

December 23, 2015
Contact: DEA Public Affairs
(202) 307-7977

DEA Eases Requirements for FDA-Approved Clinical Trials on Cannabidiol

DEC 23 (WASHINGTON) - The United States Drug Enforcement Administration (DEA) recently eased some of the regulatory requirements imposed by the [Controlled Substances Act \(CSA\)](#) for those who are conducting FDA-approved clinical trials on cannabidiol (CBD), an extract of the marijuana plant. These modifications will streamline the research process regarding CBD's possible medicinal value and help foster ongoing scientific studies. The DEA notified affected researchers by letter of the changes, which take effect immediately.

Federal Regulation ([21 CFR 1301.18](#)) requires researchers conducting CBD-based clinical trials under an [FDA Investigational New Drug Application](#) to have a DEA research registration. This registration permits the possession of an approved amount of CBD for a specific research protocol. Prior to now, researchers who expanded the scope of their studies and needed more CBD than initially approved for had to request, in writing, a modification to their DEA research registrations – potentially delaying that research while the modification underwent an approval process that includes both the DEA and the Food and Drug Administration (FDA). Under these changes, a previously registered CBD clinical researcher who is granted a waiver can readily modify their protocol and continue their research seamlessly. This waiver effectively removes a step from the approval process.

Marijuana is a [Schedule I](#) controlled substance because of the presence of [tetrahydrocannabinol \(THC\)](#), marijuana's psychoactive ingredient. Because CBD contains less than 1 percent THC and has shown some potential medicinal value, there is great interest in studying it for medical applications. Currently, CBD is a Schedule I controlled substance as defined under the CSA. Though the FDA approves drugs for medical use in the United States, the DEA regulates the handling of all controlled substances, including those being used by researchers to conduct studies.