April 21, 2020

Dear Gov. Northam;

I hope this finds you well. Congratulations on being the first state to declare Cannabidiol (CBD) as a food under the law of the Commonwealth. With the signing of Senate Bill 918 into law, we wanted to inquire about the Administration and Board's plans for implementation of the law, especially in light of the position of the U.S. Food and Drug Administration (FDA).

The FDA has maintained its stance that is presented on its webpage as *"FDA has concluded that THC and CBD products are excluded from the dietary supplement definition under sections 201(ff)(3)(B)(i) and (ii) of the FD&C Act, respectively. Under those provisions, if a substance (such as THC or CBD) is an active ingredient in a drug product that has been approved under 21 U.S.C. § 355 (section 505 of the FD&C Act), or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are outside the definition of a dietary supplement. FDA considers a substance to be "authorized for investigation as a new drug" if it is the subject of an Investigational New Drug application (IND) that has gone into effect. Under FDA's regulations (21 CFR 312.2), unless a clinical investigation meets the limited criteria in that regulation, an IND is required for all clinical investigations of products that are subject to section 505 of the FD&C Act."* Moreover, the page goes on to add further clarity that "*There is an exception to sections 201(ff)(3)(B)(i) and (ii) if the substance was "marketed as" a dietary supplement or as a conventional food before the drug was approved or before the new drug investigations were authorized, as applicable. However, based on available evidence, FDA has concluded that this is not the case for THC or CBD. For more information on this provision, including an explanation of the phrase "marketed as*" please see *the Dietary Supplement Health and Education Act of 1994 Public Law 103-417*. Additionally, we are aware of the warning letters FDA has sent to companies marketing CBD as dietary supplements.

Despite the agency's actions and message, the market for CBD products in the US is surging and consumers are confused. According to a recent NPA survey, 44% of Americans are less likely to use CBD products after learning that theFDA has no standards in place to protect consumers, including 30% who say they would be far less likely to use the products based upon this information. Likewise, the poll also found that 47% of people who use CBD products would stop using them if they or someone they knew became ill after consuming CBD. Seventy percent of registered voters believe FDA should have already established safety standards for CBD products. Other crucial findings of the poll include:

• 65% believe Congress should direct FDA to quickly set safety standards for CBD products.

• 67% did not know or weren't sure that CBD products being sold today are illegal.

• 41% wrongly assumed FDA had already developed safety standards for CBD.

• 30% who have not used CBD products and 76% of CBD users were more likely to try them if they knew the FDA approved regulations determining a level that could be considered safe for use in foods and nutritional supplements.

With these factors in mind is the goal of the Commonwealth to challenge the current position of the FDA with regard to CBD or, is it to work with them on developing a Federal Standard with regards to CBD safety and quality standards? Additionally, what is the anticipated timeline for the Administration in the development of a compliance plan for those companies involved with the entire supply chain of CBD

(seed-to-shelf) regarding daily exposure to CBD, labeling standards, testing standards for THC and current Good Manufacturing Practices (cGMPs)?

Our Association and our member companies appreciate the action and leadership on this important issue. Wewould welcome the opportunity to meet with you to discuss this matter as described above and to consider any other ways that we could assist the Commonwealth with regards to CBD and ensuring its safe and responsible use by Virginians. Thanks for your consideration of this matter,

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