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FILING CAPTION: Inhalant delivery systems packaged in a manner attractive to minors

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RULES:

333-015-0300, 333-015-0305, 333-015-0340, 333-015-0345, 333-015-0350, 333-015-0355, 333-015-0357, 333-015-0360, 333-015-0375

AMEND: 333-015-0300

RULE TITLE: Packaging and Labeling: Purpose, Scope and Effective Date

NOTICE FILED DATE: 06/26/2018

RULE SUMMARY: Amend OAR 333-015-0300: The Oregon Liquor Control Commission (OLCC) recently revised Oregon Administrative Rules (OAR) related to packaging and labeling requirements for recreational marijuana. The Purpose portion of the OHA rules is amended to refer to OLCC's revised OARs.

RULE TEXT:

- (1) The purpose of OAR 333-015-0305 to 333-015-0375 is to set the minimum standards for the labeling and packaging of inhalant delivery systems that are sold to a consumer.
- (2) These minimum standards are applicable on and after July 1, 2016.
- (3) These rules do not apply to an inhalant delivery system or prefilled inhalant delivery system that contains cannabinoids if that inhalant delivery system or prefilled inhalant delivery system complies with the packaging and labeling requirements in OAR 845-025-7000 to 845-025-7190.

STATUTORY/OTHER AUTHORITY: ORS 431A.175

STATUTES/OTHER IMPLEMENTED: ORS 431A.175

AMEND: 333-015-0305

RULE TITLE: Packaging and Labeling: Definitions

NOTICE FILED DATE: 06/26/2018

RULE SUMMARY: Amend OAR 333-015-0305: The Definitions portion of the rules is amended to refine the meaning of "packaged in a manner attractive to minors" as it relates to inhalant delivery systems. Specifically, "packaging" is defined, and "packaged in a manner attractive to minors" is removed from definition and moved into a separate rule. Additional definitions are amended slightly to ensure consistent language throughout the rules.

RULE TEXT:

For the purposes of OAR 333-015-0300 to 333-015-0375:

- (1) "Authority" means the Oregon Health Authority.
- (2) "Cannabinoid" means any of the chemical compounds that are the active constituents of marijuana.
- (3) "Cartoon" means any drawing or other depiction of an object, person, animal or creature or any similar caricature that satisfies any of the following criteria:
 - (a) The use of comically exaggerated features;
 - (b) The attribution of human characteristics to animals, plants or other objects, or the similar use of anthropomorphic technique; or
 - (c) The attribution of unnatural or extra-human abilities, such as imperviousness to pain or injury, X-ray vision, tunneling at very high speeds or transformation.
- (4) "Child-resistant" means having inner or outer packaging that is:
 - (a) Intended to protect children from nicotine exposure in the household environment or other environment where the product is used;
 - (b) Designed or constructed to be significantly difficult for children under five years of age to open and not difficult for adults to use properly, as defined by 16 CFR 1700.20 (1995); and
 - (c) Re-sealable for any product intended for more than a single use, such as a fillable inhalant delivery system.
- (5) "Consumer product" means any article, or component part thereof, produced or distributed for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise.
- (6) "Distributor" means a person or company that supplies stores or businesses with goods.
- (7) "Fillable inhalant delivery system" means a product that is sold without nicotine or non-nicotine inhalants, not permanently sealed and can be opened and filled with any inhalant.
- (8) "Inhalant" means nicotine, or any other substance that:
 - (a) Is in a form that allows the nicotine, cannabinoid or substance to be delivered into a person's respiratory system;
 - (b) Is inhaled for the purpose of delivering the nicotine, cannabinoid or other substance into a person's respiratory system; and
 - (c)(A) Is not approved by, or emitted by a device approved by, the United States Food and Drug Administration (FDA) for a therapeutic purpose; or
 - (B) If approved by, or emitted by a device approved by, the United States Food and Drug Administration for a therapeutic purpose, is not marketed and sold solely for that purpose.
- (9)(a) "Inhalant delivery system" means:
 - (A) A device that can be used to deliver nicotine or cannabinoids in the form of a vapor or aerosol to a person inhaling from the device; or
 - (B) A component of a device described in this section or a substance in any form sold for the purpose of being vaporized or aerosolized by a device described in this section, whether the component or substance is sold separately or is not sold separately.
- (b)(A) Inhalant delivery system does not include any product that has been approved by the United States Food and

Drug Administration for sale as a tobacco cessation product or for any other therapeutic purpose, if the product is marketed and sold solely for the approved purpose; and

(B) Tobacco products.

(10) "Inner package" or "inner packaging" means the materials used to wrap or protect a product that must be opened by a consumer in order to have access to the product and that may also be but is not required to be the outer package.

(11) "Liquid nicotine container" means a consumer product that consists of a container that:

(a) Has an opening from which nicotine in a solution or other form is accessible and can flow freely through normal and foreseeable use by a consumer; and

(b) Is used to hold soluble nicotine in any concentration.

(12) "Manufacturer or distributor contact information" means the name, city, state and country of the manufacturer who made the inhalant delivery system.

(13) "Minor" means an individual under 18 years of age.

(14) "Nicotine" means any form of the chemical nicotine, including any salt or complex, regardless of whether the chemical is naturally or synthetically derived.

(15) "Non-nicotine liquid container" means a container that:

(a) Has an opening from which liquid non-nicotine or liquid non-cannabinoid substances can flow freely through normal and foreseeable use by a consumer; and

(b) Is not used to hold liquid nicotine or cannabinoids.

(16) "Outer package" or "outer packaging" means the external material used to wrap or protect a product that is visible to a consumer in the retail setting such as, but not limited to, a box or container.

(17) "Outlet" means any location in Oregon which sells at retail or otherwise distributes tobacco products or inhalant delivery systems to consumers including, but not limited to, locations that sell such products over the counter or through vending machines.

(18) "Packaging" means any of the materials used to wrap or protect an inhalant delivery system and includes but is not limited to the inner packaging and outer packaging.

(19) "Prefilled inhalant delivery system" means an inhalant delivery system that is permanently sealed, prefilled, disposable and not intended to be disassembled by the consumer.

(20) "Retail setting" means a place of business in which merchandise is primarily sold directly to an ultimate consumer.

(21) "These rules" means OAR 333-015-0300 to 333-015-0375.

STATUTORY/OTHER AUTHORITY: ORS 431A.175

STATUTES/OTHER IMPLEMENTED: ORS 431A.175

AMEND: 333-015-0340

RULE TITLE: Packaging Requirements for Liquid Nicotine Containers

NOTICE FILED DATE: 06/26/2018

RULE SUMMARY: Amend OAR 333-015-0340: The Packaging Requirements for Liquid Nicotine Containers portion of the rules is amended to ensure consistent language throughout the rules. Specifically, "child-resistant safety packaging" is amended to "child-resistant" and "may not be placed in an inner or outer package" is changed to "may not be packaged in a manner that is attractive to minors."

RULE TEXT:

A liquid nicotine container for sale to a consumer:

(1) Must be:

(a) Child-resistant; and

(b) Labeled in accordance with these rules.

(2) May not be packaged in a manner that is attractive to minors.

STATUTORY/OTHER AUTHORITY: ORS 431A.175

STATUTES/OTHER IMPLEMENTED: ORS 431A.175

AMEND: 333-015-0345

RULE TITLE: Packaging Requirements for Non-nicotine Liquid Containers

NOTICE FILED DATE: 06/26/2018

RULE SUMMARY: Amend OAR 333-015-0345: The Packaging Requirements for Non-nicotine Liquid Containers portion of the rules is amended to ensure consistent language throughout the rules. Specifically, "child-resistant safety packaging" is amended to "child-resistant" and "may not be placed in an inner or outer package" is changed to "may not be packaged in a manner that is attractive to minors."

RULE TEXT:

A non-nicotine liquid container for sale to a consumer:

- (1) Must be child-resistant.
- (2) May not be packaged in a manner that is attractive to minors.

STATUTORY/OTHER AUTHORITY: ORS 431A.175

STATUTES/OTHER IMPLEMENTED: ORS 431A.175

AMEND: 333-015-0350

RULE TITLE: Packaging Requirements for Prefilled Inhalant Delivery Systems

NOTICE FILED DATE: 06/26/2018

RULE SUMMARY: Amend OAR 333-015-0350: The Packaging Requirements for Prefilled Inhalant Delivery Systems portion of the rules is amended to ensure consistent language throughout the rules. Specifically, "placed in an inner or outer package" is changed to "packaged in a manner" that is attractive to minors.

RULE TEXT:

A prefilled inhalant delivery system for sale to a consumer:

- (1) Must be labeled in accordance with these rules.
- (2) May not be packaged in a manner that is attractive to minors.

STATUTORY/OTHER AUTHORITY: ORS 431A.175

STATUTES/OTHER IMPLEMENTED: ORS 431A.175

AMEND: 333-015-0355

RULE TITLE: Packaging Requirements for Fillable Inhalant Delivery Systems

NOTICE FILED DATE: 06/26/2018

RULE SUMMARY: Amend OAR 333-015-0355: The Packaging Requirements for Fillable Inhalant Delivery Systems portion of the rules is amended to ensure consistent language throughout the rules. Specifically, "placed in an inner or outer package" is changed to "packaged in a manner" that is attractive to minors.

RULE TEXT:

(1) A fillable inhalant delivery system that is not packaged with a liquid nicotine container for sale to a consumer:

(a) Must be labeled in accordance with these rules.

(b) May not be packaged in a manner that is attractive to minors.

(2) A fillable inhalant delivery system that is packaged with a liquid nicotine container for sale to a consumer must comply with OAR 333-015-0340.

STATUTORY/OTHER AUTHORITY: ORS 431A.175

STATUTES/OTHER IMPLEMENTED: ORS 431A.175

ADOPT: 333-015-0357

RULE TITLE: Packaging Attractive to Minors

NOTICE FILED DATE: 06/26/2018

RULE SUMMARY: Adopt OAR 333-015-0357: The Packaging Attractive to Minors section is adopted as a separate rule.

RULE TEXT:

(1) An inhalant delivery system is packaged in a manner that is attractive to minors if because of the packaging's presentation, shape, graphics, coloring or writing, it is likely to appeal to minors.

(2) The Authority considers the following non-exclusive list to be likely to appeal to minors:

(a) Cartoons;

(b) Celebrities, athletes, mascots, fictitious characters played by people, or other people likely to appeal to minors;

(c) Food or beverages likely to appeal to minors such as candy, desserts, soda, food or beverages with sweet flavors including fruit or alcohol;

(d) Terms or descriptive words for flavors that are likely to appeal to minors such as tart, tangy, sweet, cool, fire, ice, lit, spiked, poppin', juicy, candy, desserts, soda, sweet flavors including fruit, or alcohol flavors; or

(e) The shape of any animal, commercially recognizable toy, sports equipment, or commercially recognizable candy.

STATUTORY/OTHER AUTHORITY: ORS 431A.175

STATUTES/OTHER IMPLEMENTED: ORS 431A.175

AMEND: 333-015-0360

RULE TITLE: Verification of Packaging that is Child-Resistant

NOTICE FILED DATE: 06/26/2018

RULE SUMMARY: Amend OAR 333-015-0360: The Verification of Packaging that is Child-Resistant portion is amended to ensure consistent language throughout the rules. Specifically, "child-resistant packaging results" is changed to "results of whether packaging is child-resistant".

RULE TEXT:

Oregon-based outlets must provide verification of a manufacturer's written laboratory testing report describing the results of whether packaging is child-resistant based on the protocol set forth in 16 CFR 1700.20 (1995) to the Authority upon the Authority's request.

STATUTORY/OTHER AUTHORITY: ORS 431A.175

STATUTES/OTHER IMPLEMENTED: ORS 431A.175

AMEND: 333-015-0375

RULE TITLE: Civil Penalties

NOTICE FILED DATE: 06/26/2018

RULE SUMMARY: Amend OAR 333-015-0375: The Civil Penalties portion is amended to include language stating that prior to issuing a civil penalty, OHA will issue a warning letter to a manufacturer, retailer or distributor for a product that is in violation of these rules.

RULE TEXT:

- (1) Prior to issuing a civil penalty the Authority will issue a warning letter to the manufacturer, retailer or distributor for a product that is in violation of these rules.
- (2) Civil penalties may be imposed for each violation of OAR 333-015-0340 to 333-015-0360 against a manufacturer, retailer or distributor according to the following schedule:
 - (a) \$0 together with the issuance of a warning letter described in section (1) of this rule to the manufacturer, retailer or distributor for the first violation related to each product.
 - (b) Minimum of \$500 for the second violation within a 24-month period of the first violation.
 - (c) Minimum of \$800 for the third violation within a 24-month period of the second violation.
 - (d) Minimum of \$2000 for the fourth violation within a 24-month period of the third violation
 - (e) Minimum of \$8000 for the fifth violation within a 36-month period of the fourth violation.
 - (f) Minimum of \$15,000 for the sixth or subsequent violation within a 48-month period of the fifth violation.
- (3) A civil penalty may not to exceed \$15,000 for each violation or \$1,050,000 for all violations found in a single inspection.
- (4) Each product that does not comply with these rules or that is distributed, sold, or allowed to be sold in violation of these rules is a separate violation. For example, if 10 liquid nicotine containers are distributed, sold, or allowed to be sold without child-resistant packaging the civil penalty could be \$5000 (10 x \$500).

STATUTORY/OTHER AUTHORITY: ORS 431A.178

STATUTES/OTHER IMPLEMENTED: ORS 431A.178