

FDA REGULATION OF DIETARY SUPPLEMENT & CONVENTIONAL FOOD PRODUCTS CONTAINING CANNABIS AND CANNABIS-DERIVED COMPOUNDS

Background - With the increasing popularity of products containing cannabis and cannabis-derived compounds (including cannabidiol (CBD) and delta-9-tetrahydrocannabinol (THC)), FDA is aware that some companies are marketing conventional food products and products labeled as dietary supplements that contain cannabis or cannabis-derived compounds in ways that violate the Federal Food, Drug and Cosmetic Act (FD&C Act). Here is what you need to know about FDA's regulation of these types of products.

THC or CBD products cannot be sold as dietary supplements under the FD&C Act

Under section 201(ff)(3)(B) of the FD&C Act [21 U.S.C. § 321(ff)(3)(B)], THC and CBD products are excluded from the dietary supplement definition. Under that provision, if a substance (such as THC or CBD) is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. § 355], or has been authorized for investigation as a new drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, then products containing that substance are excluded from the definition of a dietary supplement. There is an exception to section 201(ff)(3)(B) if the substance was "marketed as" a dietary supplement or as a conventional food before the drug was approved or before the new drug investigations were authorized, as applicable. However, the agency is not aware of any evidence that CBD or THC were marketed in conventional foods or dietary supplements prior to being subject to substantial clinical investigations. Therefore, both CBD and THC are excluded from the dietary supplement definition and cannot be sold or marketed as such.

THC or CBD cannot be added to food for humans or animals under the FD&C Act

Under section 301(l) of the FD&C Act [21 U.S.C. § 331(l)], it is prohibited to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which has been added a substance which is an active ingredient in a drug product that has been approved under section 505 of the FD&C Act [21 U.S.C. § 355], or a drug for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public. There are exceptions, including when the drug was marketed in food before the drug was approved or before the substantial clinical investigations involving the drug had been instituted or, in the case of animal feed, that the drug is a new animal drug approved for use in feed and used according to the approved labeling. However, based on available evidence, FDA has concluded that none of these is the case for THC or CBD. FDA has therefore concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food (including any animal food or feed) to which THC or CBD has been added.

In addition, the FDA is not aware of any basis to conclude that CBD is generally recognized as safe (GRAS) among qualified experts for its use in human or animal food. There also is no food additive regulation which authorizes the use of CBD as an ingredient in human food or animal food, and the agency is not aware of any other exemption from the food additive definition that would apply to CBD. CBD is therefore an unapproved food additive, and its use in human or animal food violates the FD&C Act for reasons that are independent of its status as a drug ingredient.

Ingredients derived from cannabis that do not contain CBD or THC might be able to be used in foods and dietary supplements if all other FD&C requirements are met.

Ingredients that are derived from parts of the cannabis plant that contain only trace amounts of THC and CBD, which the seeds may pick up during harvesting and processing when they are in contact with other parts of the plant, might be able to be marketed as dietary supplements and/or conventional foods. These products must still comply with all applicable laws and regulations governing dietary supplements and conventional foods, including requirements related to safety (e.g., new dietary ingredients, food additive), processing (e.g., dietary supplement Current Good Manufacturing Practices (CGMPs), preventive controls for human and/or animal food), and labeling.

In December 2018, FDA completed its evaluation of three GRAS notices for the following hemp seed-derived food ingredients for use in human food: hulled hemp seed, hemp seed protein powder, and hemp seed oil. FDA had no questions regarding the company's conclusion that the use of such products as described in the notices is safe. Therefore, these products can be legally marketed in human foods for the uses described in the notices, provided they comply with all other requirements. Other than these three hemp seed ingredients, no other cannabis or cannabis-derived ingredients have been the subject of a required food additive petition, an evaluated GRAS or new dietary ingredient notification, or have otherwise been approved for use in food for humans or animals by FDA.