USDA HEMP PRODUCER LICENSE – DO THE OPPORTUNITIES OUTWEIGH THE RISKS?

THE USDA HEMP PRODUCER LICENSE RULE AND FRAMEWORK

On October 31, 2019, the United States Department of Agriculture ("USDA") published an interim final rule[1] with request for comments in the Federal Register regarding hemp production ("USDA Hemp Rule" or the "Interim Final Rule").[2] The USDA Hemp Rule establishes a federal hemp producer license and related requirements for state regulation of hemp production pursuant to the Agriculture Improvement Act of 2018 ("2018 Farm Bill"). Hemp is defined as the plant species *Cannabis sativa L.*[3] containing less than 0.3% delta-tetrahydrocannabinol ("THC") within a distribution, also known as the "acceptable hemp THC level."[4] The USDA Hemp Rule establishes requirements that hemp producers must meet in order to obtain the USDA Hemp Producer License:

1. Licensing requirements;
2. Filing and maintaining information regarding the land on which hemp is produced;
3. Procedures for testing the THC concentration levels for hemp;
4. Procedures for disposing of non-compliant plants;
5. Compliance provisions; and
6. Procedures for handling violations.

Under the Interim Final Rule, but currently effective, regulatory framework, a Licensed Producer will be found to have negligently violated the licensure rules if it fails to:

1. Provide a legal description of the land (along with geospatial location) where hemp is cultivated and grown;
2. Obtain a license; or
3. Produce plants within the acceptable level THC content.[5]

That said, the Interim Final Rule does provide some degree of latitude with respect to those Licensed Producers who, despite exercising reasonable efforts to produce hemp plants that are consistently within specification (<0.3% THC content), may experience limited THC concentration variation above 0.3%. Specifically, if after following proper quality control testing a hemp sample exceeds 0.3%, but less than 0.5% THC, the Interim Final Rule contemplates that this would not necessarily violate the terms of the producer's license.[6]

Unsurprisingly given the specific procedures required under the USDA Hemp Rule, Licensed Producers are also subject to reporting and record-keeping requirements.[7]

In addition, the Interim Final Rule establishes a process for USDA approval of state and tribal plans to license hemp producers. Notably, the USDA will deny a hemp producer's application for federal licensure if the state has a plan pending approval or an approved plan.[8] If a state does not have a USDA-approved state plan, then the standards of the USDA Hemp Producer License will apply.[9] It is worthy of mention that the USDA Hemp Producer License does not preempt any state laws that are more stringent than the provisions of the USDA Hemp Rule.[10]

Although hemp is declassified as a controlled substance, which removes its cultivation and growth from Drug Enforcement Agency ("DEA") oversight, the quality control laboratories that test hemp samples for THC concentration must be DEA-registered.[11] Moreover, the USDA is considering other, potentially different, mechanisms for requiring accreditation and quality standards and has requested comments on how to proceed.[12]

THE DOORS OPEN – OPPORTUNITIES BUDDING FROM HEMP PRODUCER LICENSE

The USDA Hemp Rule appears to simplify and strengthen the supply chain for obtaining hemp and hemp-derived products. Previously, hemp producers had to be DEA registered to supply hemp for research purposes and there was only one DEA registered producer in the

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country.[13] Following the 2018 Farm Bill and the USDA Hemp Rule, the DEA no longer controls the cultivation of hemp, leaving the industry seemingly poised to incrementally expand production and sales of domestic hemp and hemp-derived products, ostensibly in answer to the past five years of renewed consumer demand.

The Food and Drug Administration ("FDA") has signaled that the declassification of hemp in the 2018 Farm Bill "may streamline the process for researchers to study cannabis and its dozens of derivatives, including cannabidiol ("CBD"), that fall under the definition of hemp, which could speed the development of new drugs."[14] The FDA is beginning to recognize "the significant public interest in CBD" and the need to "work together with stakeholders and industry to fill in the knowledge gaps about the science, safety, and quality of many of these products."[15] In fact, the FDA has indicated that it is actively working to learn about the effect of cumulative exposure to CBD, the effects of CBD on special populations and the safety of CBD for use on pets and animals.[16]

States have indicated significant interest in hemp production as well. Since the USDA Hemp Rule was published, 32 states have either submitted a State Plan to the USDA or expressed an interest in submitting a State Plan.[17] As of January 7, 2020, Ohio, New Jersey, Louisiana and three tribal governments have received approval from the USDA for their plans.[18] Additionally, 47 states have legislation permitting hemp production although states vary as to whether hemp production is limited to research purposes or permitted for commercial and industrial uses as well.[19]

The interest of the FDA and state governments is potentially promising news for companies and entities interested in research and drug development for hemp-derived products.

SLOW YOUR GROW - ACTIVITY SINCE THE USDA HEMP RULE TOOK EFFECT INDICATES SIGNIFICANT RISKS

But don't get too excited. The FDA and FTC have been clear that insufficient evidence exists to support CBD products. Since the enactment of the USDA Hemp Rule, shipment of lawfully produced hemp has led to several cases involving criminal charges and seizure of the product by law enforcement,[20] indicating that local law enforcement is insufficiently trained to distinguish illegal marijuana from lawfully produced hemp. Additionally, state approaches to hemp production are widely varied.

Companies with existing hemp-derived and CBD products should be cautious: as we previously discussed here, the FDA and the Federal Trade Commission ("FTC") have issued Warning Letters to CBD companies that have made outrageous and scientifically unsupported health claims about CBD products.[21] Following a recent flurry of Warning Letters issued in November 2019, the FDA has reiterated that only one CBD drug product – designed to treat two rare forms of epilepsy – has been approved and that, under the federal Food, Drug & Cosmetic Act, it is currently illegal to market CBD as a dietary supplement or regulated food.[22] Although the FDA has indicated support for research and drug development, companies should consult with legal counsel regarding proposed advertising and marketing claims about their cannabinoid-derived products.

The 2018 Farm Bill is clear that a state may not prohibit the transshipment of hemp or hemp products lawfully produced under the USDA Hemp Producer License or under a State Plan.[23] However, this legal protection is easier to rely on in theory than in practice. There is no roadside test to measure THC levels and evaluate the product.[24] Many jurisdictions, especially those where hemp production is illegal, permit law enforcement officers to rely on the unique scent of cannabis flower to establish probable cause for stopping, detaining, arresting an individual or seizing the cannabis flower being transported. However, law enforcement officers cannot tell the difference between hemp and marijuana plants based on differences in smell alone and are often not trained to assess if a plant is lawfully produced hemp by evaluating the producer's license and laboratory testing of the plant's THC content. Although some jurisdictions, like Miami-Dade county are implementing an "odor-plus" probable cause determination, most officers are unlikely to be trained in the nuances applicable to this quickly evolving area of law. This means that shipment of hemp can subject the producer to a significant risk that their lawfully produced hemp might be seized and their driver might be charged with drug trafficking charges.

Additionally, producers and businesses should not conflate the ability to grow hemp under a USDA Hemp Producer License or an approved State Plan with the ability to process, create or sell hemp-derived products in any state. For example, many states permit hemp production for research purposes, but not for commercial purposes.[25] States that do permit hemp production for commercial purposes, like Florida, have separate rules requiring permits to process, prepare and sell food containing hemp or CBD.[26] And hemp production is still prohibited in South Dakota, Mississippi and Idaho.[27]

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PRACTICAL TAKEAWAYS

So, after weighing the benefits and the risks, where does this leave businesses and individuals interested in hemp production?

To benefit from this new regulatory construct, the parties involved should first identify whether their intended hemp producer is governed by a USDA approved state plan or the federal USDA Hemp Producer License by tracking approved, submitted and pending state plans here. Additionally, even though producers are relieved from DEA registration requirements, *laboratories* that test THC content of hemp samples must still be DEA registered and comply with forthcoming accreditation standards. The USDA has published a list of DEA registered hemp analytical testing laboratories here.

The parties should then determine the purpose for which they are interested in hemp production and ensure that their purpose aligns with the state laws applicable to hemp production, and the processing and sale of hemp-derived products. As noted previously, the FDA and FTC have indicated that a narrow path is open to research hemp-derived CBD, but CBD infused products are not otherwise FDA approved.

If the parties are interested in shipping hemp or hemp-derived products across state lines, the parties should do the following to ensure that they are protected by the 2018 Farm Bill: (1) ensure that their product is solely produced under the USDA Hemp Producer license or an approved State Plan; and (2) ensure that the product is tested by an approved, DEA registered laboratory. However, any shipping route will inevitably cross multiple law enforcement jurisdictions, each of which may have unique probable cause requirements and varying levels of officer education and training. As it relates to interstate transshipment of hemp, parties should be aware that even if they meet the requirements to gain protection from the 2018 Farm Bill, there is no guarantee that their drivers and products will not be subject to law enforcement scrutiny and the costs associated with that.

In short, anyone interested in hemp production should consult with legal counsel on the compliance and enforcement risks before engaging in the production, shipment or sale of hemp in any state. Even with the advice of sophisticated counsel, this area of law is still evolving, complicated and uncertain.

Hall Render regularly monitors regulatory and enforcement developments relating to USDA, FDA and FTC regulated products, including hemp and hemp-derivatives. If you have any questions about this guidance please contact:

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[references]

[1] Although comments are currently being accepted in response to the USDA Hemp Rule, the published requirements of the Rule are currently effective. An interim final rule is typically issued when the agency has good cause to publish a final rule without first publishing the proposed rule. Interim final rules are effective immediately upon publication, but the agency stipulates that it will alter the interim rule if warranted by comments. This specific type of rulemaking process is often used when the agency is following a statutory deadline.

[2] 84 Fed. Reg. 58522, 58522.

[3] The interim final rule acknowledges that it does not amend or alter federal law relative to the definition of hemp.

[4] 84 Fed. Reg. 58525.

[5] 84 Fed. Reg. 58530.

[6] Again, this presumes that the Licensed Producer at all times prior to such testing has exercised reasonable efforts to ensure that all hemp production produces plants with less than 0.3% THC content.

[7] 84 Fed. Reg. 58531.

[8] 84 Fed. Reg. 58528.

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[9] 84 Fed. Reg. 58523, 58527 – 58528.

[10] 84 Fed. Reg. 58523.

[11] 84 Fed. Reg. 58525.

[12] 84 Fed. Reg. 58525.

[13] Drugabuse.gov, National Institute on Drug Abuse, NIDA's Role in Providing Marijuana for Research, Revised August 2019, Available at https://www.drugabuse.gov/drugs-abuse/marijuana/nidas-role-in-providing-marijuana-research (last accessed October 31, 2019).

[14] Fda.gov, *FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD)*, October 16, 2019, Available at, https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd (last accessed October 31, 2019).

[15] Fda.gov, FDA News Release, *FDA warns 15 companies for illegally selling various products containing cannabidiol as agency details safety concerns*, November 25, 2019, Available at https://www.fda.gov/news-events/press-announcements/fda-warns-15-companies-illegally-selling-various-products-containing-cannabidiol-agency-details (last accessed January 9, 2020).

[16] Fda.gov, Consumer Updates, *What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD*, November 25, 2019, Available at https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabis-or-cannabis (last accessed January 9, 2020).

[17] Ams.usda.gov, Status of State and Tribal hemp Production Plans for USDA Approval, Updated January 7, 2020, https://www.ams.usda.gov/rules-regulations/hemp/state-and-tribal-plan-review. Six (6) states – Arkansas, Maine, Minnesota, Missouri, New Mexico, and Wisconsin – that participated in a pilot program in 2014 will continue to operate under the terms of the pilot program.

[18] Note that the following states have not submitted a plan or expressed interest in submitting a plan for USDA review: Alaska, Idaho, Kansas, Massachusetts, Michigan, Mississippi, Nevada, New Hampshire, New York, North Carolina, Oklahoma, Rhode Island, South Carolina, South Dakota, and Vermont.

[19] *See generally* National Conference of State Legislatures, *State Laws Related to Industrial Hemp*, August 2, 2019, Available at https://www.ncsl.org/research/agriculture-and-rural-development/state-industrial-hemp-statutes.aspx (last accessed January 20, 2020).

[20] Steve Davies, Agri-Pulse Communications, *Hemp transportation issue unresolved 10 months after farm bill*, October 16, 2019, Available at https://www.agri-pulse.com/articles/12715-hemp-transportation-still-an-issue-10-months-after-farm-bill (last accessed January 20, 2020); Jolie McCullough, The Texas Tribune, *He spent a month in Texas jail accused of hauling 3,350 pounds of marijuana. But lab results say it was legal hemp*, January 7, 2020, Available at, https://www.texastribune.org/2020/01/07/marijuana-texas-dps-arrest-hemp/ (last accessed January 20, 2020); Carlos Miller, Miami New Times, *Cops Keeping Arresting Innocent People for Legal Hemp*, January 8, 2020, Available at, https://www.miaminewtimes.com/marijuana/police-arrest-innocent-people-for-trafficking-legal-hemp-11421856 (last accessed January 20, 2020).

[21]*See also,* ftc.gov, Federal Trade Commission and Food and Drug Administration, *Joint Warning Letter*, March 28, 2019, Available at https://www.ftc.gov/system/files/attachments/press-releases/ftc-joins-fda-sending-warning-letters-companies-advertising-selling-products-containing-cannabidiol/advancedspine_relievus_wl.pdf (last accessed October 31, 2019); ftc.gov, Federal Trade Commission, *Warning Letters Advertising CBD-Infused Products as Treatments for Serious Diseases, Including Cancer, Alzheimer's, and Multiple Sclerosis*, September 10, 2019, Available at https://www.ftc.gov/news-events/press-releases/2019/09/ftc-sends-warning-letters-companies-advertising-their-cbd-infused (last accessed October 31, 2019).

[22] Fda.gov, Consumer Updates, *What You Need to Know (And What We're Working to Find Out) About Products Containing Cannabis or Cannabis-derived Compounds, Including CBD*, November 25, 2019, Available at https://www.fda.gov/consumers/consumer-updates/what-you-need-know-and-what-were-working-find-out-about-products-containing-cannabi

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s-or-cannabis (last accessed January 9, 2020); *See also,* fda.gov, FDA News Release, *FDA warns 15 companies for illegally selling various products containing cannabidiol as agency details safety concerns*, November 25, 2019, Available at https://www.fda.gov/news-events/press-announcements/fda-warns-15-companies-illegally-selling-various-products-containing-cannabidiol-agency-details (last accessed January 9, 2020).

[23] Pub .Law 115-334, Section 10114. Interstate Commerce, December 20, 2018, Available at, https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf (last accessed January 21, 2020); See also, United States Department of Agriculture, Memorandum: Executive Summary of New Hemp Authorities, May 28, 2019, Available at, https://www.ams.usda.gov/sites/default/files/HempExecSumandLegalOpinion.pdf (last accessed January 21, 2020).

[24] Steve Davies, Agri-Pulse Communications, *Hemp transportation issue unresolved 10 months after farm bill*, October 16, 2019, Available at https://www.agri-pulse.com/articles/12715-hemp-transportation-still-an-issue-10-months-after-farm-bill (last accessed January 20, 2020).

[25] *See generally* National Conference of State Legislatures, *State Laws Related to Industrial Hemp*, August 2, 2019, Available at https://www.ncsl.org/research/agriculture-and-rural-development/state-industrial-hemp-statutes.aspx (last accessed January 20, 2020).

[26] *Id.*

[27] *Id.* Note that South Dakota Governor Noem has recently indicated a willingness to permit hemp production, but a bill decriminalizing hemp production has yet to be passed and hemp production remains illegal. Ricardo Lewis, Dakota News Now, *Governor Noem offers plans to "Decriminalize Hemp,"* January 9, 2020, Available at, https://www.ksfy.com/content/news/Governor-Noem-offers-plans-to-Decriminalize-Hemp-566863271.html (last accessed January 20, 2020). Additionally, Idaho's governor signed an Executive Order permitting the transshipment of hemp across its borders in alignment with the 2018 Farm Bill, but hemp production is still prohibited within the state. Executive Department, State of Idaho, Executive Order No. 2019-13, *Transportation of Hemp*, November 19, 2019, Available at, https://gov.idaho.gov/wp-content/uploads/sites/74/2019/11/eo-2019-13.pdf (last accessed January 21, 2020).

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