

R68. Agriculture and Food, Plant Industry.

R68-26. Industrial Hemp Product Registration and Labeling.

R68-26-1. Authority and Purpose.

1) Pursuant to Subsections 4-41-103(4) and 4-41-403(1), this rule establishes the requirements for labeling and registration of products made from and containing industrial hemp.

R68-26-2. Definitions.

- 1) "CBD" means cannabidiol.
- 2) "Certificate of Analysis" (COA) means a document produced by a testing laboratory listing the quantities of the various analytes for which testing was performed.
- 3) "Department" means the Utah Department of Agriculture and Food.
- 4) "Industrial Hemp" means any part of a cannabis plant, whether growing or not, with a concentration of less than 0.3% tetrahydrocannabinol by weight.
- 5) "Industrial hemp product" means products derived from, or made by processing industrial hemp plants or plant parts.
- 6) "Label" means the display of each written, printed, or graphic matter upon the immediate container or statement accompanying an industrial hemp product.
- 7) "Manufacturer" means a person who makes any industrial hemp products.
- 8) "Person" means an individual, partnership, association, firm, trust, limited liability company, or corporation or any employees of such.
- 9) "THC" means total composite tetrahydrocannabinol, including delta -9-tetrahydrocannabinol and tetrahydrocannabinolic acid.
- 10) "Third- party laboratory" means a laboratory with no direct interest in a grower or processor of industrial hemp or industrial hemp products that is capable of performing mandated testing utilizing validated methods.

R68-26-3. Product Registration.

- 1) Each industrial hemp product distributed or available for distribution in Utah shall be officially registered annually with the department.
- 2) Application for registration shall be made to the department on a form provided by the department including the following information:
 - a) the name and address of the applicant and the name and address of the person whose name will appear on the label, if other than the applicants;
 - b) the name of the product;
 - c) the type and use of the product;
 - d) a complete copy of the label as it will appear on the product provided in a PDF format; and
 - e) if the product has been assigned a National Drug Code in accordance with 21 CFR 207.33, the applicant shall provide the National Drug Code number.
- 3) If the industrial hemp product being registered contains a cannabinoid, the application shall include a certificate of analysis from a third-party laboratory for the product in compliance with Section R68-26-4.
- 4) A registration fee per product, as set forth in the fee schedule approved by the legislature, shall be paid to the department with the submission of the application.
- 5) The department may deny registration for incomplete applications.

- 6) The department may exempt an industrial hemp product that is determined to be adequately regulated by a federal agency.
- 7) A new registration is required for any of the following:
 - a) changes in the industrial hemp product ingredients;
 - b) changes to the directions for use; and
 - c) a change of name for the product.
- 8) Other changes shall not require a new registration but the registrant shall submit copies of all label changes to the department as soon as they are effective.
- 9) The person registering the industrial hemp product is responsible for the accuracy and completeness of information submitted.
- 10) A registration is renewable for up to a one-year period with an annual renewal fee per product, which shall be paid on or before June 30th of each year.
- 11) An industrial hemp product that has been discontinued shall continue to be registered in the state until the product is no longer available for distribution.
- 12) A late fee shall be assessed for a renewal of an industrial hemp product registration submitted after June 30th and shall be paid before the registration renewal is issued.
- 13) The department shall not register an industrial hemp product containing a cannabinoid if the product:
 - a) is in an unapproved medicinal dosage form;
 - b) uses the cannabinoid as a food additive; or
 - c) is represented for use as a conventional food.

R68-26-4. Certificate of Analysis.

- 1) The certificate of analysis for industrial hemp products containing a cannabinoid shall be tested for:
 - a) the cannabinoid profile by percentage of dry weight;
 - b) solvents;
 - c) pesticides;
 - d) microbials; and
 - e) heavy metals.
- 2) The test results required in Subsection R68-26-4(1) shall be reported in accordance with the requirements for a cannabinoid product in Rule R68-29 including the specified units of measure.
- 3) The certificate of analysis shall include the following information:
 - a) the batch identification number;
 - b) the date received;
 - c) the date of completion;
 - d) the method of analysis for each test conducted; and
 - e) a picture of the product in its final form.
- 4) Testing shall be conducted on the product in its final form.

R68-26-5. Label Requirements.

- 1) Industrial hemp products containing a cannabinoid produced for oral human consumption shall be labeled in accordance with 21 CFR 101.1, 21 CFR 101.2, 21 CFR 101.3, 21 CFR 101.4, 21 CFR 101.5, 21 CFR 101.7, 21 CFR 101.9(j)(13), 21 CFR 101.9(j)(17), 21 CFR 101.15, and 21 CFR 101.36;

a) a label may contain the term "product facts" in place of "supplement facts" provided the information required in 21 CFR 101.36 is on the label; and

b) the label shall include the following text, prominently displayed: This product has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

2) A cannabinoid product intended to be vaporized for inhalation shall:

a) be labeled in accordance with Subsection R68-26-5(1); or

b) be labeled in accordance with 21 CFR 101.1, 21 CFR 101.2, 21 CFR 101.3, 21 CFR 101.4, 21 CFR 101.5, 21 CFR 101.7, 21 CFR 101.5, 101.15, and contain the following text, prominently displayed: "This product has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

3) Industrial hemp products containing a cannabinoid produced for absorption by humans shall be labeled:

a) in accordance with 21 CFR 701, Cosmetic Labeling; and

b) contain the following text, prominently displayed: "Warning - The safety of this product has not been determined."

4) Notwithstanding R68-26-5(1) or (3), an industrial hemp product containing a cannabinoid produced for human use that has a National Drug Code issued shall be labeled in accordance with 21 CFR 201.66.

5) In addition to the requirements of Subsections R68-26-5(1) through R68-26-5(3) an industrial hemp product containing a cannabinoid shall have on the label a scannable barcode, QR code, or web address linked to a document containing the following information:

a) the batch identification number;

b) the product name;

c) the batch date;

d) an expiration date;

e) the batch size;

f) the total quantity produced; and

g) a downloadable link for a certificate of analysis for the batch identified.

6) Industrial hemp products shall not contain medical claims on the label unless the product has been registered with the FDA and is labeled in accordance with Subsection R68-26-5(4).

7) Industrial hemp products that do not contain a cannabinoid intended for human consumption shall be labeled in accordance with 21 CFR 101, Food Labeling.

8) Industrial hemp products that do not contain a cannabinoid intended for human absorption shall be labeled in accordance with 21 CFR 701, Cosmetic Labeling and 21 CFR 740, Cosmetic Product Warnings Statements.

9) Industrial hemp products meant for animal consumption shall be labeled and comply with applicable federal laws and regulations and other applicable state laws and regulations.

10) Industrial hemp seed products intended for cultivation shall be labeled in accordance with Title 4, Chapter 16, Utah Seed Act.

11) Each industrial hemp product shall comply with the federal Food Drug and Cosmetic Act, 21 U.S.C. Chapter 9 and other applicable federal laws and regulations and applicable state laws and regulations relating to the labeling of food, cosmetics, and fiber.

R68-26-6. Inspection and Testing.

- 1) The department shall conduct randomized inspection of industrial hemp products distributed or available for distribution in the state for compliance with this rule.
- 2) The department shall periodically sample, analyze, and test industrial hemp products distributed within the state for compliance with registration and labeling requirements and the certificate of analysis, if applicable.
- 3) The department may conduct inspection of industrial hemp products distributed or available for distribution for any reason the department deems necessary.
- 4) The sample taken by the department shall be the official sample.

R68-26-7. Retailer Responsibilities.

- 1) A retailer shall:
 - a) ensure that any industrial hemp product is labeled correctly; and
 - b) ensure that all industrial hemp products sold are properly registered with the department.
- 2) Retailers shall provide the identity of the manufacturer of industrial hemp products sold upon request of the department.
- 3) A retailer may register the product in lieu of the manufacturer if the product is not registered.

R68-26-8. Violation.

- 1) Each improperly labeled industrial hemp product shall be a separate violation of this rule.
- 2) Industrial hemp products not meeting the labeling requirements shall be deemed to be misbranded.
- 3) Industrial hemp products shall be considered falsely advertised if it does not meet the labeling requirements of this rule.
- 4) It is a violation to distribute or market industrial hemp product that is not registered with the department.
- 5) It is a violation to distribute or market an industrial hemp product that contains greater than 0.3% THC.
- 6) It is a violation to distribute or market an industrial hemp product containing a cannabinoid that is not in a medical dosage form.
- 7) It is a violation to distribute or market an industrial hemp product containing a cannabinoid as a conventional food product.
- 8) It is a violation to distribute or market a product claiming a cannabinoid derived from industrial hemp as a food additive.
- 9) The Department shall use a penalty matrix to develop appropriate penalties.

KEY: CBD labeling, CBD products, hemp product registration

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Authorizing, and Implemented or Interpreted Law: 4-41-403(1); 4-41-402(2); 4-41-103(4)