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New York Moves Forward With Regulating CBD Sales, While Federal Law Remains In Limbo

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Client Advisory

New York recently published its long-awaited proposed regulations for the processing and sale of productions containing cannabinoids (CBD) extracted from hemp. The proposed regulations, available on the Department of Health's website,[1] would add a new Part 1005 to Title 10 of the New York health code to effectuate the provisions of Article 33-B of the New York Public Health Law (PHL). The regulations establish a scheme for licensing manufacturers and retailers of CBD products, with the overall goal of instituting consumer protections ensuring products are manufactured, tested and labeled to comparative standards of similar products in the dietary supplement, food and cannabis industries.[2]

In some respects, the regulations depart from the federal approach, which remains in limbo while the U.S. Food and Drug Administration (FDA) continues its rulemaking for hemp derived CBD products,[3] and the U.S. Drug Enforcement Administration (DEA) and U.S. Department of Agriculture (USDA) continue to grapple with the rules governing cultivation and processing of hemp under the 2018 Farm Bill that have been the subject of significant pushback by industry participants and certain lawmakers as too restrictive.[4]

A. What The Proposed New York Regulations Do

In the regulator's own words, the purpose of the regulation is to "organize and legitimize the cannabinoid market in New York State by creating a license framework for cannabinoid hemp processors and retailers and by establishing quality control standards that all cannabinoid hemp products must meet or exceed" while federal regulation efforts drag on.[5] Broadly, the regulations fall into four general categories.

First, the proposed regulations include a license scheme for manufacturers and retailers of hemp derived CBD. *See* §§ 1005.2-1005.3; 1005.14. Including regulation governing the transfer of licenses. *See* § 1005.15.

A processor or manufacturer application, among other requirements, must be accompanied by a summary and description of the products the applicant intends to make, proof of product liability insurance, evidence of good manufacturing practices, and copies of the organizational documents of the applicant. The application fee for manufacturers or processors will be between $500 – $1,000, and the license fee will be between $2,000 – $4,500 (depending on whether the license including extraction of CBD in addition to manufacturing of finished products). *See* § 1005.2. Licenses are valid for two years. *See* § 1005.4.

Retailers are permitted to only sell approved forms of cannabinoid hemp products purchased from sources that manufacture to the standards of the program, and sales to minors are restricted. Among other requirements, cannabinoid hemp retail applications must be accompanied by a summary and description of the type of CBD hemp products the retailer intends to sell, the name and state or country of origin of any manufacturers the retailer intends to source from, an attestation that the applicant will not sell inhalable cannabinoid hemp products to consumers under 21 years old, and proof of a certificate of authority from the Department of Taxation and Finance. Each location that sells approved CBD products would require a separate $300 licensing fee. *See* § 1005.3. Licenses are valid for one year. *See* § 1005.4.

Second, the regulations impose third-party accredited laboratory testing requirements on all lots of CBD hemp products, testing for cannabinoid profile, heavy metals, microbials, mycotoxins, pesticides and residual solvents. The regulations will hold processors to federally established standards of good manufacturing practices (GMP) at the dietary supplement or food standard depending on the finished product. *See* §§ 1005.7-1005.8, 1005.10.

Third, the regulations set out the types of products that may, and more importantly may not, be sold in New York. *See* § 1005.8. A non-exclusive list of requirements is as follows:

- Products must contain no more than 0.3% THC;
- CBD may not be added to tobacco or alcohol;
- Products cannot be in the form of an injectable, transdermal patch, inhaler, suppository, flower product including cigarette, cigar or pre-roll, or any other disallowed form as determined by the department;
- If sold as a food or beverage product, not have more than 25mg of CBD per product; and,
- If sold as an inhalable CBD hemp product, the product must include a number of additional safety measures.

CBD retailers can only sell products that are manufactured, packaged, labeled and tested according to the standards outlined in regulations and can only sell inhalable cannabinoid hemp products to consumers over 21 years old. *See* § 1005.11. The regulations also govern how such products may be advertised (including by prohibiting false or misleading statements and medical claims). *See* §§ 1005.12; 1005.16.

Fourth, the proposed regulations establish packaging and labeling standards that accurately inform the consumer of the quantity of CBD in the product, include a link or QR code to the third-party tests results, and provide appropriate warnings of the potential risks associated with their consumption. If the product contains THC, the amount of THC in the product needs to be stated on the label in milligrams on a per serving and per package basis. Packaging is prohibited from being attractive to consumers under 18 years old. *See* § 1005.9.

The regulations empower the Department of Health to oversee and enforce the rules with respect to CBD hemp products in the marketplace that do not meet New York's standards. This includes the authority to levy fines (on a sliding scale, from $1,000 for a first violation, $5,000 for a second violation, and $10,000 for each subsequent violation). *See* § 1005.17. Similar to the 2018 Farm Bill's provisions, there is a three-strikes in five years component, at which point a license holder may become ineligible.

B. How They Differ From The Federal Approach

It is important to note that New York's rules do not preempt federal regulation in any way. The 2018 Farm Bill allows both states and the federal government to regulate the manufacture and sale of hemp derived products (including CBD) in parallel. As we previously noted, the FDA is nowhere near issuing a rule on this issue, and its position remains that, strictly speaking, CBD is an active ingredient in an FDA approved medication and as a result its sale is restricted. However, it has *generally* limited itself to sending warning letters to companies that make unsubstantiated health claims or add CBD to food and beverages. New York's approach, on the other hand, is to allow the sale of properly regulated CBD products, and contemplates the sale of CBD infused foods and beverages (under certain conditions).

Another major difference is in how New York and the DEA approach CBD concentrate prior to final sale. In its August 2020 Interim Final Rule, the DEA has taken the position that hemp derived CBD stops being "hemp" (and becomes cannabis) if it exceeds the 0.3% THC concentration at any part in the manufacturing process (even if it is brought back into compliance prior to sale). This has attracted a lot of scrutiny from observers, and consternation by industry participants. In contrast, New York's rule is more lenient, allowing for concentrations of up to 3% THC

for "[i]intermediate sales of hemp extract," provided that the sale is between "licensed processors in New York State and the proper documents accompany the extract during transport." *See* § 1005.7.

It should not be surprising that New York has diverged from the federal government on this issue. It did so earlier this year, when it opted not to submit a hemp cultivation plan under the 2018 Farm Bill because it views some of the testing provisions in the USDA's cultivation rules as unworkable. However it is equally important to remember that New York doesn't have the power to overrule what the federal government (and the DEA) consider a marijuana (as opposed to a hemp) extract.

Conclusion

New York's draft rules are a welcome step forward for New York's CBD industry, as they seek to create some structure for industry participants, and protections for consumers. However, until the federal regulators work through some of their own issues, uncertainty still remains for the industry.

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For more information concerning the matters discussed in this publication, please contact the author **Alexander G. Malyshev** (212-238-8618, malyshev@clm.com), or your regular Carter Ledyard attorney.

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[1] New York Proposed Regulations (https://regs.health.ny.gov/sites/default/files/proposed-regulations/20-21hemp.pdf)

[2] See *id*. at 52 (Legislative Objectives).

[3] *See* FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD) (https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-cbd).

[4] *See* DEA Interim Final Rule for Hemp (https://www.deadiversion.usdoj.gov/fed_regs/rules/2020/fr0821.htm); USDA Interim Final Rule for Domestic Hemp Production (https://www.federalregister.gov/documents/2019/10/31/2019-23749/establishment-of-a-domestic-hemp-production-program) (compliance deadline delayed).

[5] *See* New York Proposed Regulations at 52-54 (Needs and Benefit).

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