New York State Hemp Businesses Must Plan for 2021 Regulations

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In late October, the New York State Department of Health (DOH) published proposed regulations for cannabinoid hemp products. The proposed regulations perform three major functions:

(1) Implementing licensing requirements and fees;

(2) Clarifying what products may be sold; and

(3) Setting quality control standards.

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Regulatory developments continue to be directly relevant to New York State's hemp businesses. After all, there is a strong demand for cannabinoid hemp products such as cannabidiol (CBD), and New York State is a leading marketplace, with more than 700 farmers and 100 manufacturers. The DOH's proposed 2021 regulations should likewise be of high importance to hemp businesses. Indeed, Kaelan Castetter, co-founder and vice president of the New York Cannabis Growers and Processors Association, has referred to these proposed regulations as the "nation's most comprehensive . . . on hemp extract products."

In this article, we unpack the three regulatory functions—licensing, product sales and quality controls—and explain how New York State's hemp businesses should plan.

Licensing Requirements and Fees

The regulations establish licensing requirements across New York State's hemp supply chain. If a business intends to manufacture or process hemp products, it will need to apply for and purchase a license from the State. Hemp manufacturers will be charged a $500 application fee and pay $2,000 for a two-year license, while hemp processors will be charged a $1,000 application fee and pay $4,500 for a two-year license. A business seeking to sell hemp products must purchase a license for each retail location and/or website, which costs $300 and will be valid for one year. Retailers will not be charged an application fee.

Product Sales

The regulations also specify what products may and may not be sold to consumers in New York State. The following are permitted to be sold:

- Food and beverage products (25-milligram-cannabinoid limit per unit);
- Dietary supplements (3,000-milligram-cannabinoid limit per unit);
- Vaping products; and
- Cosmetics.

The proposed regulations also list a number of items that may not be sold, including hemp flower, inhalers, suppositories and transdermal products.

Quality Control

Finally, the regulations implement various quality control mechanisms designed to protect end consumers of hemp products. For instance, the regulations require that producers abide by specific manufacturing practices based on the intended end use of the product. The regulations further mandate that all hemp products be laboratory-tested before being sent to market, and the test results be available for customer review through a URL on the product label. Finally, each product label must contain other information about the product, including the total amount of cannabinoids, the number of cannabinoids per serving, a nutritional fact panel and whether the product contains THC, along with certain warnings.

These quality control-focused regulations put the responsibility on businesses to institute and refine their quality assurance departments or outsource those functions to reputable vendors in the space. Moreover, processors and manufacturers should be prepared to memorialize all procedures given that they could be subject to audit by the DOH or the Food and Drug Administration.

What's Next?

The DOH accepted public comment on the proposed regulations until January 11, 2021, with the final regulations expected to be published in the near future. While small changes are anticipated, the bulk of the proposed regulations are expected to withstand public feedback.

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