August 12, 2019

The Honorable Ryan Quarles
Commissioner
Kentucky Department of Agriculture
Corporate Drive Complex
Frankfort, KY 40601

Dear Commissioner Quarles:

Thank you for your letter to Acting Commissioner Ned Sharpless, dated May 31, where you encourage the Food and Drug Administration (FDA or the Agency) to use states as a resource as the Agency applies its rigorous, science-based approach to products containing cannabis or cannabis-derived compounds. Your message has been forwarded to FDA's CBD Policy Working Group for response.

FDA has been taking a consistent approach to cannabis and cannabis-derived compounds. We treat substances derived from cannabis just like we do any other substances, and they are subject to the same authorities as any other substance. When appropriate, this means focused help for specific products to help speed their development (https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review). That said, we know that some of the laws have changed, as well as the market. On the state level, some jurisdictions have eliminated certain prohibitions on cannabis or cannabis-derived compounds. On the Federal level, the Agriculture Improvement Act of 2018 (Farm Bill) removed hemp from the definition of marijuana in the Controlled Substance Act (CSA), which means that cannabis plants and derivatives tbat contain no more than 0.3 percent THC on a dry weight basis are no longer controlled substances under Federal law. This change may streamline the process for researchers to study hemp and certain cannabis derivatives, including cannabidiol (CBD), which could speed the development of new drugs from those substances. At the same time, that legislation specifically preserved FDA's responsibility over such products.

While some laws have changed, and as more cannabis products come to the market, whether lawfully or otherwise, FDA's role is becoming more practically relevant to many affected stakeholders. We recognize the need to be clear and open about where things stand in regard to FDA regulation of cannabis products, and about the efficient and science-based way in which we are moving forward. This includes being transparent and up-front with our state partners and the public as we continue to collect information and data to deepen our understanding of cannabis and cannabis-derived compounds, including CBD.

While we recognize the potential benefits of CBD, questions remain regarding its safety. During our review of the marketing application for Epidiolex, we identified certain safety risks, including the potential for liver injury. Furthermore, unsubstantiated therapeutic claims – such as claims that CBD products can treat serious diseases – can lead consumers to put off getting important medical care. Over the past several years, the Agency has issued several warning letters to firms that were marketing unapproved new drugs claiming to contain CBD, including for uses such as treating cancer or Alzheimer's disease. These products were not approved by FDA for the diagnosis, cure, mitigation, treatment, or prevention of any disease. Consumers

should beware of purchasing and using any such products. FDA also tested the chemical content of cannabinoid compounds in some of the products, and many were found not to contain the levels of CBD they claimed to contain. The information we have underscores the need for further study and high quality, scientific information about the safety and potential uses of CBD.

As you know, as part of our effort to seek additional scientific information regarding the safety and potential uses of CBD, FDA recently held a public hearing in which we solicited stakeholder views and concerns. We opened a public docket to obtain additional feedback from stakeholders, with a specific interest in information and views related to safety. In response to requests, we extended the comment period beyond the original closing date until July 16 to allow all stakeholders the chance to submit comments.

FDA understands the importance of communicating clearly with state officials and the public about our approach to CBD, and we are taking an Agency-wide, integrated, and collaborative approach to addressing the regulation of products made from CBD that fall under our jurisdiction. While we continue to believe that the drug approval process is the best way to ensure the safety of new drugs, including those made with CBD, the Agency is committed to evaluating potential pathways for various types of CBD products to be lawfully marketed for non-drug uses, including products marketed as foods and dietary supplements. We have formed an internal Agency working group to consider this issue, including a consideration of what statutory or regulatory changes might be needed and what the impact of such marketing would be on the public health. Should we move ahead with rulemaking to allow the use of CBD in non-drug products, there will be opportunity for additional comments and we welcome any information or perspectives that you, other state officials, or the public wish to share.

We remain steadfast in our effort to obtain research, data, and other safety and public health input to inform our approach and to address consumer access in a way that protects public health, maintains incentives for cannabis drug development, and creates a robust administrative record. We will continue to work closely with our state and Federal partners as we learn more about CBD and cannabis through rigorous and appropriate scientific research. We will also continue to update you, our other state partners, and the public about our path forward and provide information that is based on sound science and data obtained through that research.

Thank you for contacting us concerning this issue. If you have further questions regarding this or any other FDA-related matter, please contact our Intergovernmental Affairs team at IGA@fda.hhs.gov.

Sincerely,

Amy Abernethy, M.D., Ph.D.
Principal Deputy Commissioner
Co-Chair, FDA CBD Policy Working Group