

**DIVISION 7
MARIJUANA LABELING AND CONCENTRATION LIMITS**

333-007-0010

Purpose, Scope and Effective Date

(1) The purpose of OAR 333-007-0010 through 333-007-0100 is to set the minimum standards for the labeling of marijuana items that are sold to a consumer, patient or designated primary caregiver. These minimum standards are applicable to:

- (a) A Commission licensee as that is defined in OAR 845-025-1015; and
- (b) A person registered with the Authority under ORS 475B.400 to 475B.525 who is not exempt from the labeling requirements as described in section (2) of this rule.

(2) The labeling requirements in these rules do not apply to:

(a) A grower if the grower is transferring usable marijuana or an immature marijuana plant to:

- (A) A patient who designated the grower to grow marijuana for the patient; or
- (B) A designated primary caregiver of the patient who designated the grower to grow marijuana for the patient.

(b) A designated primary caregiver of a patient if the caregiver is transferring a marijuana item to a patient of the designated primary caregiver.

(3) Nothing in these rules prohibits the Commission or the Authority from:

(a) Imposing additional labeling requirements in their respective rules governing licensees and registrants as long as those additional labeling requirements are not inconsistent with these rules; or

(b) Requiring licensees or registrants to provide informational material to a consumer, patient or designated primary caregiver at the point of sale.

(4) A person licensed by the Commission must comply with these rules at all times.

Stat. Auth.: ORS 475B.605 Stats. Implemented: ORS 475B.605

333-007-0020

Definitions

For the purposes of OAR 333-007-0010 through 333-007-0100, unless otherwise specified:

(1) "Activation time" means the amount of time it is likely to take for an individual to begin to feel the effects of ingesting or inhaling a marijuana item.

(2) "Authority" means the Oregon Health Authority.

(3) "Cannabinoid concentrate or extract" means a substance obtained by separating cannabinoids from marijuana by a mechanical, chemical or other process.

(4)(a) "Cannabinoid edible" means:

(A) Food or potable liquid into which a cannabinoid concentrate or extract or the dried leaves or flowers of marijuana have been incorporated; or

(B) For purposes of labeling, includes any cannabinoid concentrate, extract or cannabinoid product that is intended for human consumption or marketed in a manner that implies the item is for human consumption.

- (b) For purposes of labeling "cannabinoid edible" does not include a cannabinoid tincture.
- (5)(a) "Cannabinoid product" means a cannabinoid edible or any other product intended for human consumption or use, including a product intended to be applied to a person's skin or hair, that contains cannabinoids or the dried leaves or flowers of marijuana.
- (b) "Cannabinoid product" does not include:
- (A) Usable marijuana by itself;
 - (B) A cannabinoid concentrate or extract by itself; or
 - (C) Industrial hemp, as defined in ORS 571.300.
- (6) "Cannabinoid tincture" means a solution of alcohol, cannabinoid concentrate or extract, and perhaps other ingredients intended for human consumption or ingestion, and that is exempt from the Liquor Control Act under ORS 471.035.
- (7) "Cannabinoid topical" means a cannabinoid product intended to be applied to skin or hair.
- (8) "CBD" means cannabidiol.
- (9) "Commission" means the Oregon Liquor Control Commission.
- (10) "Consumer" has the meaning given that term in ORS 475B.015 and does not include a patient or designated primary caregiver.
- (11) "Container"
- (a) Means a sealed, hard or soft-bodied receptacle in which a marijuana item is placed.
 - (b) Does not mean inner wrapping or packaging that is not intended to display the marijuana item for sale to a consumer.
- (12) "Date of harvest" means the date the mature marijuana plants in a harvest lot were removed from the soil or other growing media. If the harvest occurred on more than one day, the "date of harvest" is the day the last mature marijuana plant in the harvest lot was removed from the soil or other growing media.
- (13) "Delta-9 THC" is the principal psychoactive constituent (the principal cannabinoid) of cannabis.
- (14)(a) "Designated primary caregiver" means an individual:
- (A) Who is 18 years of age or older;
 - (B) Who has significant responsibility for managing the well-being of a person who has been diagnosed with a debilitating medical condition; and
 - (C) Who is designated as the person responsible for managing the well-being of a person who has been diagnosed with a debilitating medical condition on that person's application for a registry identification card or in other written notification submitted to the Authority.
- (b) "Designated primary caregiver" does not include a person's attending physician.
- (15) "Food" means a raw, cooked, or processed edible substance, or ingredient used or intended for use or for sale in whole or in part for human consumption, or chewing gum.
- (16) "Grower" has the same meaning as "person responsible for a marijuana grow site."
- (17) "Harvest lot" means marijuana that is uniform in strain, cultivated utilizing the same growing practices and harvested at the same time.
- (18) "Human consumption" means to ingest, generally through the mouth, food, drink or other substances such that the substance enters the human body but does not include inhalation.
- (19) "Licensee" has the meaning given that term in ORS 475B.015.
- (20) "Major food allergen" means an ingredient that is one of the five foods listed in subsections (a) to (e) of this section, or from one of the three food groups listed in

subsections (f) to (h) of this section, or is an ingredient that contains protein derived from one of the following:

- (a) Milk;
- (b) Egg;
- (c) Fish;
- (d) Crustacean shellfish;
- (e) Tree nuts;
- (f) Wheat;
- (g) Peanuts; and
- (h) Soybeans.

(21)(a) "Marijuana" means the plant Cannabis family Cannabaceae, any part of the plant Cannabis family Cannabaceae and the seeds of the plant Cannabis family Cannabaceae.

(b) "Marijuana" does not include industrial hemp, as defined in ORS 571.300.

(22) "Marijuana item" means marijuana, usable marijuana, a cannabinoid product, or a cannabinoid concentrate or extract.

(23) "Medical grade cannabinoid product, cannabinoid concentrate or cannabinoid extract" means a cannabinoid product, cannabinoid concentrate or cannabinoid extract that has a concentration of THC that is permitted under ORS 475B.625 in a single serving of the cannabinoid product, cannabinoid concentrate or cannabinoid extract for a patient.

(24) "Medical grade symbol" means the image established by the Authority and made available to licensees indicating the cannabinoid product, concentrate or extract may only be sold or transferred to a designated primary caregiver or patient, for use only by a patient.

(25) "Medical marijuana dispensary" means a facility registered under ORS 475B.450.

(26) "Net weight" means the gross weight minus the tare weight of the packaging.

(27) "Package unique identification number" mean the unique identification number that was generated by the Commission's seed to sale tracking system at the time the marijuana item was packaged and labeled for sale to the consumer, patient, or designated primary caregiver.

(28) "Patient" has the same meaning as "registry identification cardholder."

(29) "Person responsible for a marijuana grow site" means a person who has been selected by a patient to produce medical marijuana for the patient, and who has been registered by the Authority for this purpose and has the same meaning as "grower."

(30) "Place of address" means the name, mailing address, city, state and zip code of the processor who made the cannabinoid edible.

(31) "Principal display panel" means the part of a label on a package or container that is most likely to be displayed, presented, shown or seen under customary conditions of display for sale or transfer.

(32) "Processor" means a person:

- (a) Licensed by the Commission to process marijuana under ORS 475B.090; or
- (b) Registered with the Authority under ORS 475B.435 as a processing site and who is not exempt from labeling requirements under ORS 475B.605

(33) "Process lot" means:

- (a) Any amount of cannabinoid concentrate or extract of the same type and processed at the same time using the same extraction methods, standard operating procedures and batches from the same or different harvest lots; or

(b) Any amount of cannabinoid products of the same type and processed at the same time using the same ingredients, standard operating procedures and batches from the same or different harvest lots or process lots of cannabinoid concentrate or extract.

(34) "Producer" means a person:

(a) Licensed by the Commission to produce marijuana under ORS 475B.070; and

(b) Registered with the Authority under ORS 475B.420 as a grower and who is not exempt from labeling requirements under ORS 475B.605.

(35) "Product identity" means a truthful or common name of the product that is contained in the package.

(36) "Registrant" means a person registered with the Authority under ORS 475B.400 to 475B.525.

(37) "Registry identification cardholder" means a person to whom a registration card has been issued under ORS 475B.415.

(38)(a) "Test batch" means a group of test samples that are collectively submitted to a laboratory for testing purposes.

(b) "Test batch" does not mean a combination of marijuana flowers, marijuana leaves, cannabinoid products, or cannabinoid concentrate or extract.

(39) "Test sample" means anything collected by an individual authorized by the Authority to collect a sample from a licensee or registrant that is provided to a laboratory for testing, including but not limited to marijuana items, soil, growing medium, water, solvent or swab of a counter or equipment.

(40) "THC" means tetrahydrocannabinol and has the same meaning as delta-9 THC.

(41) "These rules" means OAR 333-007-0010 through 333-007-0100.

(42) "Universal symbol" means the image, established by the Authority and made available to licensees and registrants, indicating the marijuana item contains marijuana.

(43)(a) "Usable marijuana" means the dried leaves and flowers of marijuana.

(b) "Usable marijuana" does not include:

(A) The seeds, stalks and roots of marijuana; or

(B) Waste material that is a by-product of producing or processing marijuana.

Stat. Auth.: ORS 475B.605 Stats. Implemented: ORS 475B.605

333-007-0030

Marijuana Plant Labeling Requirements

Prior to a marijuana plant being sold or transferred to a consumer, patient or designated primary caregiver a tag or label must be affixed to the plant or plant container that has the following information:

(1) Producer's business or trade name and licensee or registrant number;

(2) Business or trade name of licensee or registrant that packaged or distributed the product, if different from the producer;

(3) Name of the strain; and

(4) Universal symbol.

Stat. Auth.: ORS 475B.605 Stats. Implemented: ORS 475B.605

333-007-0040

Marijuana Seed Labeling Requirements

Prior to marijuana seeds being sold or transferred to a consumer, patient or designated primary caregiver the container holding the seeds must have a label that has the following information:

- (1) Producer's business or trade name and licensee or registrant number;
- (2) Business or trade name of licensee or registrant that packaged or distributed the product, if different from the producer;
- (3) Name of the strain of seed;
- (4) Date of harvest;
- (5) Number of seeds or net weight in U.S. customary and metric units as appropriate; and
- (6) Universal symbol.

Stat. Auth.: ORS 475B.605 Stats. Implemented: ORS 475B.605

333-007-0050

Usable Marijuana Labeling Requirements

Prior to usable marijuana being sold or transferred to a consumer, patient or designated primary caregiver the container holding the usable marijuana must have a label that has the following information:

- (1) Producer's business or trade name and licensee or registrant number;
- (2) Business or trade name of licensee or registrant that packaged or distributed the product, if different from the producer;
- (3) For licensees, package unique identification number and for registrants, harvest lot number;
- (4) Date of harvest;
- (5) Name of strain;
- (6) Net weight in U.S. customary and metric units;
- (7) Concentration of THC and CBD, as calculated under OAR 333-064-0100;
- (8) Activation time expressed in words or through a pictogram;
- (9) Name of the lab that performed any test, any associated test batch number and any test analysis date;
- (10) Universal symbol;
- (11) For usable marijuana for sale to a consumer warnings that state:
 - (a) "For use by adults 21 and older. Keep out of reach of children."
 - (b) "It is illegal to drive a motor vehicle while under the influence of marijuana."
- (12) For usable marijuana for use by a patient warnings that state:
 - (a) "For use by OMMP patients only. Keep out of reach of children."
 - (b) "It is illegal to drive a motor vehicle while under the influence of marijuana."

Stat. Auth.: ORS 475B.605 Stats. Implemented: ORS 475B.605

333-007-0060

Cannabinoid Topical Labeling Requirements

Prior to a cannabinoid topical product being sold or transferred to a consumer, patient or designated primary caregiver the container holding the cannabinoid product must have a label that has the following information:

- (1) Processor's business or trade name and licensee or registrant number;
 - (2) Business or trade name of licensee or registrant that packaged or distributed the product, if different from the processor;
 - (3) For licensees, package unique identification number and for registrants, process lot number;
 - (4) Product identity (common or usual name);
 - (5) Date the product was made;
 - (6) Net weight or volume in U.S. customary and metric units;
 - (7) Amount suggested for use by the consumer or patient at any one time;
 - (8) Concentration or amount by weight or volume of THC and CBD in the container;
 - (9) List of ingredients in descending order or predominance by weight or volume used to process the cannabinoid topical;
 - (10) Activation time, expressed in words or through a pictogram;
 - (11) Name of the lab that performed any test, any associated test batch number and any test analysis date;
 - (12) Universal symbol;
 - (13) For licensees, a medical grade symbol if applicable;
 - (14) A statement that reads: "This product is not approved by the FDA to treat, cure, or prevent any disease";
 - (15) For cannabinoid topicals for sale to a consumer warnings that state:
 - (a) "For use only by adults 21 and older. Keep out of reach of children."
 - (b) "DO NOT EAT" in bold, capital letters.
 - (16) For cannabinoid topicals for use by a patient warnings that state:
 - (a) "For use by OMMP patients only. Keep out of reach of children."
 - (b) "DO NOT EAT" in bold, capital letters.
- Stat. Auth.: ORS 475B.605 Stats. Implemented: ORS 475B.605

333-007-0070

Cannabinoid Edible Labeling Requirements

Prior to a cannabinoid edible being sold or transferred to a consumer, patient or designated primary caregiver the container holding the edible must have a label that has the following information:

- (1) Processor's business or trade name, place of address, and licensee or registrant number;
- (2) Business or trade name and place of address of licensee or registrant that packaged or distributed the product, if different from the processor;
- (3) Product identity (common or usual name);
- (4) For licensees, package unique identification number and for registrants, process lot number;

- (5) Date the edible was made;
 - (6) Net weight or volume in U.S. customary and metric units;
 - (7) Serving size and number of servings per container;
 - (8) Concentration or amount by weight or volume of THC and CBD in each serving and in each container;
 - (9) List of all ingredients in descending order of predominance by weight or volume used to process the cannabinoid edible;
 - (10) List of potential major food allergens:
 - (a) Using a "contains" statement to summarize the major food allergen information at the end of or immediately adjacent to the ingredient list; or
 - (b) Placing the term for the appropriate major food allergen in parenthesis within the ingredient list after the common or usual name of the ingredient derived from that major food allergen;
 - (11) The amount, in grams, of sodium, sugar, carbohydrates and total fat per serving;
 - (12) If the edible is perishable, a statement that the edible must be refrigerated or kept frozen;
 - (13) Name of the lab that performed any test, any associated test batch number and any test analysis date;
 - (14) Activation time, expressed in words or through a pictogram;
 - (15) Universal symbol;
 - (16) For licensees, a medical grade symbol if applicable;
 - (17) A statement that reads: "This product is not approved by the FDA to treat, cure, or prevent any disease";
 - (18) For cannabinoid edibles for sale to a consumer warnings that state:
 - (a) "For use only by adults 21 and older. Keep out of reach of children."
 - (b) "It is illegal to drive a motor vehicle while under the influence of marijuana."
 - (c) "BE CAUTIOUS" in bold, capital letters, followed by "Cannabinoid edibles can take up to 2 hours or more to take effect."
 - (19) For cannabinoid edibles for use by a patient warnings that state:
 - (a) "For use by OMMP patients only. Keep out of reach of children."
 - (b) "It is illegal to drive a motor vehicle while under the influence of marijuana."
 - (c) "BE CAUTIOUS" in bold, capital letters, followed by "Cannabinoid edibles can take up to 2 hours or more to take effect."
- Stat. Auth.: ORS 475B.605 Stats. Implemented: ORS 475B.605

333-007-0080

Labeling Requirements for Cannabinoid Concentrates and Extracts

Prior to a cannabinoid concentrate or extract being sold or transferred to a consumer, patient or designated primary caregiver the container holding the concentrate or extract must have a label that has the following information:

- (1) Processor's business or trade name and licensee or registrant number;
- (2) Business or trade name of licensee or registrant that packaged or distributed the product, if different from the processor;
- (3) For licensees, package unique identification number and for registrants, process lot number;

- (4) Product identity (concentrate or extract);
 - (5) Date the concentrate or extract was made;
 - (6) Net weight or volume in U.S. customary and metric units;
 - (7) If applicable, serving size and number of servings per container or amount suggested for use by the consumer or patient at any one time;
 - (8) Concentration or amount by weight or volume of THC and CBD in each amount suggested for use and in the container;
 - (9) Activation time, expressed in words or through a pictogram;
 - (10) Name of the lab that performed any test, any associated test batch number and any test analysis date;
 - (11) Universal symbol;
 - (12) For licensees, a medical grade symbol if applicable;
 - (13) A statement that reads: "This product is not approved by the FDA to treat, cure, or prevent any disease";
 - (14) For cannabinoid concentrates and extracts for sale to a consumer warnings that state:
 - (a) "For use only by adults 21 and older. Keep out of reach of children."
 - (b) "It is illegal to drive a motor vehicle while under the influence of marijuana."
 - (c) "DO NOT EAT" in bold, capital letters.
 - (15) For cannabinoid concentrates and extracts for use by a patient warnings that state:
 - (a) "For use by OMMP patients only. Keep out of reach of children."
 - (b) "It is illegal to drive a motor vehicle while under the influence of marijuana."
 - (c) "DO NOT EAT" in bold, capital letters.
- Stat. Auth.: ORS 475B.605 Stats. Implemented: ORS 475B.605

333-007-0083

Cannabinoid Tincture Labeling Requirements

Prior to a cannabinoid tincture being sold or transferred to a consumer, patient or designated primary caregiver the container holding the tincture must have a label that has the following information:

- (1) Processor's business or trade name, place of address and licensee or registrant number;
- (2) Business or trade name and place of address of licensee or registrant that packaged or distributed the product, if different from the processor;
- (3) Product identity (common or usual name);
- (4) For licensees, package unique identification number and for registrants, process lot number;
- (5) Date the tincture was made;
- (6) Net weight or volume in U.S. customary and metric units;
- (7) Serving size and number of servings per container;
- (8) Concentration or amount by weight or volume of THC and CBD in each serving and in each container;
- (9) List of all ingredients in descending order of predominance by weight or volume used to process the cannabinoid tincture;

- (10) Name of the lab that performed any test, any associated test batch number and any test analysis date;
 - (11) Universal symbol;
 - (12) For licensees, a medical grade symbol if applicable;
 - (13) Activation time expressed in words or through a pictogram;
 - (14) A statement that reads: "This product is not approved by the FDA to treat, cure, or prevent any disease";
 - (15) For cannabinoid tinctures for sale to a consumer warnings that state:
 - (a) "For use only by adults 21 and older. Keep out of reach of children."
 - (b) "It is illegal to drive a motor vehicle while under the influence of marijuana."
 - (16) For cannabinoid tinctures for use by a patient warnings that state:
 - (a) "For use by OMMP patients only. Keep out of reach of children."
 - (b) "It is illegal to drive a motor vehicle while under the influence of marijuana."
- Stat. Auth.: ORS 475B.605 Stats. Implemented: ORS 475B.605

333-007-0085

Cannabinoid Products Other than Cannabinoid Edibles, Topicals, or Tinctures

Prior to a cannabinoid product other than a cannabinoid edible, topical or tincture being sold or transferred to a consumer, patient or designated primary caregiver the container holding the product must have a label that has the following information:

- (1) Processor's business or trade name and licensee or registrant number;
- (2) Business or trade name of licensee or registrant that packaged or distributed the product, if different from the processor;
- (3) Place of address for the processor and packager, if applicable;
- (4) Product identity (common or usual name);
- (5) For licensees, package unique identification number and for registrants, process lot number;
- (6) Date the product was made;
- (7) Net weight or volume in U.S. customary and metric units;
- (8) Serving size and number of servings per container;
- (9) Concentration or amount by weight or volume of THC and CBD in each serving and in each container;
- (10) List of all ingredients in descending order of predominance by weight or volume used to process the cannabinoid product;
- (11) Name of the lab that performed any test, any associated test batch number and any test analysis date;
- (12) Universal symbol;
- (13) For licensees, a medical grade symbol if applicable;
- (14) Activation time expressed in words or through a pictogram;
- (15) A statement that reads: "This product is not approved by the FDA to treat, cure, or prevent any disease";
- (16) For cannabinoid products for sale to a consumer warnings that state:
 - (a) "For use only by adults 21 and older. Keep out of reach of children."
 - (b) "It is illegal to drive a motor vehicle while under the influence of marijuana."
- (17) For cannabinoid products for use by a patient warnings that state:

- (a) "For use by OMMP patients only. Keep out of reach of children."
 - (b) "It is illegal to drive a motor vehicle while under the influence of marijuana."
- Stat. Auth.: ORS 475B.605 Stats. Implemented: ORS 475B.605

333-007-0090

General Label Requirements; Prohibitions; Exceptions

(1) Principal Display Panel.

- (a) Every container that contains a marijuana item for sale or transfer to a consumer, patient or designated primary caregiver must have a principal display panel, as that term is defined in OAR 333-007-0020.
- (b) If a container is placed within packaging for purposes of displaying the marijuana item for sale or transfer to a consumer, patient or designated primary caregiver, the packaging must have a principal display panel as that term is defined in OAR 333-007-0020.
- (c) The principal display panel must contain the product identity, net weight, and universal symbol, if applicable.
- (d) If the product is a medical grade cannabinoid product, concentrate or extract processed by a licensee the principal display panel must include the medical grade symbol.

(2) A label required by these rules must:

- (a) Be placed on the container and on any packaging that is used to display the marijuana item for sale or transfer to a consumer, patient or designated primary caregiver.
- (b) Comply with the National Institute of Standards and Technology (NIST) Handbook 130 (2016), Uniform Packaging and Labeling Regulation, incorporated by reference.
- (c) Be in no smaller than 8 point Times New Roman, Helvetica or Arial font;
- (d) Be in English, though it can be in other languages; and
- (e) Be unobstructed and conspicuous.

(3) A marijuana item may have one or more labels affixed to the container or packaging.

(4) A marijuana item that is in a container that because of its size does not have sufficient space for a label that contains all the information required for compliance with these rules:

- (a) May have a label on the container that contains a marijuana item and on any packaging that is used to display the marijuana item for sale or transfer to a consumer, patient or designated primary caregiver that includes at least the following:

- (A) Information required on a principal display panel, if applicable for the type of marijuana item;
- (B) Licensee or registrant business or trade name and licensee or registrant number;
- (C) For licensees, package unique identification number and for registrants, batch or process lot number;
- (D) Concentration of THC and CBD; and
- (E) Required warnings; and

- (b) Must include all other required label information not listed in subsection (4)(a) of this rule on an outer container or package, or on a leaflet that accompanies the marijuana item.

- (c) May:

- (A) Use a peel-back or accordion label with the information required in subsection (4)(b) of this rule, if the peel-back or accordion label can be easily identified by a patient or consumer as containing important information.
- (B) Use 6 point font for the information listed in paragraph (4)(a)(A) to (D) of this rule.
- (5) A marijuana item in a container that is placed in packaging that is used to display the marijuana item for sale or transfer to a consumer, patient, or designated primary caregiver must comply with the labeling requirements in these rules, even if the container qualifies for the exception under section (4) of this rule.
- (6) The universal symbol:
- (a) Must be at least 0.48 inches wide by 0.35 inches high.
 - (b) May only be used by licensees or registrants.
 - (c) May be downloaded at www.healthoregon.org/marijuana.
- (7) Medical grade symbol. The medical grade symbol must be at least 0.35 inches in diameter.
- (8) A label may not:
- (a) Contain any untruthful or misleading statements including, but not limited to, a health claim that is not supported by the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), and for which there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims; or
 - (b) Be attractive to minors, as that is defined in OAR 845-025-7000.
- (9) A marijuana item that falls within more than one category, for example a product that is both a cannabinoid concentrate and cannabinoid edible, must comply with the labeling requirements that apply to both categories, with the exception of the "DO NOT EAT" warning if the product is intended for human consumption or the "BE CAUTIOUS" warning if the effects of the product are customarily felt immediately.
- (10) The THC and CBD amount required to be on a label must be based on the value calculated by the laboratory that did the testing in accordance with OAR 333-064-0100, plus or minus ten percent, except that a label may not have a THC value that exceeds the applicable maximum concentration limit. A registrant or licensee that has more than one laboratory test result for THC or CBD from the same batch may either express the THC or CBD amounts on the label:
- (a) As a range, based on the high and low THC and CBD values for each sample that was tested; or
 - (b) As an average of all the THC values for each sample or an average of all the CBD values for each sample.
- (11) If a marijuana item has more than one test batch number, laboratory, or test analysis date associated with the marijuana item that is being sold or transferred, each test batch number, laboratory and test analysis date must be included on a label.
- (12) If a marijuana item is placed in a package that is being re-used, the old label or labels must be removed and it must have a new label or labels.
- (13) A licensee or registrant must have documentation that demonstrates the validity of the calculation of the amount of sodium, sugar, carbohydrates and total fat in a cannabinoid edible and must make that documentation available to the Commission or the Authority upon request.

(14) Exit packaging must contain a label that reads: "Keep out of the reach of children."

(15) A cartridge containing a cannabinoid concentrate, extract or product intended for use with an inhalant delivery system as that is defined in ORS 431.840 is not required to be labeled in accordance with these rules except that the cartridge must have a label with the universal symbol. All the remaining label requirements must be included on the packaging that is used to display the cartridge for sale or transfer.

Stat. Auth.: ORS 475B.605

Stats. Implemented: ORS 475B.605

333-007-0100

Pre-Approval of Labels

(1) A registrant must submit labels for pre-approval in accordance with OAR 845-025-7060 and must keep all records related to the pre-approval process and provide those records at the request of the Authority.

(2) A registrant may not transfer a marijuana item unless the label has been pre-approved in accordance with OAR 845-025-7060.

Stat. Auth.: ORS 475B.610 Stats. Implemented: ORS 475B.610

333-007-0200

Concentration and Serving Size Limits: Definitions, Purpose, Scope and Effective Date

(1) In accordance with ORS 475B.625, the Authority must establish, for marijuana items sold or transferred to a consumer, patient or designated primary caregiver through a Commission licensed marijuana retailer or medical marijuana dispensary:

(a) The maximum concentration of THC permitted in a single serving of a cannabinoid product or cannabinoid concentrate or extract; and

(b) The number of servings permitted in a cannabinoid product container or cannabinoid concentrate or extract container.

(2) OAR 333-007-0200 through 333-007-0220 apply to:

(a) A Commission licensee as that is defined in OAR 845-025-1015; and

(b) A person registered with the Authority under ORS 475B.400 to 475B.525 who is not exempt under ORS 475B.630.

(3) The concentration of THC permitted under OAR 333-007-0210 through 333-007-0220 must take into account both the amount of Delta-9 THC in the cannabinoid product or cannabinoid concentrate or extract and the amount of tetrahydrocannabinolic acid (THCA) in the cannabinoid product or cannabinoid concentrate or extract that if heated would convert THCA to THC. A cannabinoid product or cannabinoid concentrate or extract that contains a high amount of THCA must meet the concentration limits established in OAR 333-007-0200 through 333-007-0220 even if heated.

(4) The amounts of THC listed on a label are based on an average from samples taken from a harvest or process lot and may not represent the exact amount of THC in a marijuana item purchased by a consumer, patient or designated primary caregiver.

(5) A marijuana item received or transferred by a dispensary must meet the concentration and serving size limits in OAR 333-007-0220.

(6) For purposes of OAR 333-007-0200 through 333-007-0220:

(a) The definitions in OAR 333-007-0020 apply unless otherwise specified.

(b) "Cannabinoid capsule" means a small soluble container, usually made of gelatin, that encloses a dose of a cannabinoid product, concentrate or extract intended for human ingestion.

(c) "Cannabinoid edible" means a food or potable liquid into which a cannabinoid concentrate or extract or the dried leaves or flowers of marijuana have been incorporated.

(d) "Cannabinoid suppository" means a small soluble container designed to melt at body temperature within a body cavity other than the mouth, especially the rectum or vagina containing a cannabinoid product, concentrate or extract.

(e) "Cannabinoid transdermal patch" means an adhesive substance applied to human skin that contains a cannabinoid product, concentrate or extract for absorption into the bloodstream.

(f) "Medical marijuana item" is a marijuana item for sale or transfer to a patient or designated primary caregiver and includes medical grade cannabinoid products, cannabinoid concentrates and cannabinoid extracts.

(g) "Retail adult use marijuana item" is a marijuana item for sale to a consumer.

(h) "Scored" means to physically demark a cannabinoid edible in a way that enables a reasonable person to:

(A) Intuitively determine how much of the product constitutes a single serving; and

(B) Easily physically separate the edible into single servings either by hand or with a common utensil, such as a knife.

Stat. Auth.: ORS 475B.625 Stats. Implemented: ORS 475B.625

333-007-0210

Retail Marijuana Item Concentration and Serving Size Limits

(1) The maximum concentration or amount of THC permitted in a container and the maximum concentration or amount of THC permitted in a serving of a retail adult use marijuana item is listed in Table 1. [Table not included.]

(2) A cannabinoid edible must be scored unless it is not capable of being scored in which case the cannabinoid edible must be:

(a) Sold and packaged with a measuring device that measures single servings; or

(b) Placed in packaging that clearly enables a consumer to determine when a single serving has been consumed.

(3) Serving size is as determined by the processor.

(4) A retail adult use marijuana item that does not fall within a category in Table 1 such as cannabinoid suppositories and transdermal patches or is a cannabinoid product intended for human consumption that is not specifically categorized must meet the concentration and serving size limits applicable to a cannabinoid edible in Table 1.

[ED. NOTE: Tables referenced are not included in rule text.]

Stat. Auth.: ORS 475B.625 Stats. Implemented: ORS 475B.625

333-007-0220

Medical Marijuana Item Concentration Limits

(1) The maximum concentration or amount of THC permitted in a container and the maximum concentration or amount of THC permitted in a serving of a medical marijuana item is listed in Table 2.

(2) A cannabinoid edible must be scored unless it is not capable of being scored in which case the cannabinoid edible must be:

(a) Sold and packaged with a measuring device that measures single servings; or

(b) Placed in packaging that clearly enables a patient to determine when a single serving has been consumed, as that serving size is determined by the processor.

(3) Serving size is as determined by the processor.

(4) A medical marijuana item that does not fall within a category in Table 2 or is a cannabinoid product intended for human consumption that is not specifically categorized must meet the concentration and serving size limits applicable to a cannabinoid edible in Table 2.

[ED. NOTE: Tables referenced are not included in rule text.]

Stat. Auth.: ORS 475B.625 S