

FDA to Hold Public Hearing May 31 Regarding Cannabis



On May 31, 2019, the Food and Drug Administration (FDA) will hold a public hearing to obtain scientific data and information about the safety, manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis-derived compounds, including cannabidiol (CBD). The hearing comes approximately five months after the Agricultural Improvement Act of 2018 (more commonly known as the Farm Bill), went into effect and removed industrial hemp from the Schedule I prohibition under the Controlled Substances Act (CSA) (industrial hemp means cannabis plants and derivatives that contain no more than 0.3 percent tetrahydrocannabinol, or THC, on a dry weight basis).

Though the [Farm Bill](#) removed industrial hemp from the Schedule I list, the Farm Bill preserved the regulatory authority of the FDA over cannabis and cannabis-derived compounds used in food and pharmaceutical products under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and section 351 of the Public Health Service Act. The FDA has been clear that it intends to use this authority to regulate cannabis and cannabis-derived products, including CBD, in the same manner as any other food or drug ingredient.

For example, the FDA has issued warning letters to companies illegally selling CBD products intended to treat diseases such as cancer, which did not obtain new drug approvals. The FDA's warning letters also cited food products to which CBD had been added and CBD products marketed as dietary supplements. To date, the FDA has only approved one product containing CBD for use as a drug; in June 2018, the FDA approved Epidiolex for the treatment of

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epilepsy. Epidiolex is classified as a Schedule V substance and is currently available by prescription in all 50 states.

The agenda for the public hearing is available [here](#). Parties interested in viewing the hearing via webcast may do so by registering on the FDA website [here](#). A link to the recorded webcast will also be posted after the hearing. In addition to holding the hearing, the agency has requested comments by July 2, 2019, regarding any health and safety risks of CBD use, and how products containing CBD are currently produced and marketed. Comments may be submitted to the docket [here](#).

Beveridge & Diamond's [Industrial Hemp & Cannabis](#) industry group assists cannabis-based businesses with state-level environmental compliance, product liability, project planning, environmental risk avoidance, and, where appropriate, litigation services and defense against state-level environmental enforcement actions. For more information, please contact the author.

Possession, use, distribution, and sale of cannabis may be a federal crime. This alert is not intended to provide any guidance or assistance in violating federal law, or in providing guidance or assistance in complying with federal law.

**The FDA is accepting
comments on this issue
until July 2, 2019.**