641—154.21(124E) Packaging and labeling.

154.21(1) *Medical cannabidiol packaging.* A manufacturer shall package all medical cannabidiol intended for distribution according to the following standards:

a. The manufacturer shall properly package medical cannabidiol in compliance with the United States Poison Prevention Packing Act regarding child-resistant packaging and exemptions for packaging for elderly patients.

b. The manufacturer shall label packaged medical cannabidiol as described in subrule 154.21(3).

c. The manufacturer shall use medical containers that are:

(1) Of sufficient size to accommodate a separate dispensary label containing the information described in rule 641—154.46(124E);

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

(3) Tamper-evident; and

(4) Child-resistant.

d. Medical cannabidiol packaging shall not bear a reasonable resemblance to commonly available nonmedical commercial products.

e. The manufacturer shall package medical cannabidiol in a manner that minimizes the package's appeal to children.

f. The manufacturer shall not depict images other than the manufacturer's business name or logo on the packaging.

154.21(2) *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.

154.21(3) *Package labeling.*

a. A manufacturer shall ensure that all medical cannabidiol packaging is labeled with the following information:

(1) The name of the manufacturer;

(2) The medical cannabidiol's primary active ingredients, including concentrations of tetrahydrocannabinol, tetrahydrocannabinolic acid, cannabidiol, and cannabidiolic acid. Concentrations of tetrahydrocannabinolic acid and cannabidiolic 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) All ingredients of the product shown with common or usual names, including any colors, artificial flavors, and preservatives, listed in descending order by predominance of weight;

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

(5) Product expiration date;

(6) The date of manufacture and lot number;

(7) 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.";

(8) The universal warning symbol provided by the department; and

(9) 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."

b. Labeling text shall not include any false or misleading statements.

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

d. A manufacturer shall ensure that directions for use of the product, including recommended and maximum amount by age and weight, if applicable, are included with the product.

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