# OREGON LIQUOR & CANNABIS COMMISSION

# Artificially Derived Cannabinoid Label Application Form

## What is this form?

Per OAR 845-025-7160, licensees and industrial hemp certificate holders must include this form and the information listed below with label applications for marijuana or hemp items with artificially derived cannabinoids (ADC) that are allowed by OAR 845-025-1310. Failure to submit this form and/or accurately complete it will be grounds for the OLCC to require resubmission of the label application and possible label denial.

OAR 845-025-1310(1) requires licensees to provide certain Food and Drug Administration (FDA) or Generally Recognized as Safe (GRAS) documentation to the OLCC, this includes:

- The manufacturer has made a GRAS determination for the artificial cannabinoid;
- A letter from the FDA responding to a GRAS notice for the artificially derived cannabinoid manufactured by the same method the manufacturer uses, affirming that the FDA has no question about the notice; or
- An FDA letter of acknowledgment with no objections in response to a New Dietary Ingredient (NDI) notification for the ADC manufactured by the same method that the manufacturer uses.

Citations to least three peer-reviewed publications must be provided. The publications must show that the artificially derived cannabinoid has been reported as a naturally-occurring component of the plant Cannabis family Cannabaceae. At minimum the following must be provided in this form for each publication: the author(s), publication name, date of publication, and a link to the digital object identifier (DOI).

Licensees must also supply a copy of the food establishment license issued by the Oregon Department of Agriculture (ODA) to the manufacturer of the artificially derived cannabinoid.

This form must be signed by the licensee or an authorized representative of the licensee.

* This form uses the term “licensee,” however these requirements are also applicable to industrial hemp certificate holders.

** If an OLCC licensee has manufactured the artificially derived cannabinoid, Section 2 should be left blank.

## Section 1 – Licensee Business Information

| | |
|---|---|
| **Business Name:** | |
| **OLCC or ODA License Number:** | |
| **Phone Number & Email Address:** | |

## Section 2 – Artificially Derived Cannabinoid Manufacturer Information

| | |
|---|---|
| **Business Name:** | |
| **OLCC or ODA License Number:** | |
| **Phone Number & Email Address:** | |

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## Section 3 – FDA or GRAS Documentation

Check the box for the documentation you are providing.

☐ The manufacturer has made a GRAS determination for the artificial cannabinoid.

☐ A letter from the FDA responding to a GRAS notice for the artificially derived cannabinoid manufactured by the same method the manufacturer uses, affirming that the FDA has no question about the notice.

☐ An FDA letter of acknowledgment with no objections in response to a NDI notification for the ADC manufactured by the same method that the manufacturer uses.

☐ Check this box if these requirements do not apply because the artificially derived cannabinoid is cannabinol (CBN) allowed by OAR 845-025-1310(3).

## Section 4 – Peer-reviewed Publications

Provide the author(s), publication name, date of publication, and a link to the DOI for the three peer-reviewed publications.

| | |
|---|---|
| **Publication One:** | |
| **Publication Two:** | |
| **Publication Three:** | |

☐ Check this box if these requirements do not apply because the artificially derived cannabinoid is cannabinol (CBN) allowed by OAR 845-025-1310(3).

## Section 5 – ODA Food Establishment License

Check the box indicating that you will provide the ODA food establishment license issued to the manufacturer of the artificially derived cannabinoid.

☐ A copy of the ODA food establishment license is included.

## Section 6 – Acknowledgement

I affirm that the information contained herein is truthful and accurate. I acknowledge that if my answers are not truthful and accurate, the OLCC may take action against my license.

**Signature:** _____ **Date:** _____

**Name:** _____ **Title:** _____