

United States Senate
WASHINGTON, DC 20510

January 15, 2019

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

Dear Commissioner Gottlieb,

As authors of the Hemp Farming Act, which removed the outdated restrictions on the production and marketing of industrial hemp, we urge the U.S. Food and Drug Administration (FDA) to immediately update federal regulations governing the use of certain hemp-derived ingredients in food, beverages or dietary supplements.

As you are aware, the Hemp Farming Act, which passed as a provision in the Agriculture Improvement Act of 2018, removed from the list of controlled substances the hemp plant, also known as *Cannabis sativa* L., and derivatives of cannabis, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol (THC) concentration of less than 0.3 percent on a dry weight basis. Under this definition, Congress legalized the production and sale of industrial hemp and hemp derivatives, including hemp-derived cannabidiol (CBD).

However, current, outdated regulations limit producers from taking full advantage of the industrial hemp market by, for example, prohibiting food products containing CBD from being sold across state lines. In recent years, the public has developed a widespread interest in the production and use of CBD, one of the primary non-psychoactive compounds in *Cannabis sativa* L. We therefore request the FDA immediately begin updating regulations for hemp-derived CBD and other hemp-derived cannabinoids, and give U.S. producers more flexibility in the production, consumption, and sale of hemp products.

Farmers in Oregon and nationwide are poised to make real economic gains for their communities once these regulations are updated.

We will be closely engaged in the ongoing implementation of our legislation, as it was Congress' intent to ensure that both U.S producers and consumers have access to a full range of hemp-derived products, including hemp-derived cannabinoids. However, we realize that the FDA is operating with limited staff due to the government shutdown. We request your response and answer to the following questions within 30 calendar days of the government reopening.

1. What steps are the agency advancing to clarify to the public the authority the agency has in the production and marketing of hemp, specifically Cannabis sativa L. and its derivatives?
2. What lawful pathways are currently available for those who seek approval to introduce Cannabis sativa L. and its derivatives as a food, beverages or dietary supplement, including into interstate commerce?
3. Are there circumstances in which Cannabis sativa L. and its derivatives may be permitted as a food, beverages or dietary supplement by the agency?
4. Will the agency consider issuing a regulation, or pursuing a process, that would allow Cannabis sativa L. and its derivatives in food, beverages or dietary supplements that cross state lines?

Sincerely,



Ron Wyden
United States Senator



Jeffrey A. Merkley
United States Senator