WHERE DOES THE LAW STAND ON PRODUCING FOODS AND BEVERAGES CONTAINING CANNABIDIOL (CBD)?

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In his April 2, 2019 press release, then-FDA Commissioner Scott Gottlieb, M.D., confirmed the agency's position that passage of the Agriculture Improvement Act of 2018 (the **2018 Farm Bill**) and its removal of "hemp" from Schedule 1 of the Controlled Substances Act did not disturb the FDA's current authority to regulate products containing cannabis or cannabis-derived compounds under the Federal Food, Drug, and Cosmetic Act (**FD&C Act**) and section 351 of the Public Health Service Act. In essence, the FDA retains authority to regulate foods, beverages and health products containing cannabis or derivative products such as cannabidiol (**CBD**).

Currently, FDA treats products containing cannabis or cannabis-derived compounds as it does other FDA-regulated drug products. FDA does not view CBD derived from hemp differently than any other CBD despite the fact that it is non-psychoactive. As a case in point: CBD is an active ingredient in Epidiolex – the sole FDA-approved prescription drug containing CBD. Therefore, under the logic of the FD&C Act, CBD is a "drug." If a substance has been "approved" by the FDA as an active ingredient in a drug product, it is per se excluded from being defined as a "dietary supplement" under sections 201(ff)(3)(B)(i) and (ii) of the FD&C Act and it cannot be included as an ingredient in food.

Among other things, the FDA requires a cannabis product (hemp-derived or otherwise) that is marketed with a claim of therapeutic benefit to be approved by the FDA for its intended use before it may be introduced into interstate commerce. Additionally, it currently remains is unlawful to introduce food containing added CBD, or the psychoactive compound tetrahydrocannabinol (**THC**), into interstate commerce, or to market CBD or THC products as dietary supplements. As explained above, this is because CBD and THC are active ingredients in FDA-approved drug products and were the subject of substantial clinical investigations before they were marketed as food. In such situations, with certain exceptions that are not applicable to this analysis, the only path that the FD&C Act allows for such substances to be added to foods or

marketed as dietary supplements is if the FDA first issues a regulation, through notice-and-comment rulemaking, allowing such use. This process has not yet occurred.

It's worth noting that FDA will be convening a public hearing in Washington DC on May 31, 2019, for stakeholders to share their experiences and challenges with CBD products, including information and views related to product safety. The public hearing is intended to give stakeholders an opportunity to provide the FDA with additional input relevant to the agency's regulatory strategy related to existing products, as well as the lawful pathways by which appropriate products containing cannabis or cannabis-derived compounds – including CBD -- can be marketed, and how the agency can make these legal pathways more predictable and efficient.

Until that happens, though, it may be relevant to know that some states are trying to take matters into their own hands. For example, the California State Assembly recently passed Assembly Bill A.B. 228 that permits the inclusion of CBD in food and beverages. Colorado has already passed a similar bill. Other states such as Ohio and cities such as New York City have gone the other way, prohibiting CBD from being added to food or beverages.

Finally, contemplating the production of alcoholic beverages containing CDB, think twice! The U.S. Alcohol and Tobacco Tax and Trade Bureau (TTB) stated in an industry circular released on April 25, 2019, that it would not issue a Certificate of Label Approval (COLA) for alcohol beverages containing hemp-derived CBD.

> It remains TTB's policy that it will not approve any formulas for alcohol beverages that contain ingredients that are controlled substances under the CSA. Even if an ingredient derived from cannabis is not a controlled substance because it meets the new definition of "hemp," TTB continues to consult with the U.S. Food and Drug Administration (FDA), to determine if the use of hemp ingredients would violate the Federal Food, Drug, and Cosmetic Act (FD&C Act). As described below, FDA has issued public statements explaining why some "hemp" ingredients are not permitted in food under the FD&C Act, which FDA administers.
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> After consultation with FDA, as set forth in more detail below, TTB has determined that, at this time, it will return for correction any applications for formulas containing "hemp" ingredients (other than ingredients derived from hemp seeds or hemp seed oil). Applicants will have the option of resubmitting the formula to TTB upon receipt of a favorable individual determination from FDA on the regulatory status of their ingredients. TTB will continue to process applications for formulas for alcohol beverages that contain ingredients derived from hemp seeds or hemp seed oil.

The full text of TTB's Industry Circular 2019-1 document is accessible online at: https://ttb.gov/industry_circulars/archives/19-1.shtml

If you have questions, or if you need any additional information relating to CBD products or their regulation, please contact our Cannabis Industry Law Team at **(800) 338-3381**.