

CGA Symposium
Coffee with Counsel Agenda C.3.

US FDA and California Regulation of Food Products Containing CBD

The Agriculture Improvement Act of 2018 (2018 farm bill; P.L. 115-334) revised US law to make it legal to sell products containing *hemp-derived CBD*, but not products containing *marijuana-derived CBD*. Hemp, which is not psychoactive, and marijuana, which is psychoactive, are different subspecies of cannabis. When enacting the 2018 farm bill Congress explicitly preserved the FDA's authority to regulate hemp-derived CBD under the Federal Food, Drug and Cosmetic Act (FFDCA, 21 U.S.C. §§301 et seq.). Therefore, although US law allows hemp-derived CBD products to be sold, the FDA still has the discretion to decline to regulate hemp-derived CBD products and outlaw its distribution across state lines.

It has been 2.5 years since Congress passed the 2018 farm bill that gave the FDA the power to permit hemp-derived CBD in food products, but the FDA still has not promulgated the necessary exemption. According to its website, the FDA is staunchly sticking to this decision, as hemp-derived CBD is still considered a drug and the FFDCA outlaws selling food products that contain drugs (21 U.S.C. §331(l)). Additionally, the FDA has not approved hemp-derived CBD as a food additive because it is not currently considered to be Generally Recognized as Safe (GRAS), which is a requirement for all food additives.

Largely in reaction to the FDA's tardiness in this area, on May 19, 2021, three US Senators introduced The Hemp Access and Consumer Safety Act of 2021. If it becomes law, this bill would force the FDA to regulate hemp-derived CBD food products and allow such products to enter interstate commerce. To date, the FDA has declined to exempt hemp-based CBD from the FFDCA's prohibition against allowing any new dietary ingredient, food, or beverage to enter the market if it has been studied or approved as a drug. The Hemp Access and Consumer Safety Act would bypass the US FDA's discretionary authority and directly amend the FFDCA to allow hemp-derived CBD food products to enter the market. A similar bill was introduced in the House of Representatives on February 4, 2021 (H.R. 841). California follows federal law for food additives and dietary supplements. Since the FDA has not approved hemp-derived CBD as a food additive, California has not, either.

It appears that the approval of hemp-derived CBD as a food additive is tied to Congressional action and approval for now.