

Overview of the Legality of Hemp Seed Derivatives and Cannabis Flower Oil

Food, Drug, and Cosmetic Act

Section 301 of the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 331, prohibits the “receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.” Section 402 of the FDCA, 21 U.S.C. § 342, deems a food to be “adulterated” 1) “if it bears or contains any poisonous or deleterious substance which may render it injurious to health ...” or 2) “if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409....” The term “food additive,” as defined by Section 201 of the FDCA, 21 U.S.C. § 321, means any component that is not generally recognized among scientific experts as having been adequately shown through scientific procedures or common use to be safe for consumption. Section 409 of the FDCA, 21 U.S.C. § 348, deems a food additive unsafe unless it is exempt for investigational use or there is in effect a regulation “prescribing the conditions under which such additive may be safely used.”

Hemp seed derivatives (such as hemp oil, hemp flour, hemp powder, and hemp cake) and cannabis flower oil are derived from the cannabis sativa plant and contain tetrahydrocannabinol (“THC”), a hallucinogenic substance with a high potential for abuse. THC is fat soluble and is known to accumulate in the body’s cells. Frequent ingestion of products containing THC can result in nerve impairment and hormone disruption. Hemp seed derivatives and cannabis flower oil are not recognized among scientific experts as having been shown through scientific procedures or experience to be safe for human consumption. None of the substances is exempt for investigational use, and none is the subject of a regulation prescribing the conditions under which it may safely be used as a food additive. In light of these facts, products containing hemp seed derivatives and cannabis flower oil are “adulterated” under Section 402 of the FDCA, 21 U.S.C. § 342(a). Their introduction and receipt in interstate commerce are, therefore, prohibited under Section 301 of the FDCA, 21 U.S.C. § 331. Section 304 of the FDCA, 21 U.S.C. § 334, authorizes criminal proceedings against violators of the Act.

Controlled Substances Act

Section 812 of the Controlled Substance Act (“CSA”), 21 U.S.C. § 812, lists marihuana as a Schedule I controlled substance, prohibiting the production and possession of any material containing any quantity of marihuana absent government approval. Section 802 of the CSA, 21 U.S.C. § 802, defines marihuana as all parts of the cannabis sativa plant except the mature stalks and sterilized, infertile seeds.

Obviously, it is not possible to grow exclusively the mature stalks and sterilized, infertile seeds of the cannabis sativa plant. The cultivation of the cannabis sativa plant is, therefore, prohibited under the CSA. Hemp is a variety of cannabis sativa plant. It follows that the domestic cultivation of hemp is prohibited under the CSA.

Cannabis flower oil, by definition, is derived from the flower of the cannabis plant, not the mature stalks or sterilized, infertile seeds of the plant. The flower of the cannabis plant falls under the definition of marihuana under the CSA. The manufacture and possession of products containing cannabis flower oil are prohibited under the CSA.

Hemp oil, flour, powder, and cake, on the other hand, are derived from the sterilized, infertile seeds of the cannabis sativa plant. Such hemp seed derivatives are not prohibited by the CSA's definition of marihuana. However, Section 812 of the CSA places any material that contains any quantity of THC on Schedule I. Thus, the production and possession of any product containing any amount of THC in the absence of government approval are prohibited.

Before products containing THC were marketed for human consumption, the regulatory definition of THC under the CSA was limited to synthetic THC. In response to the marketing of products containing hemp seed derivatives as food, the Drug Enforcement Administration ("DEA"), on March 21, 2003, published two rules clarifying that the CSA's listing of THC in Schedule I includes products containing both synthetic and natural THC. Hemp seed derivatives contain naturally occurring THC. The sale and possession of products containing hemp seed derivatives are prohibited under the DEA's March 2003 rules.

The hemp industry petitioned the United States Circuit Court for the Ninth Circuit for review of the DEA rules interpreting the CSA definition of THC. The Ninth Circuit Court ruled on February 6, 2004, that the DEA may not legally enforce the THC rules. The Ninth Circuit did not address whether food products containing hemp seed derivatives had the potential for abuse or whether these substances were safe for ingestion. Rather, the Court deemed inadequate the procedures the DEA followed in adopting the THC rules. On the substantive question of whether the definition of THC under the CSA is limited to synthetic THC, the Ninth Circuit cited the authority of a previous DEA regulation. The court did not cite the CSA itself, as the plain language of the statute does not limit the definition of THC to synthetic sources.

The Ninth Circuit has jurisdiction solely over the federal district courts in California, Oregon, Washington, Arizona, Montana, Idaho, Nevada, Alaska, and Hawaii. The DEA may not legally enforce its regulations as to food products containing hemp seed derivatives in those states. However, the DEA regulations governing food products containing hemp seed derivatives remain in effect and fully enforceable in all 41 states that do not fall under Ninth Circuit jurisdiction.