FDA Regulation of CBD is TBD

By Gregory T. Measer, Joseph W. Schafer

March 17, 2023 | **CLIENT ALERTS**

After rounding out 2022 with a series of warning letters to companies selling products containing cannabidiol ("CBD") the U.S. Food and Drug Administration ("FDA") began 2023 by issuing a press release announcing its long-awaited conclusion that **the existing FDA regulatory frameworks for food and dietary supplements are not appropriate for CBD**. Though not unexpected, this decision leaves it up to Congress to address the current lack of CBD regulation.

In 2018, FDA approved Epidiolex – a seizure treatment drug containing CBD. Also in 2018, Congress passed the 2018 Farm Bill which, in part, removed hemp and hemp-derived products (like CBD) from the Drug Enforcement Agency's ("DEA") schedule of controlled substances (while marijuana and marijuana products—i.e. those products containing 0.3% or greater Delta-9 THC by dry weight—remained a Schedule 1 federally illegal substance). This was a huge step forward for the hemp industry on a national scale, which led to a major uptick in manufacturing of hemp-derived products, such as CBD gummies and tinctures, as well compliant Delta-8 and Delta-9 THC versions of the same.

At the time, FDA reaffirmed its authority to regulate products containing cannabis or cannabis-derived compounds

and reminded companies marketing the therapeutic effects of drugs derived from cannabis that they need to seek FDA approval. FDA also reminded the CBD industry that the Federal Food Drug & Cosmetic Act prohibits the sale of any food (including dietary supplements) to which an approved drug has been added. Therefore, the Epidiolex approval effectively prohibited any future use of CBD in foods and dietary supplements.

After the 2018 Farm Bill became law, FDA convened a working group to assess how best to regulate CBD going forward, while occasionally issuing warning letters to sellers marketing CBD products for pain relief, opioid addiction, COVID-19, and other medical conditions. However, with the recent press release FDA has made clear that they will no longer be pursuing any rulemaking for non-drug uses of CBD. FDA cites various safety concerns of the use of CBD, including potential harm to the liver, use by vulnerable populations (like children and those who are pregnant), and unknown interactions with certain medications. FDA also suggested that any new federal regulatory framework may include requirements for clear labels, prevention of contaminants, content limits, and a minimum purchase age.

Now that FDA has punted the issue back to Congress, it is unclear whether the agency will ramp up enforcement efforts against CBD manufacturers, distributors, or retailers. The trend in recent warning letters indicates that their focus is currently on the marketing of specific medicinal uses of CBD products. Outside of FDA, there have been pushes to clarify the regulatory classification of CBD and other cannabis-derived products, potentially through the upcoming 2023 Farm Bill. Until then, the CBD industry and states will need to continue to navigate the inherent conflict between federal prohibition, widespread availability and increasing consumer demand.

The Lippes Mathias LLP Cannabis Practice Team will continue to monitor developments in the national hemp industry, including any subsequent enforcement actions FDA chooses to take, the results of the forthcoming 2023 Farm Bill, and trends in federal cannabis policy that could affect future efforts by hemp operators. Should you have any questions, please contact one of our attorneys, Gregory M. Measer (gmeaser@lippes.com) or Joseph W. Schafer (jschafer@lippes.com).