

64ER20-32 MMTC Packaging and Labeling.

(1) All usable product shall be placed inside of a receptacle at the MMTC's department-approved processing facility. Receptacles shall be placed inside of a package with a patient package insert that complies with subsection (10) of this rule before the usable product is dispensed by an MMTC.

(2) Before dispensing usable product in any receptacle and packaging, an MMTC shall comply with the procedure in Rule 64-4.023, F.A.C., to obtain department approval of the use of the receptacle, label, and package.

(3) Receptacles for all usable products shall comply with the following:

(a) The receptacle shall be child resistant. In the case of multiple-use usable products and multi-serving edibles, the receptacle shall be resealable such that it continues to be child resistant after each use or serving.

(b) The receptacle shall have a firmly affixed and readable label(s) that includes only the information required or permitted by s. 381.986(8)(e)11.f., F.S., and this rule. An MMTC may affix multiple labels to the receptacle as needed to convey the required or permissible information. Labels may be accordion, expandable, extendable, or layered to permit labeling of small receptacles as long as none of the required information is obstructed.

(c) All required information on the label(s) shall be prominently and conspicuously placed thereon.

(d) The universal symbol on every receptacle shall be at least ¼ inch wide and ¼ inch high and shall be placed on the outer layer of receptacle labeling.

(e) The receptacle shall not include depictions of the product or any graphics or images other than one image of the MMTC's department-approved logo and the universal symbol.

(f) The receptacle may include instructions, health information, or warnings and precautions. An MMTC shall not include unsubstantiated claims that the usable product cures any medical condition.

(4) Receptacles for derivative products that are not edibles shall be a single solid color or clear and shall not be neon. Where applicable, the lid of a receptacle shall be the same single solid color or white.

(5) Receptacles and wrapping for edibles shall comply with the following:

(a) The receptacle shall be plain, opaque, and white.

(b) The receptacle shall have a firmly affixed and readable label(s) that includes the following:

1. A list of all the edible's ingredients in order of prominence which uses the common or usual name of food ingredients and identifies major allergens in accordance with the Food Allergen Labeling and Consumer Protection Act of 2004, Public Law 108-282, Title II (effective 8/2/2004), which is incorporated by reference and available at

<https://knowthefactsmmj.com/rules-and-regulations/>;

2. Storage instructions;

3. An expiration date;

4. A legible and prominent warning to keep away from children and pets; and

5. A warning stating that the edible has not been produced or inspected pursuant to federal food safety laws.

(c) Each edible shall be individually sealed in plain, opaque, and white wrapping marked only with the marijuana universal symbol.

1. Any edible dispensed as a single serving portion shall be individually wrapped and placed inside of the receptacle.

2. Multi-serving lozenges, gelatins, and chocolates may be wrapped as single serving portions or together as a multi-serving edible and placed inside of the receptacle.

3. Each single serving portion of a multi-serving baked good shall be individually wrapped and placed inside of the receptacle.

4. Each single serving portion of a multi-serving drink powder shall be individually wrapped and placed inside of the receptacle.

(6) Receptacles for usable products in a form for smoking shall comply with the following:

(a) The receptacle shall be plain, opaque, and white.

(b) The receptacle shall have a firmly affixed and readable label that includes the following:

1. A legible and prominent warning to keep the product away from children; and

2. A warning stating that marijuana smoke contains carcinogens and may negatively affect health.

(7) Packaging for derivative products that are not edibles shall comply with the following:

(a) A package shall be one single solid color and may have one additional accent color, not including the department-approved logo, universal symbol, and text. The single solid color and the additional accent color shall not be neon.

(b) The text on a package shall be a single solid color which shall not be neon.

(c) The universal symbol shall be printed on the package and shall be no less than 10 percent of the overall surface area of the package.

(d) The package shall identify every ingredient, in order of prominence, unless the ingredients are identified on

the receptacle label or patient package insert.

(8) Packaging for edibles and marijuana in a form for smoking shall comply with the following:

(a) The package shall be plain, opaque, and white.

(b) The universal symbol shall be printed on the package and shall be no less than 10 percent of the overall surface area of the package.

(9) Packaging for all usable products may include the following permissive information:

(a) The MMTC's department-approved logo;

(b) Any information required by ss. 381.986(8)(e)11.f. and 12., F.S.;

(c) A Quick Response (QR) code, or similar bar code or smart code that allows a patient to access the usable product's certificate of analysis and information related to the usable product being dispensed, provided that the information conveyed is information that is permitted to appear on the receptacle label, package, or patient package insert. Upon request of a patient or caregiver, an MMTC shall provide paper copies of the information available pursuant to this paragraph.

(d) Product Stock-Keeping Unit (SKU), barcode, or other similar product identifier;

(e) Cultivar name in black or white, print lettering, in a sans-serif font which shall not be larger than 12-point font. If the cultivar name does not comply with s. 381.986(8)(e)11.f.(VI), F.S., it shall be abbreviated on the package; and

(f) Instructions, health information, or warnings and precautions. An MMTC shall not include unsubstantiated claims that the usable product cures any medical condition.

(10) The package for every usable product shall include a patient package insert intended for the patient or caregiver that provides the information required by s. 381.986(8)(e)12., F.S., and no additional information, except that the patient package insert may include the information identified in subsection (9).

(11) Notwithstanding the foregoing, this rule shall not preclude an MMTC from including information on a receptacle label, or package that is otherwise required by law or rule.

(12) An MMTC shall have 6 months from the effective date of this rule to comply with requirements contained herein. Variance requests seeking approval of new edibles shall immediately comply with the requirements of this rule.

Rulemaking Authority 381.986(8)(k), 381.986(10)(h), 381.0011(1), 381.0011(2), 381.0011(7), FS. Law

Implemented 381.986(8)(e) FS. History-New 8-26-20.