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ADVERTISING, MARKETING & PROMOTIONS

>> ALERT

FDA PUBLIC HEARING ON THE USE OF CANNABIS AND CANNABIS-DERIVED COMPOUNDS IN FOOD AND DIETARY SUPPLEMENTS

As the passage of the 2018 Farm Bill removed hemp from the schedule of controlled substances under federal law (creating a pathway for legal hemp-derived cannabidiol, also known as CBD), interest in manufacturing and marketing products containing CBD has skyrocketed.

However, then-Food and Drug Administration (FDA) Commissioner Scott Gottlieb issued a statement shortly after the passage of the Farm Bill to re-affirm that the FDA will treat food and dietary supplements with added CBD or tetrahydrocannabinol (THC) as "drugs" because CBD and THC are active ingredients in FDA-approved drugs. With Congress indicating that hemp-derived CBD is permissible though the Farm Bill and FDA stating that CBD may not be used in foods and dietary supplements, the industry is in a quandary over how to legally manufacture and market products containing CBD.

The FDA held a public hearing on May 31 in response to industry requests for more definitive rules on the use of CBD in food and dietary supplements. As a sign of the significant interest in this topic, over 1,300 people attended (live or via webcast) and 400 applicants requested to issue statements, with the FDA holding a lottery to select 113 speakers. The speakers included representatives from industry groups, trade organizations and state regulators.

THE BOTTOM LINE

- >> The FDA is in uncharted territory and has requested additional safety data to assess whether CBD and other cannabis-derived compounds can be safely added to food and dietary supplements.
- >> The industry believes that CBD has the potential for significant health benefits, but is open to strong regulations over its use.
- >> In order for comments to be considered, they must be submitted to the docket by July 2, 2019.

Acting Commissioner Dr. Ned Sharpless opened the meeting by noting that under current law, it remains illegal to add drugs to food and dietary supplements and the FDA would need to issue new regulations to create an exception for CBD, which it has never done before. Dr. Sharpless additionally noted, "there are real risks associated with [CBD and THC] and critical questions remain about the safety of their widespread use in foods and dietary supplements, as well as other consumer products – including cosmetics, which are subject to a separate regulatory framework."

A few themes emerged from the public comments. While certain groups were entirely against the FDA allowing the use of cannabis-derived compounds, including the Marijuana Victims Alliance, most commenters advocated for additional clinical trials to gauge the safety and efficacy of CBD, a national testing program and clear regulations, including adverse event reporting and labeling requirements. The commenters also requested that

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the FDA work quickly to sift through the data submitted and adopt interim regulations to address products that have already reached the market.

The docket to submit comments will remain open until July 2, 2019, but several commenters asked for additional time to submit data.

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