CBD-based products, we urge the agency to:

- **Strengthen industry oversight of marketed CBD-based products**. Regulation and oversight of marketed CBD-based products, foods, dietary supplements, and medicines rightly fall under the jurisdiction of the FDA. With the significant expansion of the CBD-based product market and subsequent availability, it is imperative FDA take action to protect consumer safety and public health. We urge FDA to remain faithful to its science-based, regulatory approach to product regulation generally.

[1] https://bdsanalytics.com/u-s-cbd-market-anticipated-to-reach-20-billion-in-sales-by-2024/
[2] https://www.consumerreports.org/cbd/cbd-goes-mainstream/

- **Establish clear differentiation between FDA-approved medicines for treatment of disease versus consumer-focused products, such as dietary supplements and foods.** This will help support incentives for research and development of FDA-approved cannabis-based medicines and will likely improve the safety and quality of products seeking to enter the market. Amongst other things, concentration limits for both CBD and THC[3] must be set in order to distinguish an FDA regulated medicine from a dietary supplement/food, or other non-pharmaceutical product.
- **Proceed judiciously in developing regulatory structures without use of enforcement discretion**. We urge the agency to act thoughtfully in the development and implementation of a comprehensive regulatory structure for CBD-based products. Given the complex nature of this burgeoning market, the FDA should be afforded adequate time to solicit public feedback and draft a final rule. In the meantime, however, we urge the agency to not adopt a policy of enforcement discretion. Use of enforcement discretion in this context sends the wrong signal to consumers, who rely on FDA to protect their safety, and to manufacturers and retailers of high-quality CBD-based products, who depend on FDA enforcement against bad actors in order to allow a robust, safe CBD market to develop.
- **Create an incentive structure that strongly encourages investment in rigorous CBD product-related research.** An incentive structure is needed to encourage investment in the rigorous research necessary to realize the therapeutic potential of the cannabis plant, develop robust safety and efficacy data on which healthcare professionals and patients can rely, and offer FDA-approved treatment options to patients suffering from serious ailments. This structure should encourage the development of data and standards for all CBD-based products – prescription drugs, dietary supplements, foods, and cosmetics – and include research on safe concentration limits of THC in these products.
- **Implement robust data reporting system, specific to adverse events related to use of CBD-based products.** Too often consumers, caregivers and healthcare providers either do not know how or simply do not report adverse events. This is true across product categories, but especially relevant today given the state of the CBD product market. Having insight into whether and which CBD products on the market include undisclosed THC or other potentially harmful ingredients – often resulting in consumer harm – will be critical to the development of appropriate interventions and policies throughout FDA, states, retailers, and industry.

Thank you in advance for your careful consideration of our views. We applaud the FDA for its leadership on protecting and safeguarding the health of consumers and stand ready to assist the agency as it develops and implements a coordinated oversight strategy over the CBD industry. Please know that the undersigned organizations stand ready to serve as a resource to the agency.

Sincerely,

Aimed Alliance

Anxiety and Depression Association of America

Association of Migraine Disorders

Bridge the Gap – SYNGAP Education and Research Foundation

Depression and Bipolar Support Alliance

Greenwich Biosciences

LegitScript

National Association of County Behavioral Health and Developmental Disability Directors

National Consumers League

National Council for Behavioral Health

[3] THC – Tetrahydrocannabinol