

**Congress of the United States**  
**Washington, DC 20515**

April 5, 2019

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

Dear Commissioner Gottlieb:

We are writing about cannabidiol (CBD)—an extract derived from hemp with health and wellness applications. Hemp was removed from Schedule 1 of the Controlled Substance Act following the passage of the Agriculture Improvement Act of 2018. Hemp, and its constituents, is an agricultural commodity and contains only trace amounts of tetrahydrocannabinol (THC)—the intoxicating substance found in marijuana.

Excluding hemp with less than 0.3 percent THC from the controlled substances list, and affirming its status as a legal agricultural commodity in the United States, one might assume that hemp-derived CBD would be afforded the same exemption. However, the Food and Drug Administration (FDA) maintains that CBD is unlawful as a food, beverage or dietary supplement. Provisions within the Food, Drug and Cosmetic Act (FDCA) prohibit any ingredient, previously studied as a drug component, from consideration as a dietary supplement. If it is determined that a substance was authorized for investigation as a new drug, that clinical trials had begun and that these investigations were made public before said substance was found in a food or dietary supplement, then the item in question falls outside the definition of a dietary supplement or conventional food and is therefore unlawful.

Creating a legal pathway to market for food, beverages and dietary supplements containing hemp-derived CBD makes sense and is consistent with FDA's public health goals. Recognizing CBD products as lawful foods, beverages or dietary supplements would allow the agency to impose a reasonable regulatory framework around the processing, manufacturing and marketing of hemp-derived CBD products not intended for use as drugs. It would also permit the agency to enforce existing regulations regarding registration of manufacturing facilities; observance of good manufacturing practices; supply chain security; compliance with food additive and new dietary ingredient notification for food and dietary supplements, respectively; and allow for post-surveillance with serious adverse event reporting, and mandatory recall.

We urge FDA, with its authority provided by FDCA, to study, develop and issue a regulation (subject to notice and comment) permitting the use of hemp-derived CBD as a food and dietary supplement. According to the Hemp Business Journal, hemp-derived CBD is already a \$200M market, and has the potential to reach \$650M in consumer sales over the next five years. With

growing demand for this product, it is imperative to protect consumers and find a legal pathway for hemp-derived CBD to ensure proper oversight of a popular ingredient.

We request a response at your earliest convenience.

Sincerely,

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John Curtis  
Member of Congress

A handwritten signature in blue ink, appearing to read "Tony Cárdenas", written over a horizontal line.

Tony Cárdenas  
Member of Congress