

# The Regulatory Outlook for THC's (Mostly) Legal Cousin, Ingestible CBD

Gary Kibel, *Partner*, gkibel@dglaw.com

Louis P. DiLorenzo, *Associate*, ldilorenzo@dglaw.com

Alexa Meera Singh, *Associate*, alsingh@dglaw.com

Ingestible cannabidiol (CBD) products, including gummies, tinctures, tonics and capsules, are growing in popularity and make up a significant part of the multi-billion dollar global CBD market.

However, although CBD is generally legal under federal and most states' laws, the legal outlook for ingestible CBD remains quite complicated.

## Federal Law

Despite state legalization efforts, marijuana continues to be illegal under the United States Controlled Substances Act. However, under the Agriculture Improvement Act of 2018 (the Farm Bill), CBD may be produced and marketed if it contains no more than 0.3% tetrahydrocannabinol (THC).

The Farm Bill preserved the FDA's power to regulate products containing cannabis or cannabis-derived compounds under the Food, Drug & Cosmetic Act (FD&CA). Although the FDA does not prohibit the inclusion of CBD in cosmetics products, the FDA considers it to be a drug, and therefore prohibits the use of CBD in ingestible products such as food, beverages and dietary supplements without FDA approval. And, because the FDA has only approved the use of CBD in Epidiolex, an epilepsy drug, the overwhelming majority of food, beverages and dietary supplements are misbranded under the FD&CA.

This has led to a complicated regulatory environment for ingestible CBD products, with the FDA issuing a considerable number of warning letters to companies selling CBD products. These warning letters have focused largely on products that make unsupported claims that CBD can treat a host of medical conditions, including most recently that CBD can prevent or cure COVID-19. In addition, the FDA still maintains the position that **all** ingestible CBD products (other than Epidiolex) are unlawful while it evaluates CBD's health effects, and in some cases has also gone after CBD marketers for making more run-of-the-mill claims (or even just for simply selling ingestible CBD). Meanwhile, some in Congress have grown impatient

with the FDA. Last year legislation was introduced in the House of Representatives that would legalize ingestible CBD so long as it otherwise complies with the FD&CA, and the proposed Cannabis Administration and Opportunity Act would require the FDA to develop a regulatory pathway for legalizing CBD in dietary supplements.

## State Law

While the federal government continues to grapple with the question of how to regulate ingestible CBD, state legislatures are beginning to create their own regulatory schema for ingestible CBD.

For example, New York has enacted a detailed regulatory scheme for manufacturing and selling CBD and other hemp extracts, including in ingestible products, and now requires licensing to grow, process and sell it. California used to follow the FDA's lead, which categorizes all ingestible CBD as unlawful, but has since passed new legislation that legalizes ingestible CBD. Still, there are questions as to how inhalable CBD will be treated, as New York will require a recreational marijuana license to sell **inhalable** CBD, and California has banned inhalable CBD altogether until legislation governing taxation is passed (a curious position, considering that it was one of the first states to legalize recreational marijuana).

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## What Businesses Can Do Now

- Until the FDA provides further clarity (or Congress otherwise acts), the legal environment for ingestible CBD will remain cloudy.
- Nonetheless, the proliferation of ingestible CBD products across the United States has continued at a steady clip, and shows no signs of slowing down.
- Although it is difficult to ignore the allure of this booming market, marketers of CBD products and their advertising and media partners should comply with the patchwork of state laws and not make false or misleading health and safety claims.