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June 25, 2019

The Honorable Alex Azar
Secretary
Department of Health & Human Services
200 Independence Ave, SW
Washington, DC 20201

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

Dear Secretary Azar and Acting Commissioner Sharpless,

I write with concern regarding the current approach of the Food and Drug Administration (FDA/agency) to regulating hemp-derived cannabidiol (CBD). I urge the agency's prompt action to issue guidance announcing a formal enforcement discretion policy by August 1, 2019, and – pending publication of a permanent final rule – issue an interim final rule that ensures a regulatory pathway for lawful use of CBD as a food additive and as a dietary ingredient in dietary supplements.

As you know, Public Law 115-334 – the Agriculture Improvement Act of 2018 (2018 Farm Bill) – removed hemp and its derivatives (including cannabinoids) from the list of controlled substances. Further, the 2018 Farm Bill established hemp as a legal agricultural commodity and authorized the production, consumption, and sale of hemp and hemp-derived products in the United States, consistent with other laws, such as the Food, Drug, and Cosmetic Act (FDCA).

The passage of the 2018 Farm Bill is Congress's clear intent to further advance and support the domestic production and sale of hemp and hemp derivatives like CBD. Hemp growers and producers in states like Oregon are poised to make significant economic gains from hemp and its derivatives, but only if the federal regulatory system ensures the lawful and safe use of these recently liberated products. To that end, the United States Department of Agriculture (USDA) has issued a legal opinion through the agency's Office of the General Counsel, which, among other actions, recognizes the federal legality of hemp extract.

I am pleased the USDA has signaled – in the latest unified regulatory agenda – that it intends to issue an interim final rule to establish the regulatory framework for commercial hemp production in August 2019. This will give hemp farmers a measure of certainty, but the FDA's current inaction with respect to regulating hemp-derived CBD in manufactured products has caused confusion and uncertainty for hemp producers.

The day the 2018 Farm Bill became law (December 20, 2018), then-FDA Commissioner Gottlieb issued a statement indicating that the agency would continue to regulate hemp and

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hemp-derivatives like CBD under the existing authorities of the FDCA. His statement also reiterated FDA's view that, because FDA has authorized studies and approved CBD as a drug before the marketing of CBD-containing dietary supplements and conventional foods, existing law prevents use of hemp-derived CBD as an ingredient in a dietary supplement and its addition to conventional food.

However, FDA also highlighted that existing statutory authority allows the agency to pursue a pathway "...in which certain cannabis-derived compounds might be permitted in a food or dietary supplement." This statutory authority [21 U.S.C. §§ 321(ff)(3)(B) and 331(ll)(2)] allows for the Secretary of Health and Human Services to issue a regulation, after notice and comment, that would allow these hemp-derived products to lawfully enter the marketplace as a food or dietary supplement.

In the months since FDA's original statement, I have been pleased to hear statements from FDA leadership that acknowledge Congress's intent for the agency to take action and provide a legal pathway for the production and sale of hemp-derived products containing CBD. I also applaud the agency's appointment of an internal Cannabis Working Group as well as its convening of a public stakeholder meeting on May 31, 2019 to discuss hemp-derived CBD.

Moreover, I appreciate FDA's current risk-based enforcement approach toward hemp-derived CBD products in the marketplace, which has focused on those firms making egregious disease claims not otherwise permitted for conventional foods or dietary supplements. I view this approach as absolutely critical for the advancement of this new and rapidly growing industry. However, absent formal enforcement discretion guidance, hemp producers and their customers will continue to be left in a regulatory gray zone.

I fully embrace FDA's commitment to the promotion and protection of public health and understand that, with respect to hemp-derived CBD, the agency will be examining a number of health and safety considerations. Given these and other factors, I certainly acknowledge the challenges that FDA faces in expeditiously creating a legal pathway for hemp-derived CBD in foods and dietary supplements, especially since the agency has never used these rulemaking authorities before.

However, I, and many in the CBD industry, find FDA's indication that it may take three to five years to issue a final regulation authorizing the lawful use of hemp-derived CBD in foods and dietary supplements fully unacceptable. The regulatory confusion and uncertainty surrounding CBD cannot continue for that length of time.

Given these strong concerns, I urge FDA to immediately issue enforcement discretion guidance not later than August 1, 2019, and promptly issue an interim final rule, pending issuance of a permanent final rule, to ensure a regulatory pathway for lawful use of CBD as a food additive and as a dietary ingredient in a dietary supplement. Additionally, the agency must initiate permanent final rulemaking to allow manufacturing and sale of products containing hemp-derived CBD under the existing statutory and regulatory frameworks applicable to food and dietary supplements. I further urge you to streamline processes for submitting and prioritizing review of resulting new dietary ingredient and GRAS notifications for hemp-derived CBD

ingredients, including, without limitation, dedicating necessary agency staff to the process. I feel strongly the FDA must undertake a process to make lawful a safe level for conventional foods and dietary supplements containing hemp-derived CBD.

I believe this approach is both justified and necessary to address the unprecedented circumstances presented by the current availability of and demand for these products. I look forward to your prompt response.

Sincerely,

Ron Wyden
United States Senator