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FDA Cracks Down on Pet Products Containing CBD After USDA Clears Path for Hemp Production

Publication — 12/09/2019

Although more and more pet owners are turning to CBD products to treat their pets, new action by the FDA is a stark reminder that those CBD pet products found on-line and in stores are considered illegal at the federal level. Less than a month after the USDA published draft final rules to permit the "legal" production and interstate shipment of hemp and CBD throughout the country, the FDA issued warning letters to thirteen companies in nine states for selling various pet food, treats and animal drugs containing CBD. The FDA found that these products were either unapproved animal drugs or adulterated animal foods due solely to the presence of CBD in the products.

Notably, several of these companies are located in states where marijuana sales and possession have been legalized, including California and Colorado. In both the warning letters and an accompanying updated consumer alert, the FDA stated that, based on a lack of supporting scientific information related to use of CBD in food products:

> *"the FDA is also indicating today that it cannot conclude that CBD is generally recognized as safe (GRAS) among qualified experts for its use in human or animal food."*

This determination is significant because any animal (or human) food products that contain ingredients or additives that are not GRAS are considered to be adulterated and may not legally be sold. Predictably, this determination has already lead to the filing of a class action lawsuit against a Colorado-based CBD product manufacture that makes CBD dog treats and other products. Moreover, intentionally marketing adulterated human or animal food products may lead to fines or even criminal prosecution for executives of the offending company.

The warning letters identified the offending pet products by name as well as the two specific violations: selling (1) unapproved new animal drugs and (2) adulterated animal food products. The adulterated food violation was based on using CBD as an ingredient or additive when is not GRAS.

With respect to the unapproved animal drugs, the FDA identified numerous disease claims that companies made on their websites and social media (including Instagram, Twitter, and Facebook). The FDA defines disease claims as those indicating that the product "is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in animals and/or intended to affect the structure or any function of the body of animals." Examples of disease claims related to these CBD products include relief from anxiety, pain, allergies, seizures, and neurological issues, and treatment of cancer and arthritis. It is noteworthy that all of

these warning letters targeted companies that made one or more such explicit disease claims. While this certainly does not suggest any enforcement discretion to allow companies to market CBD-infused pet products without such express disease claims, it does indicate that those who explicitly make such claims are more likely to be the target of enforcement actions. While the FDA's actions are certainly a blow to the already-growing CBD industry, they expressly recognized “the significant public interest in CBD” and emphasized that it continues to explore pathways for various types of CBD products to be lawfully marketed. To that end, the FDA promised to work together with stakeholders and industry to fill in the knowledge gaps about the quality, science, and safety (including toxicity and drug interactions) of many CBD products.

Somewhat ironically, while the FDA is cracking down on sale of pet products containing CBD, hemp and CBD may be legally produced once the new USDA hemp rules become final.

Since the Farm Bill distinguished “hemp” (containing 0.3% or less THC by dry weight) from “marijuana” (more than 0.3% THC), hemp is now considered an agricultural commodity instead of a controlled substance. But because hemp and marijuana are both versions of the cannabis plant, the USDA needed to develop a stricter regulatory scheme to closely monitor this new commodity. Thus, the new rules generally include requirements that typically apply to other agricultural crops, such as reporting crop acreage, as well as stringent testing requirements to assure that the hemp products do in fact contain 0.3% or less THC. The new hemp rules contain both the general requirements for states wishing to submit their own rules for USDA approval and similar USDA rules that will apply for states that do not have approved rules and that do not otherwise prohibit hemp production. Although individual states may prohibit the production of hemp in its jurisdiction, it may not prohibit interstate travel of hemp grown elsewhere across its borders. So far, eleven states and ten tribes have now submitted plans to USDA for review, but none have been approved yet. Notably, Colorado has not submitted a plan to the USDA for approval.

Generally, the USDA regulatory plan requires applicants to provide detailed information about the land where hemp is grown, a detailed protocol for periodic inspection and sampling and methods for testing THC concentration, a protocol for disposing of non-conforming plants (those with too high THC concentration), and enforcement procedures for violations of federal hemp laws. Here's what hemp producers should know about these new rules:

- **Producer's license.** Just as food & beverage manufacturers have to register their facilities with the FDA, the USDA will require hemp producers to register their production facilities. Unlike typical facility registrations, the hemp registration must include identification of all “key participants” in the business as well as a criminal history for each. Licenses are good for three calendar years and are not transferable.
- **Land requirements.** Once licensed, hemp producers must provide

specific crop acreage and location (using geospatial location for all areas, including greenhouses and buildings) where hemp is produced. This information will be used by inspectors when inspecting the facilities and sampling product.

- **Sampling.** Each licensed producer will be inspected once annually within 15 days of estimated harvest, by a USDA-approved agent or law enforcement. The expense for inspecting and sampling (set at $152 per hour and estimated to be between $450 and $525 for an average 24-acre farm) must be paid by the Producer. Inspectors must examine all growing areas and obtain representative samples of each product lot. Inspectors will also estimate and note the height, density, and maturity of all plants and verify that each growing area contains plants of like variety. Samples must include the flower or bud of the plant from the top 1/3rd of the plant. For lots of less than an acre (including greenhouses), the inspector will sample at least one plant, and will sample at least one plant per acre for lots and greenhouses between 2-10 acres.
- **Testing.** Although the USDA is still taking comments and considering revisions, it will require testing to be performed by USDA-approved and DEA-certified labs that are either approved under a to-be-developed Laboratory Approval Program or have ISO 17025 accreditation. All samples will be tested (again at Producer's expense of $162 per hour). Testing will use gas or liquid chromatography with detection to derive total THC from the sum of the THC and THCA (THC Acid) content on a dry weight basis.
- **Disposal.** If test results show that the product is marijuana (THC content of over 0.3%), then the Producer must dispose of the entire non-compliant lot, using a USDA-approved entity or law enforcement in accordance with CSA or DEA regulations. The Producer must document disposal, which may consist of documentation provided by reverse-distributor or using USDA reporting requirements, and provide this documentation to the USDA.
- **Compliance and Enforcement.** The USDA will periodically conduct random audits of Producers no more than once every three years, either by reviewing requested documentation or physical inspection of the Producer's facility. USDA will provide a written summary from such audits and will also submit a notice of any violation found in the audit. The notice of violation will identify any violations found and will include a corrective action plan that must be completed by a set deadline. The Producer must also periodically report its compliance with the plan for two years thereafter. Three violations in a five-year period will result in a five-year ban from producing hemp from the date of the third violation.

Shortly after these rules were published, U.S. Senators Ron Wyden and Jeffery Merkley, co-authors of the Hemp Farming Act, wrote to the Secretary of Agriculture to express concerns about certain aspects of these rules on behalf of hemp growers in Oregon and propose corrections for each. Specifically, the senators expressed concern about the requirement that testing be performed within fifteen days of expected harvest when Oregon's current rules requires crop testing within 28 days of

harvest. The letter also expressed concern about requiring testing to be performed by a DEA-registered laboratory even though hemp is now a legal agricultural commodity, which could cause unnecessary bottlenecks and delays. The letter also objected to the requirement that THC be tested using specific methods and include conversion of THCA into THC when this requirement was specifically omitted from the 2018 Farm Bill. In addition, the senators sought to alter the sampling protocol to not require flowering tops, if not present, and to include more stalk material since Producers typically use the entire plant to produce CBD.

The comment period is still open for the new USDA rules, so it has not yet indicated what changes, if any, will be made in response to the concerns expressed by Senators Wyden and Merkley.