

FDA Issues Warning Letters to Companies Illegally Selling CBD Products

Article By:

Food and Drug Law at Keller and Heckman

- On November 21, 2022, FDA [posted](#) warning letters that had been issued to 11-11-11 Brands, Naturally Infused LLC, Newhere Inc dba CBDFX, Infusionz LLC, and CBD American Shaman, LLC for illegally selling CBD-containing products. Collectively, the warning letters raised several legal objections to the sale of CBD in human and animal food and drugs, and dietary supplements, including the following:
 - The sale of a CBD-containing food or animal food renders that food or animal food adulterated because CBD has not been authorized for use by a food additive regulation, subject to a prior sanction, and does not satisfy the criteria for GRAS. On the contrary, FDA noted that the “available data raises serious concerns about potential harm from CBD added to conventional food,” including potential for liver injury, harmful interaction with certain drugs, and interference with sexual development, function, and behavior.
 - The sale of CBD in a human or animal product intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or intended to affect the structure or function of the body, and that has not been approved by FDA, is an unlawful introduction into interstate commerce of an unapproved new human drug or animal drug. The only CBD-containing drug approved by FDA is Epidiolex, which is approved to treat severe epilepsy.
 - It is unlawful to market any CBD-containing product as a conventional food or dietary supplement because CBD has been approved for use as a drug.
 - When a drug is used to treat a condition which is not amenable to self-diagnosis or treatment (e.g., sleep apnea), as was the case with many of the products at issue, that drug is misbranded if it does not include adequate directions for use. FDA-approved prescription drugs are exempt from this requirement, but none of the products at issue have been approved by FDA.
- FDA was particularly concerned with some of the products at issue that appeal to children (e.g., candies, cookies, and gummies) as children may be at greater risk to adverse effects

from consumption of CBD. Additionally, in the Naturally Infused LLC Warning Letter, FDA objected to the presence of Delta-8 THC, noting that its use in food renders that food adulterated because it is not authorized by a food additive regulation, the subject of a prior sanction, or GRAS. Indeed, FDA noted that the available data raises “serious concerns” about its use, including “potential for adverse effects on the central nervous and cardiopulmonary systems” and gestational neurodevelopment interference.

- FDA has already issued a number of warning letters to companies using CBD in various products this year (see [here](#) and [here](#)) and the safety concerns raised by the Agency suggest that it will be a continuing enforcement priority. Keller and Heckman will continue to monitor and report on regulatory developments related to CBD.

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National Law Review, Volumess XII, Number 326

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