

3796:3-2-02

Processor packaging and labeling.

(A) A processor distributing medical marijuana to a dispensary shall meet the following requirements:

- (1) A processor shall place medical marijuana in a child-proof, tamper-evident, light-resistant package approved by the department prior to distribution to a dispensary. Approved packaging shall maintain the integrity and stability of the medical marijuana, and shall comply with the rules promulgated by the state of Ohio board of pharmacy pursuant to Chapter 3796. of the Revised Code.
- (2) A label shall be affixed to every package and state in legible English:
 - (a) The name and license number of the cultivator where the packaged plant material was cultivated or the name and license number of the processor where the medical marijuana products were manufactured;
 - (b) The name and license number of the dispensary facility receiving the shipment;
 - (c) The product identifier;
 - (d) The registered name of the medical marijuana plant material strain that was registered with the department or the registered name, form, and dose of the medical marijuana product that was registered with the department;
 - (e) A unique batch or lot number as defined in paragraph (A) of rule 3796:1-1-01 of the Administrative Code that will match the medical marijuana or medical marijuana products with a batch or lot, in order to facilitate any warnings or recalls the department deems appropriate;
 - (f) The dates of manufacture, final testing, and packaging;
 - (g) The total weight in grams of medical marijuana or medical marijuana products in each package;
 - (h) The name and license number of the independent testing laboratory that performed the required tests on the batch or lot from which the medical marijuana or medical marijuana products in the package were taken;
 - (i) The laboratory analysis and cannabinoid profile, including the percentage content by weight or total milligrams and milligrams per unit for:
 - (i) Delta-8-tetrahydrocannabinol; ~~Delta-9-tetrahydrocannabinol (THC)~~;

- (ii) Delta-8-tetrahydrocannabinolic acid; ~~Delta-9-tetrahydrocannabinolic acid (THCA);~~
 - (iii) Delta-9-tetrahydrocannabinol; ~~cannabidiol (CBD); and~~
 - (iv) Delta-9-tetrahydrocannabinolic acid; ~~cannabidiolic acid (CBDA);~~
 - (v) Cannabidiol (CBD);
 - (vi) Cannabidiolic acid (CBDA);
 - (vii) THC Content as defined in 3796:1-1-01; and
 - (viii) any other cannabinoid determined by the Department.
- (j) The expiration date, which shall not exceed one calendar year from the date of manufacture;
- (k) If the product is edible, the following additional information:
- (i) A list of all ingredients and subingredients, providing that all ingredients comply with the standards of identity under rule 901:3-1-12 of the Administrative Code;
 - (ii) A list of all major food allergens as identified in 21 USC 343; and
 - (iii) A statement with the following language: "Caution: When eaten or swallowed, the effects and impairment caused by this drug may be delayed."
- (l) If a marijuana extract was used in the manufacture of the product, a disclosure of the type of extraction process and any solvent, gas, or other chemical used in the extraction process or any other compound added to the extract; and
- (m) A statement with the following language: "This product is for medical use and not for resale or transfer to another person. This product may cause impairment and may be habit-forming. This product may be unlawful outside the State of Ohio."
- (n) If the product was manufactured using plant material that was acquired from a dispensary pursuant to paragraph (B) of rule 3796:3-2-01 of the Administrative Code, a statement with the following language: "This

product was manufactured using medical marijuana that exceeded the expiration date defined in OAC 3796:1-1-01."

- (o) The intended method of administration of the medical marijuana product.
- (B) A processor that elects to or is required to determine portions for an edible medical marijuana product under rules promulgated by the state of Ohio board of pharmacy pursuant to Chapter 3796. of the Revised Code shall apply a universal symbol that denotes that the product contains medical marijuana as an ingredient, as determined by the department, to each portion of the medical marijuana product, in accordance with the following:
- (1) If the medical marijuana product is presented as separate single portions, the processor shall apply the universal symbol to each single portion;
 - (2) If the medical marijuana product is presented as a single unit comprised of more than one portion, the processor shall make clearly visible lines of demarcation between portions and apply the universal symbol to each portion; and
 - (3) The size of the universal symbol marking shall be determined by the size of the portion instead of the overall product size, and shall not be less than one-fourth inch by one- fourth inch.
- (C) The label may contain the approval or certification logo of a third-party certifier of manufacturing or cultivation practices if:
- (1) The third-party certifier does not have a direct or indirect financial interest in any medical marijuana entity licensed in the state of Ohio; and
 - (2) The certification protocols used by the third-party certifier have been reviewed and approved by the department.
- (D) A label shall not contain:
- (1) Any false or misleading statement or design;
 - (2) Depictions of the product, cartoons, or images that are not registered with the department, which includes any insignia related to a governmental entity;
 - (3) Any sum totals of cannabinoids or terpenes, except as defined in paragraph (A) (49) of rule 3796:1-1-01 of the Administrative Code; or
 - (4) Any information that would violate paragraph (E) of rule 3796:5-7-01 of the Administrative Code.

- (E) A processor may provide a dispensary free samples of plant material sold at the dispensary. A free sample shall be packaged in a sample jar protected by a plastic or metal mesh screen to allow patients and caregivers to smell the plant material before purchase. A sample jar may not contain more than three grams of a particular strain of plant material. The sample jar and the plant material within may not be sold to a patient or caregiver and shall be destroyed by the dispensary after use by the dispensary. The dispensary shall document the destruction of every free sample in accordance with the rules established pursuant to Chapter 3796. of the Revised Code.

- (F) It is prohibited for anyone to knowingly or intentionally alter, obliterate, or otherwise destroy any container or label attached to an approved container. In the event a container or label is altered, obliterated, or otherwise destroyed, the department may act in accordance with rule 3796:5-6-01 of the Administrative Code.

Effective:

Five Year Review (FYR) Dates: 9/8/2022

Certification

Date

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