CCSS
The Collaborative for CBD Science & Safety

VIA ELECTRONIC DELIVERY

Thursday, September 17, 2020

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

RE: Comments from the Collaborative for CBD Science and Safety on "Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research" (FDA-2020-D-1079)

Dear Commissioner Hahn:

The Collaborative for CBD Science and Safety (CCSS; http://www.CBD-Collaborative.org/) is an informal organization of stakeholders throughout the healthcare delivery system and supply chain who have come together to exchange information, build alliances around shared interests and priorities, and respond to policies and practices affecting cannabidiol (CBD) availability, research, safety, and quality. We first wish to thank you and your colleagues for your ongoing efforts to ensure the health and wellbeing of individuals nationwide, particularly during the current COVID-19 pandemic. We write today in response to the recent draft guidance for industry released regarding "Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research."

Embedded within our organization's name is our commitment to rigorous science and the development of robust research. We believe that decision-making throughout the cannabis and cannabis-derived product industry, including commercialization of cannabidiol (CBD), must rely upon scientific standards and best practices that promote the availability of high-quality products made accessible to consumers and patients nationwide. Equally important is the development of a regulatory framework that ensures clarity and consistency for product development and manufacture for industry, healthcare providers, and consumers alike. It is imperative that laws and regulations incentivize further research of CBD, recognizing current patient demand and consumer use and interest in all these products.

We commend the FDA for its release of the draft guidance document and ongoing efforts to create a better infrastructure by which to research and develop cannabis and cannabis-derived products. CCSS further calls FDA's attention to the fact that a significant portion CBD and CBD-containing products currently on the market (whether marketed as drugs, dietary supplements, foods or cosmetics) have not undergone sufficiently rigorous requirements that would protect consumers from harm–both physical and financial. FDA must assure that incentives exist for research and development geared towards CBD-based prescription drugs and related products. Such incentives for continued drug development of CBD for potential disease-related applications are critical to fostering continued research in this area.

A limited review of ClinicalTrials.gov demonstrates the need for greater incentives and a clearer path forward as a significant number of such trials remain in Phase 1 or early Phase 2. In order to advance our understanding and utilization of cannabis and cannabis-derived products (both consumer goods and medical products), research efforts must extend beyond "proof of concept" and help answer many of the research questions referenced in the indefinite reopening the public docket in March 2020.

FDA, however, must also recognize the potential non-drug applications of CBD and other hemp-derived compounds. In the absence of a clear regulatory framework by FDA for the manufacturing and marketing of these products, the marketplace has exploded with products of uncertain origin, contents and safety, with high quality, well-researched products on shelf next to less reputable ones. Innovative marketers are offering these products for a host of non-drug uses including moisturizers, relaxation, sleep, temporary muscle soreness relief, and others. It is important to continue purposeful research into the safety and benefit profiles of these products recognizing ongoing and growing consumer use. Focusing incentives only on drug research, without acknowledging these other uses, will lead to continued proliferation of substandard, and potentially dangerous, products.

The ongoing need for further clinical research and evidence development within this space is clear. As a Collaborative, we encourage the FDA to continue to provide guidance to industry that will incentivize and prioritize the development of legitimate scientific research that will work towards the creation of safe, high-quality products for the consumers and patients who need them across all product categories.

We thank you for your considerations of these comments and stand ready to assist the agency in forthcoming efforts to prioritize consumer and patient health and safety.

Respectfully,

The Collaborative for CBD Science and Safety

cc: Amy Abernethy, MD, PhD, *Principal Deputy Commissioner, FDA*
Lowell Schiller, *Principal Associate Commissioner for Policy, FDA*
Janet Woodcock, MD, *Director, Center for Drug Evaluation and Research, FDA*
Patrizia Cavazonni, MD, *Deputy Director for Science Operations, Center for Drug Evaluation and Research, FDA*