02.Sept.2021

The Honorable Charles Schumer
Senate Majority Leader
United States Senate
The Capitol, S-230
Washington, DC 20510

The Honorable Cory Booker
717 Hart Office Building
Washington, DC 20510

The Honorable Ron Wyden
221 Dirksen Office Building
Washington, DC 20510

Regarding: The *Cannabis Administration and Opportunity Act*, Discussion Draft

Dear Majority Leader Schumer, Senators Booker and Wyden:

Thank you for the work in drafting the *Cannabis Administration and Opportunity Act* (Discussion Draft). In addition to de-scheduling the plant, the Discussion Draft broaches a federal regulatory framework for the cannabis plant, of which an appropriate federal regulatory backstop has been absent from other cannabis-related legislative measures. This is a much-needed critical step and we appreciate your serious consideration of how best to structure federal oversight.

The below signed stakeholders are providing comments in response to the provision in the Discussion Draft concerning the hemp-derived cannabidiol (CBD) ingredient. The signatories collectively are either brand holders, have an interest in the U.S. domestic hemp production program or work with stakeholders in consumer-packaged goods for CBD and other hemp ingredients. The absence of comments to other provisions in the Discussion Draft is not an indication of approval or disapproval of those provisions. The scope of the comments in this letter is limited to CBD specifically, and other hemp ingredients generally, and additional comments (if any) will be provided under separate cover.

The crux of the regulatory confusion and market instability with CBD lies with the Food and Drug Administration's (FDA) application of the drug exclusion rule[1] to CBD, which has been applied to all forms of CBD and hemp that contains CBD, through an agency position versus the formal rule making process. Since the Food, Drug, and Cosmetic Act (FDCA) is fully equipped to regulate CBD and other hemp ingredients – in a food, dietary supplement, or beverage, once this key issue is resolved, hemp and CBD stakeholders will have the certainty needed to navigate the FDCA and produce safe, quality products. Hemp should be treated the same as any other ingredient and as such, a special regulatory pathway is not needed nor justified. With that, we value this opportunity to provide comments and welcome further discussion.

In response to Sec. 505 Regulation of Cannabidiol in the Discussion Draft, we recommend,

1) that the food and beverage categories, in addition to dietary supplement products, be included in any clarifying hemp-derived cannabidiol and other hemp legislation.

2) the removal of the requirement that all CBD and hemp-containing dietary supplement products submit a new dietary ingredient (NDI) notification to the FDA.

    (i) Certain dietary supplement brands will have to submit NDI notifications, as required under DSHEA; however, to require all CBD and hemp-containing products to submit NDI notifications is a costly exercise – certainly for small operations – and to what end. Statistics show that the NDI process has not been overly successful, nor do we believe the agency is equipped to timely review NDI notifications. Furthermore, the current NDI process is subject to a draft guidance document, which carries no legal weight, has yet to be finalized, and has arguably reached beyond the statutory standard of 'reasonably expected to be safe.' This adds to the uncertainty on the exact type of data and information that is needed to satisfy the NDI notification (not approval) measure. If CBD and hemp-containing dietary supplement products were truly new to the market, then perhaps a blanket NDI requirement would be appropriate; however, these products have been on the market for several years.

3) the inclusion of further instruction to the Secretary that if the option to set a recommended daily serving of CBD is exercised, that any such threshold to be established is limited to the level of CBD as found in the drug product Epidiolex®.

4) the inclusion of language that, moving forward, FDA must proceed with formal rulemaking before applying the drug exclusion rule to any substance. This language would serve to avoid future regulatory paralysis for CBD, hemp, and other ingredients.

[1] U.S. Food, Drug, and Cosmetic Act (FDCA) §§201(ff), 301(ll) (21 U.S.C. §§321(ff), 331(ll)).

We believe these recommendations help balance the interests of all stakeholders to include consumers, U.S. hemp farmers, brand holders and the FDA- and we also believe these recommendations will facilitate a boost to the U.S. economy. Due to the unique confluence of events to include the enactment of a U.S. domestic hemp production program, the great and growing consumer demand for high-quality hemp and CBD products, FDA's concession that a legislative solution is the most expedient, and the number of states that have enacted programs to regulate and allow hemp-CBD containing within their intrastate markets, we fully support and welcome a legislative solution. That said, the legislative solution must be appropriate otherwise the solution to the current issue is merely replaced with a subsequent regulatory quagmire.

U.S. hemp farmers are ready to be the supply source to meet the consumer demand for high-quality hemp and CBD products. Thank you for the willingness to address the regulatory uncertainty of cannabidiol and other hemp-derived ingredients in the *Cannabis Administration and Opportunity Act*. If you would like to further discuss or connect with any of the below signatories, please reach out directly or ring Tami Wahl, 202.975.9221.

Sincerely,

Rod Kight, Kight Law Group

William Kleidon, California Hemp Council

Blake Butler, Southeast Hemp Association

Garrett Perdue, Root Bioscience

Dan Hentschke, Charlotte CBD

Mike Sims, Crowntown Cannabis

Dr. Shawn Seitz, Alpha Tech Pet

Eric Steenstra, Vote Hemp

Mike Lewis, Hemp Industries Association

Jeremy Johnson, Traditional Medicinals

Ross Sloan, West Town Bank

Tyler Stone, Sycamore BioPharma

Ander Schreiner, Ssiirrii, Inc. dba Earthy Now

Daniel Young, Grasslands Botanicals

Janel Ralph, RE Botanicals and Palmetto Harmony

Tami L. Wahl, Modern Advocates