

July 16, 2019

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Via Electronic Submission

Norman E. Sharpless, M.D., Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Re: Docket No. FDA-2019-N-1482
Scientific Data and Information About Products Containing Cannabis or
Cannabis-Derived Compounds

Dear Commissioner Sharpless,

We, the undersigned State Attorneys General, submit this comment in response to the Food and Drug Administration's ("FDA") requests for comments on the safety, manufacturing, and sale of products containing cannabis or cannabis-derived compounds.¹ Importantly, in considering regulation of products that contain cannabis or cannabis-derived compounds, including cannabidiol (CBD), the FDA should continue to incorporate State Attorneys General feedback and ensure that states maintain a role as regulators in this emerging market.

As the primary enforcers of our respective states' consumer protection laws, we offer a unique perspective as to the new legalized market of certain cannabis and cannabis-derived compounds, including CBD products. We write to express our hope that the FDA continues to explore manufacturing, testing, and marketing best practices so that consumers are not at risk of misleading advertising or harm to their health from dangerous additives or undisclosed risks of use. Although products containing cannabis or cannabis-derived compounds may well offer real benefits to consumers, it is important that consumers have reliable risk and benefit information to make informed choices about initiating and continuing the use of these products. A crucial element of FDA regulation and oversight should be an on-going assessment of the potential risks or benefits of these products, particularly for specific populations such as pregnant women, adolescents and children, and the elderly. How these products interact with other dietary or pharmaceutical products should be included in this assessment. It is also important that companies not mislead consumers. Scientific and medical data from the FDA would assist in meaningful enforcement of advertising laws and regulations by the states.

Currently, companies are creating a myriad of cannabinoid products largely unburdened by any oversight or testing requirements. The inherent complexity of cannabinoids, combined with the danger of hazardous additives, raises

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¹ See Request for Comments, Scientific Data and Information About Products Containing Cannabis or Cannabis-Derived Compounds, 84 Fed. Reg. 12,969 (April 3, 2019).

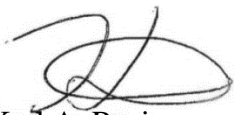
serious public health concerns that absent some rules or regulations, unscrupulous companies will be able to distribute products that include illegal cannabinoid combinations or have dangerous additives.

Beyond these dangers, there is also the potential for products to be incorrectly or misleadingly labeled and packaged in ways that take advantage of consumers and puts them at risk. Although many operational companies making cannabis and CBD products appropriately test, package, and label their products, some do not. These products should be subject to testing and manufacturing guidelines in order to keep consumers appropriately informed and safe.

Ultimately, the responsibility for protecting consumers that use cannabinoids and CBD products cannot solely be left to the companies supplying products—that responsibility must include the FDA with meaningful partnerships with the states and State Attorneys General. We applaud the FDA’s recent steps, including the formation of the CBD working group focused on exploring pathways for dietary supplements and food regulation, seeking to clarify code citations, regulating cosmetics, and researching existing science and developments.

We appreciate the FDA’s willingness to listen to and consult with State Attorneys General on regulation of cannabinoids and CBD products. We hope that the FDA will continue to recognize the important role that states play in this emerging market, and that the FDA will incorporate the ongoing feedback that State Attorneys General provide.

Sincerely,



Karl A. Racine
District of Columbia Attorney General



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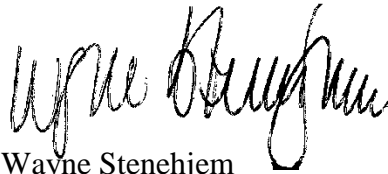
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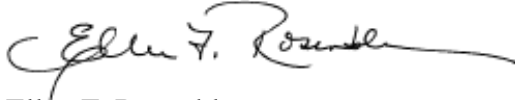
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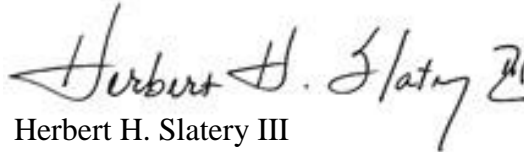
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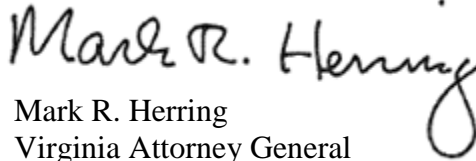
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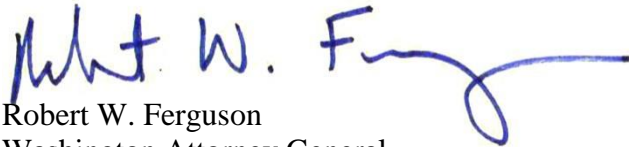
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