OFFICE OF THE SECRETARY OF STATE
LAVONNE GRIFFIN-VALADE
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE
AND TRIBAL LIAISON

ARCHIVES DIVISION
STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

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CHAPTER 845
OREGON LIQUOR AND CANNABIS COMMISSION

FILING CAPTION: Extends deadline for CBN manufacturers to meet general requirements under this rule, subject to conditions.

EFFECTIVE DATE: 08/01/2023

AGENCY APPROVED DATE: 07/20/2023

CONTACT: Nicole Blosse
971-420-4763
nicole.blosse@oregon.gov

9079 SE McLoughlin Blvd
Portland,OR 97222

Filed By:
Nicole Blosse
Rules Coordinator

AMEND: 845-025-1310

REPEAL: Temporary 845-025-1310 from OLCC 3-2023

RULE TITLE: Artificially Derived Cannabinoids

NOTICE FILED DATE: 05/25/2023

RULE SUMMARY: This rule details regulations for artificially derived cannabinoids. The changes to this rule extend the deadline for artificially derived cannabinol to meet the general requirements described in the rule, subject to conditions.

RULE TEXT:

(1) A licensee may transfer, sell, transport, purchase, possess, accept, return, or receive an artificially derived cannabinoid, including an artificially derived cannabinoid created by a refinement process using a reactive material such as bleaching clay, or a marijuana or hemp item that contains an artificially derived cannabinoid if:

(a) The artificially derived cannabinoid:

(A) Is not a controlled substance under OAR chapter 855, division 80;

(B) Was manufactured in compliance with applicable laws relating to food safety;

(C) In the Commission's judgment, is not impairing or intoxicating; and

(D) Has been reported as a naturally-occurring component of the plant Cannabis family Cannabaceae in at least three peer-reviewed publications.

(b) The item is not intended for human inhalation; and

(c) The manufacturer of the artificially derived cannabinoid:

(A) Has made a "Generally Recognized as Safe" (GRAS) determination for the artificial cannabinoid and supplied a copy of that determination to the Commission;

(B) Has provided to the Commission a Food and Drug Administration (FDA) letter responding to a "Generally Recognized as Safe" (GRAS) notice for the artificially derived cannabinoid manufactured by the same method that the manufacturer uses, affirming that FDA has no questions about the notice; or

(C) Has provided to the Commission an FDA letter of acknowledgement with no objections in response to a New Dietary Ingredient notification for the artificially derived cannabinoid manufactured by the same method that the

manufacturer uses.
(2) The Commission will notify the licensee of acceptance of documentation received under paragraph (1)(c)(A), (B) or (C) of this rule and may apply additional labeling and concentration limit rules.
(3) Until January 2, 2025, a licensee may transfer, sell, transport, purchase, possess, accept, return, or receive any marijuana or hemp item manufactured before July 1, 2023 containing the artificially derived cannabinoid cannabinol (CBN) if:
(a) The item is not intended for human inhalation; and
(b) The CBN:
(A) Is not a controlled substance under OAR chapter 855, division 80; and
(B) Was manufactured in compliance with applicable laws relating to food safety.
(4) Until January 2, 2025, a licensee may transfer, sell, transport, purchase, possess, accept, return, or receive any marijuana or hemp item manufactured on or after July 1, 2023 containing the artificially derived cannabinoid cannabinol (CBN) if:
(a) The item is not intended for human inhalation; and
(b) The CBN:
(A) Is not a controlled substance under OAR chapter 855, division 80;
(B) Was manufactured in compliance with applicable laws relating to food safety; and
(C) Was manufactured by a person with written approval from the Commission affirming that the manufacturer:
(i) Has taken substantial steps towards meeting the requirements described in subsection (1)(c) of this rule, including but not limited to initiating or contracting to initiate safety studies;
(ii) Has conducted a hazard analysis as described in 21 CFR 117.130 to identify foreseeable hazards in the process of manufacturing the CBN and provided the Commission with a copy of the analysis; and
(iii) Has provided the Commission with copies of any preventative controls, as described in 21 CFR 117.135 that minimize or prevent any hazards requiring a preventive control.
(5) A manufacturer may request written approval as described in paragraph (4)(b)(C) of this rule in a form and manner prescribed by the Commission. The Commission:
(a) Shall publish a list of manufacturers who obtain this written approval.
(b) May revoke this approval if the manufacturer no longer meets the requirements described in subsection (4)(b) of this rule. If the Commission revokes approval, the manufacturer has the right to a hearing under the procedures in ORS chapter 183.
(c) May consult with the Oregon Department of Agriculture for the purposes of reviewing the request.
(6) If the Commission requires a manufacturer to submit or produce documents to the Commission that the manufacturer believes falls within the definition of a trade secret as defined in ORS 192.501, the manufacturer must mark each document “confidential” or “trade secret.”
(7) A licensee may not transfer, sell, transport, purchase, possess, accept, return, or receive an artificially derived cannabinoid or a marijuana or hemp item that contains an artificially derived cannabinoid other than as provided in this rule.
(8) The Commission may reevaluate the regulation of artificially derived cannabinoids on an annual basis, including establishing purity standards.

STATUTORY/OTHER AUTHORITY: ORS 475C.017

STATUTES/OTHER IMPLEMENTED: ORS 475C.017