

# CLIENT ALERTS

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## FDA Issues Guidance on Cannabidiol ("CBD")

4.11.2019

The Food and Drug Administration ("FDA") has recently issued guidance on cannabidiol ("CBD") that is expected to have widespread ramifications for the industry.

The FDA determined that a CBD product marketed as offering therapeutic effects is a new drug that must be approved prior to sale. Additionally, the FDA determined that CBD products cannot be sold on the internet and are not dietary supplements.

The FDA stated that:

"FDA recognizes the potential opportunities that cannabis or cannabis-derived compounds may offer and acknowledges the significant interest in these possibilities. However, FDA is aware that some companies are marketing products containing cannabis and cannabis-derived compounds in ways that violate the Federal Food, Drug and Cosmetic Act (FD&C Act) and that may put the health and safety of consumers at risk. The agency is committed to protecting the public health while also taking steps to improve the efficiency of regulatory pathways for the lawful marketing of appropriate cannabis and cannabis-derived products."

The FDA stated that "[t]here are no other FDA-approved drug products [besides Epidiolex] that contain CBD."

The FDA has already taken action based on its new determination. On March 28, 2019, it issued three warning letters to companies selling CBD products due to unsubstantiated health claims. The companies were marketing their products as remedies for arthritis, dementia, and other ailments.

The FDA will continue to monitor the marketplace, saying that:

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“FDA continues to be concerned at the proliferation of products asserting to contain CBD that are marketed for therapeutic or medical uses although they have not been approved by FDA. Often such products are sold online and are therefore available throughout the country. Selling unapproved products with unsubstantiated therapeutic claims is not only a violation of the law, but also can put patients at risk, as these products have not been proven to be safe or effective. This deceptive marketing of unproven treatments also raises significant public health concerns, because patients and other consumers may be influenced not to use approved therapies to treat serious and even fatal diseases.”

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