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USDA Clears Path for Hemp Production While FDA Cracks Down on CBD Products

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While it appears very likely that CBD products will someday be cleared for wide-spread sale by federal regulators, that day has not yet come. Many industry participants thought that CBD products became legal when the Hemp Farming Act was passed as part of the 2018 Farm Bill in December 2018, but the path to market has not yet opened for many finished CBD products. The USDA has finally published its draft final rules that will govern the “legal” production of hemp and CBD throughout the country when finalized. But with this long-awaited step forward, there remains the significant step backwards presented by the FDA in over a dozen warning letters issued this past week.

That is, while these new USDA rules allow production of hemp and CBD, they do not alter the FDA’s continued prohibition against using CBD in food, beverages or nutritional supplements. On November 25, 2019, FDA announced that it had issued warning letters to fifteen companies for illegally selling various products containing CBD in violation of the Federal Food, Drug, and Cosmetic Act (FDCA). Just as significantly, the FDA also announced that, based on current data, it cannot conclude that CBD is generally recognized as safe (GRAS) for use in human or animal food. This is noteworthy because no food, beverage or nutritional supplements may be marketed in the US unless all of its ingredients are GRAS. While these actions are certainly a blow to the already-growing CBD industry, the FDA 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. The ironic result is that, although CBD may now be legally produced under the new USDA hemp rules, it may not be used in food, beverage, or nutritional supplement products despite growing demand and use by consumers.

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 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 5-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, who were 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.