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Regulatory Update

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FDA issues warning letters, cautions consumers on unapproved CBD products

Nearly a year after the 2018 Farm Bill legalized hemp nationwide, the legal status of one of its most popular products, cannabidiol (CBD), is becoming clearer.

On Nov. 25, the U.S. Food and Drug Administration (FDA) issued a revised consumer update regarding unapproved CBD products and issued a new round of warning letters to CBD retailers selling products in violation of the Food, Drug and Cosmetics Act (FDCA). The agency also warned of potential health risks and safety concerns associated with numerous unapproved CBD products. The FDA publicized its determination that CBD cannot be considered as Generally Recognized as Safe (GRAS) under federal law, foreclosing one of the regulatory paths available to the FDA for allowing CBD as a food ingredient.

These recent actions underscore the FDA's interpretation that food products, unapproved drugs, dietary supplements and cosmetics containing CBD sold in interstate commerce often violate the FDCA.

FDA warning letters

In this recent round of enforcement efforts, the FDA issued fifteen warning letters to CBD companies selling a variety of products in interstate commerce, including balms, capsules, oils, tinctures, lotions, gummies, chews and sprays that were marketed for use by adults, children and animals.

The letters outline the FDA's legal analysis which concludes that the products at issue were marketed in interstate commerce as unapproved new drugs, misbranded drugs, adulterated foods or improperly labeled as dietary supplements in violation of the FDCA. The crux of this analysis is that CBD is an active ingredient in an approved drug as well as other drugs under clinical investigation.

These products triggered FDCA violations in a variety of ways:

- **Unapproved new drugs –** CBD products making claims to prevent, diagnose, mitigate, treat or cure serious diseases, such as cancer, AIDS, schizophrenia and diabetes.
- **Misbranded drugs –** CBD products marketed as drugs that also fail to bear adequate directions for use.
- **Dietary supplement labeling –** Improperly using the label "dietary supplement" when it does not meet the definition under the FDCA.
- **Adulterated human food –** CBD products marketed as conventional human foods and contain a drug approved by the FDA.

Each warning letter identified an "unapproved new drug" violation with products making aggressive health claims surrounding cancer or other similar serious conditions, suggesting the FDA continues to focus its efforts at "egregious, over-the-line" health claims as referenced by former FDA Commissioner Scott Gottlieb.

FDA consumer update

The FDA simultaneously issued a consumer update, signaling that unapproved CBD products remain prohibited under the FDCA. The agency noted it has seen only limited data about CBD safety and that some of the data points to risks that should be considered before taking CBD.

The FDA warned that unapproved CBD products may pose safety risks and make unproven health claims. The FDA fears consumers may put off getting proper diagnosis, treatment or supportive care due to unsubstantiated claims associated with CBD products.

Additionally, the FDA noted the information it currently has "underscores the need for further study and high quality, scientific information about the safety and potential uses of CBD." The consumer update further notes:

- **No FDA evaluation of CBD products –** There has been no FDA evaluation of whether unapproved CBD products are effective for their intended use, what the proper dosage might be, how they could interact with FDA-approved drugs or whether they have dangerous side effects or other safety concerns.
- **Potential health risks –** Specifically, the FDA also identified some of the potential risks associated with using CBD products, including liver injury and male reproductive toxicity. Other potential health risks remain unknown to date, including the effects of sustained daily usage by adults as well as the effects on children, breastfed newborns and developing fetuses.
- **Side effects –** Other side effects include drowsiness, gastrointestinal distress and increased irritability and agitation.
- **Unregulated manufacturing process and product safety is unknown –** The manufacturing process of unapproved CBD drug products has not been subject to FDA review and the effects of CBD containing potentially unsafe levels of contaminants, such as pesticides and heavy metals, are unknown.

CBD remains a legal product

Despite this recent action from the FDA, hemp-derived CBD remains a legal product under federal law, but it must be marketed without violating the FDCA. Additionally, the warning letters and consumer update highlight that the FDA is targeting its enforcement to companies engaged in interstate commerce and making egregious, unsubstantiated health claims.

As is the case with other cannabis issues, the disconnect between state and federal law means companies are finding ways to bring products to market while limiting their risk. However, stakeholders must be aware of the risks under state and federal law when marketing any product containing CBD.

Expect more information from the FDA soon

The consumer update also notes that the FDA is "evaluating the regulatory frameworks that apply to certain cannabis-derived products that are intended for non-drug uses, including whether and/or how the FDA might consider updating its regulations, as well as whether potential legislation might be appropriate." More information will be coming soon from the FDA, but it may be awhile before CBD can be marketed legally as a food ingredient or dietary supplement under federal law.

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