

Recreational Marijuana Program

Compliance Education Bulletin

Bulletin CE2024-06

November 21, 2024



The Oregon Liquor & Cannabis Commission (OLCC) is providing the following information to recreational marijuana licensees and hemp certificate holders.

The bulletin is part of OLCC’s compliance education. It is important that you read it and understand it. If you don’t understand it, please contact the OLCC for help at olcc.hemp@olcc.oregon.gov. Failure to understand and follow the information contained in this bulletin *could result in an OLCC administrative violation affecting your ability to work or operate your business.*

Compliance Education Bulletin CE2024-06 covers the manufacture, distribution, and sale of hemp and marijuana products containing artificially derived cannabidiol (CBD).

Background

In 2021, following the passage of 2021 House Bill 3000, OLCC adopted regulations on artificially derived cannabinoids in marijuana and hemp items in the OLCC-licensed marijuana market (at OLCC-licensed marijuana retailers) and on hemp items sold to Oregon consumers outside of the OLCC-licensed marijuana market (at grocery and convenience stores, restaurants, smoke shops, online retail, etc.).

History of artificially derived cannabinoid regulations in the OLCC market

Under the rules adopted in 2021, artificially derived cannabinoids could only be present in marijuana and hemp items under limited circumstances. Specifically, the artificially derived cannabinoid:

- Must also occur naturally in the cannabis plant;
- Cannot be intoxicating;
- Cannot be used in a product intended for human inhalation;
- Must be manufactured in compliance with applicable food safety laws; **and**
- Must have gone through one of the ordinary processes for introducing a novel ingredient into food or dietary supplements. To meet this requirement, the manufacturer of the artificially derived cannabinoid must do one of the following:
 1. Make a determination that the artificially derived cannabinoid, as manufactured by the manufacturer, is “Generally Recognized as Safe” (GRAS); **or**
 2. Submit a GRAS notice to FDA and receive a response affirming that FDA has no questions about the notice; **or**
 3. Submit a New Dietary Ingredient Notification (NDIN) to the FDA for the artificially derived cannabinoid, as manufactured by the manufacturer, and receive a “no objections” response from the FDA.

At the same time, OLCC created a time-limited exemption for artificially derived CBD that did not meet the GRAS or NDIN requirement. As long as the artificially derived CBD met all other requirements, products containing this CBD could be sold for 18 months, until July 1, 2023.

In 2023, OLCC amended the rule to extend this exemption for an additional 18 months, until January 2, 2025. During rulemaking, artificially derived CBN manufacturers affirmed that this would be adequate time to finish making a GRAS determination or submitting an NDIN. Along with the extension, OLCC added a requirement that artificially derived CBN manufacturers obtain preapproval to continue supplying CBN for use in products in the OLCC market. OLCC maintains [a list of approved manufacturers](#). To obtain approval, the manufacturer must provide documentation that they have:

- Taken substantial steps toward meeting the GRAS or NDIN requirement;
- Conducted a hazard analysis as described in 21 CFR 117.130 to identify foreseeable hazards in the process of manufacturing the CBN; and
- Documented any preventative controls, as described in 21 CFR 117.135 that minimize or prevent any hazards requiring preventive control.

The rule change described in this Bulletin extends the current exemption for artificially derived CBN to continue to be sold for an additional six months, until July 1, 2025.

History of artificially derived cannabinoid regulations in the general market

When OLCC adopted cannabinoid limits for the general market in 2021, products for sale to Oregon consumers were not permitted to contain any artificially derived cannabinoids.

In 2024, the Oregon legislature passed House Bill 4121 which required that rules for artificially derived cannabinoids in hemp items in the general market be no more restrictive than the rules for hemp and marijuana items in the OLCC-licensed marijuana market. On October 17, 2024, OLCC adopted rules to implement this legislation, allowing artificially derived CBN to be sold under essentially the same conditions as in the OLCC-regulated marijuana market until January 2, 2025.

The rule change described in this Bulletin extends the current exemption for artificially derived CBN to continue to be sold for an additional six months, **until July 1, 2025**.

Rules Changes

On November 21, 2024, the Commission adopted temporary rules extending the current exemption for artificially derived CBN to continue to be sold for an additional six months, **until July 1, 2025**. This change applies to marijuana and hemp items in the OLCC-licensed marijuana market (OAR [845-025-1310](#)) and to hemp items sold to Oregon consumers outside of the OLCC-licensed marijuana market (OARs [845-026-0400](#) and [845-026-0410](#)). **The Commission intends this to be the *final* extension.**

If an artificially derived CBN manufacturer makes a GRAS determination or submits an NDIN and receives a “no objections” response from the FDA, any artificially derived CBN subject to that GRAS determination or NDIN can continue to be sold after July 1, 2025, even if it was produced prior to the GRAS determination or NDIN submission. For example, if the manufacturer makes a GRAS determination on August 1, 2025, any remaining inventory of products containing artificially derived CBN subject to that GRAS determination may resume sales on that date.

Artificially Derived CBN

“Artificially derived cannabinoids” are cannabinoids created synthetically by taking a starting material derived from hemp or marijuana and introducing reagents or catalysts to initiate a chemical reaction. These are sometimes referred to as “semisynthetic” cannabinoids. Artificially derived cannabinoids do not include decarboxylation of cannabinoid acids without the use of a chemical catalyst (for example, decarboxylating THCA to THC by applying heat).

CBN is often manufactured synthetically from CBD because CBD is an inexpensive and readily available starting material. This synthetically manufactured CBN is an artificially derived cannabinoid. At this point, most hemp-derived CBN that OLCC is aware of is an artificially derived cannabinoid.

Whether a substance is an artificially derived cannabinoid depends entirely on how it is produced. Cannabinoids like delta-9-THC and CBN occur naturally in the cannabis plant, but delta-9-THC or CBN that is manufactured synthetically from CBD is still an artificially derived cannabinoid.

Naturally Derived CBN

CBN is also a naturally occurring component of cannabis that occurs when THC oxidizes. This is a natural process that occurs without the use of chemical catalysts or reagents. This naturally occurring CBN extracted from cannabis (hemp or marijuana) is not an artificially derived cannabinoid.

Processors can also accelerate the oxidation of THC to CBN by adjusting the environmental conditions, such as applying heat and light. Because this process does not involve the use of any chemical catalysts or reagents, CBN produced in this way is also considered naturally derived and is not an artificially derived cannabinoid.

What this means for Retailers and Wholesalers

After **July 1, 2025**, any hemp and marijuana products containing artificially derived CBN without a GRAS determination or NDIN can no longer be sold to consumers in Oregon. Retailers must remove these products by the end of the day on July 1, 2025. Wholesalers may no longer distribute these products after July 1, 2025.

Retailers and wholesalers should work with the product manufacturer and have a plan for handling any remaining inventory after July 1. Between now and July 1, 2025, retailers and wholesalers may want to be mindful of inventory levels of products containing artificially derived CBN.

Labels for these products will state on the front that it contains “artificially derived cannabinoids” and on the ingredient listing it will include the words “artificially derived cannabinol (CBN) hemp extract” (or something similar). Common examples of these products are edibles and tinctures.

What this means for Processors and Hemp Certificate Holders

Processors and hemp handlers who make products containing artificially derived CBN under the current exemption can continue to produce those products. However, these businesses should be mindful of the **July 1, 2025** deadline and have a plan for what to do with these products if the CBN manufacturer does not make a GRAS determination or NDIN submission and receive a response by that date.

Processors and handlers should work with their retail and distribution partners to plan for any products remaining in inventory that may become ineligible for sale or transfer after July 1, 2025. Since retailers cannot transfer items directly to a hemp handler, hemp handlers may want to identify a processor to work with to facilitate the return of excess products to the handler facility.

If the processor or handler anticipates that a GRAS determination or NDIN submission may be made in the near future, they may choose to store these products in anticipation of the possibility that they may again become eligible for distribution and sale. The processor can have the products returned to store at their own licensed premises or work with a wholesaler to store the products on their behalf.

Processors who make CBN products and do not anticipate having a compliant source of artificially derived CBN by July may want to identify a source of naturally derived CBN to begin using in their products. Unless you already have an approved label variant for the version of the product made with

naturally derived CBN (i.e. without the phrase “artificially derived” on the label), you will need to have the label change approved for the new formulation (see below).

Packaging and Labeling

Businesses that transition from using artificially derived CBN to naturally derived CBN in their manufacturing processes will need to update the labels accordingly. These changes require resubmission and pre-approval (see OAR [845-025-7160\(8\)](#)). Businesses can submit label amendment requests through [CAMP](#), OLCC’s online licensing system. Questions regarding packaging and labeling can be sent to marijuana.packaging@olcc.oregon.gov or 503-872-5459.

What this means for CBN in the general market

Artificially derived CBN in the general market is subject to essentially the same requirements as artificially derived CBN in the OLCC-regulated marijuana market.

If the manufacturer has made a GRAS determination or submitted an NDIN to the FDA and received a “no objections” response, the CBN may be used in products as long as it was manufactured in compliance with applicable food safety laws and it is not intoxicating at the intended concentration in the finished product.

Artificially derived CBN without a GRAS determination or NDIN may only be present in products until July 1, 2025. Again, the requirements are essentially the same as in the marijuana market. The only difference is that the manufacturer of the artificially derived CBN does not need pre-approval from OLCC to supply their CBN for use in products. However, the manufacturer must still meet the same criteria as required for OLCC approval in the marijuana market:

- Manufacturer has taken substantial steps toward meeting the GRAS or NDIN requirement;
- Manufacturer has conducted a hazard analysis as described in 21 CFR 117.130 to identify foreseeable hazards in the process of manufacturing the CBN; and
- Manufacturer has documented any preventative controls, as described in 21 CFR 117.135 that minimize or prevent any hazards requiring preventive control.

After **July 1, 2025**, any hemp products containing artificially derived CBN without a GRAS determination or NDIN can no longer be sold to consumers in Oregon. Retailers in Oregon must remove these products by the end of the day on July 1, 2025. Online retailers must ensure these are no longer offered for sale to Oregon consumers by the end of the day on July 1, 2025. Manufacturers of these products should work with their retail and distribution partners to identify these products so their partners can remain in compliance.

See OAR [845-026-0400\(4\)](#) and OAR [845-026-0410\(4\)](#) for the requirements in rule.

Questions?

If you have any questions about these changes or this Bulletin, please send them to olcc.hemp@olcc.oregon.gov.