

NEW YORK'S NEW HEMP EXTRACT LAW AND THE CBD MARKETPLACE



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On December 19, 2019, Governor Andrew Cuomo signed into law legislation introduced by state Senator Jen Metzger and Assembly member Donna Lupardo, regulating the production and marketing of hemp extract in New York State. Senate Bill 6184¹ and Assembly Bill 7680² together establish a state permitting process for growers, processors and sellers of hemp extract, while also requiring laboratory testing of hemp extract products, including cannabidiol (CBD), as well as specific product labeling. The legislation was signed pursuant to a chapter agreement, which provided for a more streamlined regulatory pathway for hemp products. The new law also grants the NY Department of Agriculture and Markets supervision over hemp growers, and delegates to the NY Department of Health supervision over hemp extracts.

As part of the new regulatory environment for CBD in New York, a registration requirement now exists for sellers of hemp extract products. Noteworthy, however, is the fact that the new law defers the decision on whether to legalize the addition of hemp extracts, including CBD, to foods or beverages. Still, the new law moves New York state ahead of the federal government, which is still working to determine how best to regulate the CBD industry.

¹ The legislative history and text of Senate Bill S6184A (2019) can be accessed online at: <https://www.nysenate.gov/legislation/bills/2019/s6184>

² The legislative history and text of Assembly Bill A7608A (2019) can be accessed online at: <https://www.nysenate.gov/legislation/bills/2019/a7680>

The Federal Farm Bill of 2018 and New York's New Hemp Extracts Law

The 2018 Federal Farm Bill (Agriculture Improvement Act of 2018, P.L. 115-334) removed hemp from Schedule 1 of the Controlled Substances Act. 21 U.S.C. §§801 *et seq.*; Title 21 C.F.R. Part 1308.11. Botanically, hemp and marijuana are from the same species of plant, Cannabis sativa, but from different varieties or cultivars. However, hemp and marijuana are genetically distinct forms of cannabis that are distinguished by their use and chemical composition as well as by differing cultivation practices in their production. While marijuana generally refers to the cultivated plant used as a psychotropic drug (whether used for medicinal or recreational purposes), hemp is cultivated for use in the production of a wide range of products, including foods and beverages, personal care products, nutritional supplements, fabrics and textiles, paper, construction materials, and other manufactured and industrial goods. Hemp is defined under the 2018 Farm bill as “the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.”³

By legalizing hemp at the federal level, the 2018 Farm Bill also legalized CBD that is derived from hemp, creating new opportunities for New York farmers and businesses. Hemp extracts currently are being used to produce a broad range of CBD consumer products, including edibles, ointments, topical creams and unguents, *etc.*

Despite being delisted from the Controlled Substances Act, however, these products have not received federal regulatory review or approval – in large part because the US Food and Drug Administration, which has jurisdiction to regulate such products, still is working to develop appropriate production standards, labeling requirements and marketing guidelines for CBD products.

To address the gap in federal oversight of CBD products, New York's new law establishes a regulatory framework for regulating hemp extract production, processing, and commerce within the state, updating the hemp permitting process and regulating the extract industry through production standards, testing, and labeling, creating needed industry certainty while also protecting consumers. The new hemp bill will give New York farmers a competitive edge in the hemp industry by allowing for regulated and quality products to be produced, focusing on New York-grown hemp.

³ Sec. 297A(1), Agriculture Improvement Act of 2018, P.L. 115-334.

The new law provides the regulatory framework for:

- two-year renewable licensing required for those looking to grow, manufacture, or process hemp and hemp extract products;
- a permit requirement on retailers, as well as wholesalers, and manufacturers, selling “cannabis products derived from hemp extracts” so that sellers of CBD products will be required to apply for a CBD permit. The scope of products covered by this retail permit requirement, and the qualification criteria the permitting requirements may be. Both issues will presumably be clarified in future regulations by the department.
- packaging and labeling requirements (including negative health impact warning information and restrictions on health claims);
- independent laboratory testing oversight by approved labs will be required, as well as the use of to include QR-Codes linked to consumer information;
- the issuance of retail, wholesale and distributor permits to sell hemp-derived products, conditioned on qualifications that include “good moral character,” hemp production experience, competency, and (if requested by the New York Department of Agriculture and Markets) fingerprints of each researcher, principal or officer of the license applicant; and
- investment incentives favoring hemp-derived products for farm operations across New York state, subject to new regulations governing CBD extract production that are to be promulgated by the Department of Agriculture and Markets.

Why the Federal Jury Remains Out on CBD Foods and Beverages

In an FDA Website posting dated December 31, 2019, the agency reaffirmed its position that federal law currently prohibits hemp-derived CBD from being combined in food or beverages. FDA contends that marketing products containing cannabis and cannabis-derived compounds violates the Federal Food, Drug and Cosmetic Act (FD&C Act), and consequently those products may put the health and safety of consumers at risk. To enforce its position, the agency issued warning letters to 22 different firms that market unapproved new drugs, dietary supplements or other consumer products that allegedly contain CBD.⁴

The deeper reasoning for the ban has to do with the absence of reliable scientific, peer-reviewed data on how CBD effects the human body – especially brain activity and muscle-motor functions. The FDA insists that the ongoing federal ban against CBD foods and beverages is necessary because the federal government has seen only limited data about CBD safety, and these data point

⁴ See, Warning Letters and Test Results for Cannabidiol-Related Products, *FDA.gov*. The full list of CBD-related warning letters issued by the FDA in 2019, along with copies of each letter, can be accessed online at: <https://www.fda.gov/news-events/public-health-focus/warning-letters-and-test-results-cannabidiol-related-products>

to material health and safety risks that need to be assessed before legalizing consumer consumption of CBD foods and beverages.

For example, the FDA has published guidance warning pregnant women against the use of CBD, tetrahydrocannabinol (THC), and marijuana in any form during pregnancy or while breastfeeding.⁵ The agency also is warning against the use of CBD by drivers, advising that “*CBD can cause sleepiness, sedation and lethargy, based on data from Epidiolex, the only FDA-approved prescription drug made with CBD]. Because of these side effects, consumers should use caution if planning on operating a motor vehicle after consuming any CBD products.*”⁶

Similarly, the Office of the U.S. Surgeon General has published guidance warning that “long-term effects [of CBD] are largely unknown, and most CBD products are untested and of uncertain purity.”⁷

When the new Hemp Extracts law was sent to Governor Cuomo for his signature, it included preferential provisions favoring the commercialization of hemp and hemp extracts produced in New York, as opposed to similar products produced in other states. For example the legislation as drafted permitted the sale of beverages containing no more than 20 milligrams of CBD per 12 ounces, but only if the CBD in the beverage was derived from hemp extract grown, extracted and manufactured in the state of New York.

This provision sounded alarms in the Governor’s Office, as a patent violation of the so-called “dormant Commerce Clause doctrine” that prevents one state from erecting trade barriers that discriminate in favor of local commercial interests while unduly burdening out-of-state competitors. The legislation’s favoritism for New York-produced hemp extracts raised concerns with hemp industry groups who claimed the legislation as drafted was “unconstitutional,” and “protectionist.”

New York faced a very similar situation with the wine industry, in a dispute that ultimately was settled by the U.S. Supreme Court. In its 2005 decision of *Granholm v. Heald*,⁸ the Court ruled that New York’s laws favoring domestic wineries with a physical presence in New York unfairly discriminated against out-of-state wineries that wanted to sell to New York consumers on equal terms with their in-state competitors. As a result, New York was required to eliminate the discrimination and put all the wineries on an equal footing.

⁵ See U.S. Food and Drug Administration, “What You Should Know About Using Cannabis, Including CBD, When Pregnant or Breastfeeding,” accessible online at: <https://www.fda.gov/consumers/consumer-updates/what-you-should-know-about-using-cannabis-including-cbd-when-pregnant-or-breastfeeding>

⁶ “Taking Cannabidiol (CBD) Products and Driving Can Be Dangerous,” *FDA Website* (Dec. 17, 2019). This content is accessible online at <https://www.fda.gov/consumers/consumer-updates/some-medicines-and-driving-dont-mix>.

⁷ Office of the Surgeon General, “U.S. Surgeon General’s Advisory: Marijuana Use and the Developing Brain,” accessible online at: <https://www.hhs.gov/surgeongeneral/reports-and-publications/addiction-and-substance-misuse/advisory-on-marijuana-use-and-developing-brain/index.html>

⁸ 544 U.S. 460 (2005).

With the *Granholm* precedent in mind, Governor Cuomo decided the matter required more study. Consequently, the new hemp extract law defers decision-making on hemp extracts, including CBD, as additives for food and beverages.

In line with the FDA and the Surgeon General, the New York City Department of Health enacted a ban on retailers and restaurant owners providing such products to consumers as of July 1, 2019. Violators could see their products “embargoed,” making them unavailable for sale, and may face fines from \$250-\$600, according to the NYC Health Code. Despite the passage of New York’s new hemp extract law, the NYC Health Department’s ban on the use of CBD in foods or beverages remains in place (for now).

At the state level, the New York Department of Agriculture & Markets issued an advisory letter on July 19, 2019 that said CBD is illegal in New York when added to food or drinks pursuant to Agriculture and Markets law (AML sec. 200).

The Prospects for Further Legislation

Looking ahead, it’s clear that New York legislators will be looking to resolve the issue of CBD in foods and beverages. Cannabis industry analyst BDS Analytics issued a report in May of 2019 projecting that the U.S. market for CBD products – encompassing foods and beverages, as well as cosmetics, health products, pet products, skin care, and pharmaceuticals – would exceed \$20 billion by 2024.⁹ From the Bronx in the South, to Long Island in the East, through the Hudson Valley and North up to Erie County, more than 400 New York growers had nearly 18,000 acres of hemp under cultivation, much of it harvested in 2019. In 2017, there were barely 100 state-licensed growers in New York.

This optimism is further buoyed by industry projections that the impending growth of the CBD edibles market eventually will overtake smoked marijuana in terms of users and revenues. Industry data analysts such as The Arcview Group observe that in 2017 edible revenues in both the U.S. and Canada were only \$1 billion, but they have since moved at a rapid pace and have become mainstream, garnering a massive new audience. ArcView projects that legal cannabis-derived edible products, from candy and chocolate to infused beverages, are projected to grow from 12 percent to 14 percent of the total cannabis market by 2022.¹⁰

While New York lawmakers will have to wrestle with the legal constraints of the dormant Commerce Clause doctrine, there is no doubt that New York’s CBD industry is moving forward at full speed. As evidence of that, the Ontario, Canada-based cannabis company Canopy Growth invested \$150 million in developing an industrial hemp park in Kirkwood, NY. In fact, Governor

⁹ See, Press Release, “U.S. CBD Market Anticipated to Reach \$20 Billion in Sales by 2024,” *BDS Analytics* (May 9, 2019); this content is accessible online at: <https://bdsanalytics.com/u-s-cbd-market-anticipated-to-reach-20-billion-in-sales-by-2024/>

¹⁰ See, “The Tasty Future of Cannabis Edibles,” *The Arcview Group* (Apr. 22, 2019). Access to this report is by subscription or purchase; more information is available online at <https://arcviewgroup.com/product/edibles/>

Cuomo signed the state's new hemp extract law at a signing ceremony held at the Kirkwood facility. Canopy will use the Broome County facility to process hemp into CBD for production of tinctures, ointments, salves, canine treats and other products for commercial sale.

Likewise, there is good reason to believe that the New York City Department of Health will adopt regulations to allow for the use of CBD in foods and beverages, although that likely will have to follow production standards and labeling requirements specifically designed for such consumables. The NYC Health Department expressly tied the city's own ban to the FDA's position that it remains unlawful to add CBD to food or drink. However, that federal position is predicated on the absence of meaningful standards regarding product content, validation and labeling. That may change in 2020.

New York's new hemp extract law amends the state's Agriculture & Markets Law to establish a framework for the packaging and labeling of hemp extract products. All hemp extracts will have to be labeled in accordance with department standards, include a supplement fact panel where applicable, and must display a QR Code setting forth the applicable serving size, concentration, and growing region of the product.

Moreover, the new law also requires the creation of a "New York State Industrial Hemp and Hemp Extract Workgroup," to be composed of hemp researchers, producers, processors, manufacturers and trade associations. The Workgroup is charged with (i) making recommendations for the state's hemp and hemp extract programs, (ii) developing state policy initiatives and best practices for the safe operation and effective oversight of the industry, and (iii) identifying new opportunities to promote and market industrial hemp and hemp extracts.

If these efforts proceed forward and yield meaningful results, the prospects are promising for withdrawal of New York City's ban on the use of CBD in foods and beverages.

For more information on the legalization, development and expansion of the hemp, CBD and hemp-extract industries in the United States, contact GrayRobinson's Regulated Products Law Department at **(800) 338-3381**, or contact the author directly at Richard.Blau@gray-robinson.com.