

## **FDA Holds First Public Hearing on CBD Regulation**

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**As the market for Cannabidiol (CBD) products continues to rapidly expand across the country, federal agencies are in the early phase of establishing regulations for the processing, dispensing, and ingestion of CBD products. The U.S. Food and Drug Administration (FDA) is set to hold its first public hearing on May 31, 2019, where it intends to gather relevant information and scientific data related to the consumption of CBD.**

At issue in the public hearing is the manner in which the FDA will regulate the CBD industry without stifling new business development. Key items to watch include:

### **Consumer safety concerns.**

Testimony is slated to address what levels of cannabis and cannabis-derived compounds are safe for human consumption; how the mode of delivery (e.g., ingestion, absorption, inhalation) affects the safety of, and exposure to, CBD compounds; and how cannabis and cannabis-derived compounds interact with other substances, such as drug ingredients.

### **Interaction with the Federal Food, Drug and Cosmetic Act?.**

The FDA considers many activities used to produce and market CBD to violate the Federal Food, Drug and Cosmetic Act (FDCA). The agency recently sent multiple [warning letters](#) to companies for making “egregious” and “unsubstantiated” claims related to the treatment of serious illnesses and the unlawful use of the compound in food, beverages and dietary supplements.

### **Impact on pharmaceutical development.**

It is expensive to develop a new drug. The FDA will consider how current models to incentivize drug research and development could be impacted if the commercial availability of products with CBD compounds, such as foods and dietary supplements, become significantly more widespread.

CBD is a non-intoxicating substance derived from hemp and is widely considered to have beneficial

health characteristics. As hemp is a form of cannabis, CBD was historically classified as an illegal substance under federal law. With the enactment of the 2018 Farm Bill, however, Congress explicitly removed hemp from the list of substances that are federally banned under the Controlled Substances Act. Accordingly, hemp is no longer considered a controlled substance under federal law.

While hemp is no longer federally prohibited, the 2018 Farm Bill also made it quite clear that the FDA continues to have the authority to regulate CBD under the FDCA and Section 351 of the Public Health Service Act.

The FDA has stated that the purpose of the hearing is not to produce new policy or announce any decisions, but rather to serve as a platform for all parties to put forth their views.

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