Co-Sign Letter to FDA Urging Quick Action on CBD

Dear Colleague:

Please join us in urging the U.S. Food and Drug Administration (FDA) to act quickly to provide legal clarity and to establish a regulatory pathway for food products containing hemp-derived cannabidiol (CBD).

As you know, the 2018 Farm Bill removed CBD and hemp-derived products from the Controlled Substances Act, while preserving FDA's regulatory authority over CBD under the Federal Food, Drug and Cosmetic Act (FDCA). This significant development – coupled with a more permissive approach by the States – has already led to the quick growth of a new industry that is fueling local economies and creating jobs. However, FDA's current regulatory approach on CBD has created significant regulatory and legal uncertainty for participants in this quickly evolving industry. FDA maintains that food products containing CBD remain illegal under the FDCA because it is the active ingredient in an epilepsy drug, Epidiolex, that is undergoing clinical trials. Although the agency is exploring alternative regulatory pathways, the FDA claims that a rulemaking process could take the agency anywhere between 3-5 years to complete.

The FDA's projected regulatory timeframe is untenable, especially in light of the fact that the Department of Agriculture (USDA) is expected to greenlight the legal production of industrial hemp for the 2020 crop year any day now. Given the widespread availability of CBD products, growing consumer demand, and the expected surge in the hemp farming in the near future, it's critical that FDA act quickly to provide legal and regulatory clarity to support this new economic opportunity.

Please join us in signing this bipartisan letter to Acting FDA Commissioner Ned Sharpless urging the agency to adopt a risk-based policy of enforcement discretion that targets bad actors while eliminating uncertainty for responsible industry stakeholders and consumers. Additionally, we are requesting that FDA to issue an interim final rule to regulate CBD as a dietary supplement and food additive.

For more information or to sign the letter, please contact Kelliann Blazek in Rep. Pingree's office at kelliannblazek@mail.house.gov, or Elissa Gilliam in Rep. Comer's office at elissa.gilliam@mail.house.gov to cosign the letter by COB Tuesday, September 17th.

Sincerely,

Rep. Chellie Pingree
Member of Congress

Rep. James Comer
Member of Congress

September 12, 2019

The Honorable Ned Sharpless
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Acting Commissioner Sharpless:

We write concerning the U.S. Food and Drug Administration's (FDA) current regulatory position towards hemp-derived cannabidiol (CBD). We urge the agency to quickly adopt a policy of enforcement discretion and to consider issuing an interim final rule to regulate CBD as a dietary supplement and food additive while simultaneously moving forward with a robust framework for evaluating the safety and accurate labeling of these products.

As you know, the 2018 Farm Bill[1] removed CBD and hemp-derived products from the Controlled Substances Act, while preserving FDA's regulatory authority over CBD under the Federal Food, Drug and Cosmetic Act. This significant development – coupled with a more permissive approach adopted by a plurality of States – has already led to the quick growth of a new industry that is fueling local economies and creating new jobs. During these challenging times for the agricultural economy, farmers are excited to plant legal hemp and are eagerly awaiting the U.S. Department of Agriculture's (USDA) soon-to-be released regulatory framework that will enable farmers to invest in a new crop. Business and consumer interest in CBD and hemp products has skyrocketed, and companies are already capitalizing on the growing demand. CBD products are available in a variety of forms, such as tinctures, pills, lotions and oils, and these products are sold in nearly every retail format, including coffee shops, grocery stores, convenience stores, and even fast food chains. Once industrial hemp production is greenlit by USDA, growth in the market for hemp-derived products is expected to multiply.[2]

We appreciate FDA's proactive approach towards pursuing a legal pathway for the production and sale of hemp-derived products containing CBD, especially its convening of a stakeholder meeting on May 31, 2019 and the establishment of an internal Cannabis Working Group. However, FDA's current regulatory posture on CBD has created significant regulatory and legal uncertainty for participants in this quickly evolving industry. We are discouraged by FDA's estimation that a rulemaking process could span 3 to 5 years. We believe there are more expeditious measures that FDA could take that would establish regulatory clarity while pursuing enforcement actions against bad actors.

First, the agency should promptly issue guidance announcing a policy of enforcement discretion that maintains FDA's current risk-based enforcement approach towards hemp-derived CBD products. Since 2017, the agency has issued nine warning letters to firms that market CBD in

[1] Agricultural Improvement Act of 2018 (P.L. 115-334).
[2] U.S. CBD Market Report, Brightfield Group (2019), https://www.brightfieldgroup.com/library/us-cbd-market-report-2019.

instances of fraud and egregious health marketing claims. We support FDA continuing to pursue enforcement actions against the worst offenders, but it can do so while eliminating regulatory uncertainty for farmers, retailers, and consumers. Without a formal enforcement discretion policy, anyone participating in the growing marketplace for legal hemp-derived products will continue to face significant legal and regulatory uncertainty.

Second, we call on FDA to consider issuing an interim final rule, pending issuance of a permanent final rule, to establish a clear regulatory framework for CBD as a dietary supplement and food additive. Although FDA currently classifies CBD as a drug because it is the active ingredient in Epidiolex, an approved epilepsy drug, it has the authority to also classify lower doses as a food additive or dietary supplement.[3] This two-track regulatory approach could enable lower dosed products with limited health risks to enter the market as a dietary supplement, while requiring higher dosages in drugs, such as Epidiolex, to be prescribed by medical professionals. The medical research conducted on CBD to date has shown limited health risks associated with low dosages of CBD, with potentially significant health benefits.[4] Unfortunately, the absence of a clear pathway to market for CBD-containing products means consumers currently face a variety of risks, from unsubstantiated health and benefit claims, to a lack of standardization in product labeling and packaging, to products that may not contain the ingredients it purports to contain.

Given the widespread availability of unregulated CBD products, growing consumer demand, and the expected surge in hemp farming in the near future, we believe that FDA must quickly act to provide legal clarity and to establish a regulatory framework that supports this exciting new opportunity. Regulatory certainty will allow the legal hemp industry to flourish while opening up exciting new economic opportunities for farmers and entrepreneurs in a way that protects consumers.

We appreciate your attention to this important matter.

Sincerely,

[3] 21 U.S.C. §§ 3219(ff)(3)(B) and 331(11)(2).

[4] The Health Effects of Cannabis and Cannabinoids, National Academies of Sciences, Engineering, and Medicine (January 2017), https://www.nap.edu/resource/24625/Cannabis_committee_conclusions.pdf.