Health Care Alert: FDA Announces Public Hearing to Inform Regulatory Next Steps with Respect to CBD Products

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On April 3, 2019, the federal Food and Drug Administration (FDA) published a notice in the Federal Register (available in full here) announcing a public hearing and related comment period regarding stakeholders' experience with products containing the cannabis derivative cannabidiol, popularly known as "CBD."

By way of background, the Agriculture Improvement Act of 2018 (also known as the 2018 Farm Bill) recently removed "hemp" – defined as cannabis and cannabis derivatives with tetrahydrocannabinol (THC) concentrations of no more than 0.3 percent on a dry weight basis – from the definition of "marijuana" under the federal Controlled Substances Act (CSA). While hemp is no longer a controlled substance under federal law, hemp and any products derived from it, including CBD, still remain subject to regulation under the Food, Drug & Cosmetic Act (FD&C Act).

The FD&C Act prohibits the introduction into interstate commerce of any drug product that is not generally recognized as safe and effective for its intended use(s) without prior approval from the FDA. Because CBD is the active ingredient in at least one FDA-approved drug, GW Pharmaceuticals' Epidiolex®, the FDA currently considers CBD products – even those derived from hemp – to be subject to this prohibition.

However, products originally treated as drugs may be marketed as foods or dietary supplements (both of which are subject to substantially less onerous regulatory requirements than drugs) if so authorized by FDA regulation. The public hearing and related comment period announced by the FDA are intended to inform the agency's decision-making process regarding whether to promulgate such a regulation, as well as how to structure an appropriate regulatory scheme for CBD products. In particular, the FDA is seeking data and information regarding:

- What levels of cannabis and cannabis-derived compounds cause safety concerns;

- How the mode of delivery affects the safety of, and exposure to, such compounds;
- How cannabis and cannabis-derived compounds interact with other substances, including drug ingredients; and
- Other questions outlined in the Federal Register announcement.

The public hearing is scheduled to take place on ***May 31, 2019***, from 8 a.m. to 6 p.m. Eastern Time. The FDA will also accept written comments through July 2, 2019.

At the state level, the Ohio Senate on March 28, 2019 unanimously passed a bill that would adopt the federal definition of "hemp" and expressly exclude it, as well as any derivate products with THC concentrations below the 0.3 percent threshold, from the criminal definition of "marijuana" under the Ohio Revised Code. Because the Revised Code historically has not distinguished between cannabis derivatives based on THC concentration, CBD products – including those derived from hemp – are currently legal in Ohio only within the parameters of the Medical Marijuana Control Program, and state agencies have recently taken steps to halt sales of such products by entities without distributor licenses.

The bill, Senate Bill 57, would permit any person to possess, buy, or sell hemp products in Ohio, including CBD with a THC concentration of no more than 0.3 percent. Additionally, it would establish programs for the issuance of licenses to cultivate hemp and to process it into CBD; as currently drafted, a license would not be required to process hemp into any other type of product.

Senate Bill 57 is currently under consideration by the Ohio House of Representatives and was referred to the Committee on Agriculture and Rural Development on April 2, 2019. The current text of the bill is available in full here. If you have questions about the regulation of CBD, the requirements of the FD&C Act, and/or would like assistance with the comment submission process, please contact Jolie Havens, Elizabeth Smith, Mairi Mull, or your regular Vorys attorney.