641—154.30(124E) Packaging and labeling.

154.30(1) *Trade names.* A manufacturer's medical cannabidiol trade names shall comply with the following:

a. Names shall be limited to those that clearly reflect the form's medical cannabidiol nature;

b. Any name that is identical to, or similar to, the name of an existing nonmedical cannabidiol product is prohibited;

c. Any name that is identical to, or similar to, the name of an unlawful product or substance is prohibited; and

d. Any name that contains language that suggests using medical cannabidiol for recreational purposes or for a condition other than a qualifying debilitating medical condition is prohibited.

154.30(2) *Medical cannabidiol packaging.*

a. Requirements of medical cannabidiol package containers. The manufacturer shall use medical containers that are:

(1) Of sufficient size to accommodate a separate dispensary label containing the information described in paragraph 154.30(2)*"c"*;

(2) Designed to maximize the shelf life of the contained medical cannabidiol;

(3) Tamper-evident; and

(4) Child-resistant.

b. Medical cannabidiol package prohibitions. The packaging for medical cannabidiol shall not:

(1) Bear a reasonable resemblance to commonly available nonmedical commercial products;

(2) Depict images other than the manufacturer's business name or logo on the packaging;

(3) Reasonably appeal to children. More information is provided in rule 641—154.22(2); or

(4) Reasonably appeal to recreational or adult use.

c. Requirements of medical cannabidiol packaging. A manufacturer shall ensure that all medical cannabidiol packaging includes the following information:

(1) The name of the manufacturer, and trade name if applicable;

(2) A label claim concentration for cannabinoid content including:

1. Tetrahydrocannabinol;

2. Tetrahydrocannabinolic acid. Concentrations of tetrahydrocannabinolic acid may be omitted if the manufacturer uses decarboxylation or other means to substantially remove the acids from the product prior to testing;

3. Cannabidiol; and

4. Cannabidiolic acid. Concentrations of cannabinolic acid may be omitted if the manufacturer uses decarboxylation or other means to substantially remove the acids from the product prior to testing;

(3) The number of servings per package (excluding products intended for inhalation);

(4) The directions for use of the product, including recommended and maximum amount by age and weight, if applicable;

(5) All ingredients of the product shown with common or usual names, including but not limited to any additives, terpenes or artificial flavors, diluents and carriers, and preservatives, listed in descending order by predominance of weight. Any third-party hemp-derived cannabinoids in medical cannabidiol products shall be specifically indicated on the ingredients list, separately from medical cannabidiol produced within the manufacturer's facility;

(6) Instructions for storage, including light and temperature requirements, if any; and

(7) The universal warning symbol provided by the department.

d. The following information shall be included with medical cannabidiol packaging, or contained within a package insert:

(1) A notice with the statement, including capitalization: "This product has not been analyzed or approved by the United States Food and Drug Administration. There is limited information on the side effects of using this product, and there may be associated health risks and medication interactions. This product is not recommended for use by pregnant or breastfeeding women. KEEP THIS PRODUCT OUT OF REACH OF CHILDREN.";

(2) A notice with the statement: "This medical cannabidiol is for therapeutic use only. Use of this product by a person other than the patient listed on the label is unlawful and may result in the cancellation of the patient's medical cannabidiol registration card. Return unused medical cannabidiol to a dispensary for disposal.";

A package may contain multiple labels if the information required by this rule is not obstructed.

154.30(3) *Medical cannabidiol labeling.*

a. After receiving a passing certification of analysis for a package lot from a laboratory, and prior to distribution to dispensaries, a manufacturer shall affix a label to each individual package of medical cannabidiol that contains the following information:

(1) A unique lot number;

(2) The date of manufacture;

(3) Product expiration date. This date shall be one year from the date of manufacture unless a manufacturer has conducted stability studies and received approval from the department for an extended expiration date.

b. Cannabinoid content for:

(1) Tetrahydrocannabinol;

(2) Tetrahydrocannabinolic acid. Concentrations of tetrahydrocannabinolic acid may be omitted if the manufacturer uses chemical decarboxylation or other means to substantially remove the acids from the product prior to testing;

(3) Cannabidiol; and

(4) Cannabidiolic acid.

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