



Product and Dosage Requirements

Orally-Consumed Medical Cannabis Products

April 2021



The following guidance is provided by the Maryland Medical Cannabis Commission (Commission) to assist medical cannabis businesses to comply with state laws and regulations governing: (1) Categorization of cannabis-infused products and edible cannabis products, and (2) Restrictions on product form and dosage. This document includes regulatory changes effective as of April 19, 2021.

This document is not legal advice. It is meant to assist licensed medical cannabis businesses with understanding product and dosage requirements, and to comply with State statutes and regulations. Please consult an attorney if you have any questions regarding the legal requirements that apply.

I. Product Categories

Edible Cannabis Product

An edible cannabis product is a medical cannabis product intended for human consumption by oral ingestion, in whole or in part, including medical cannabis products that dissolve or disintegrate in the mouth. (See COMAR 10.62.01.01B(15))

Medical Cannabis-Infused Product

A non-edible medical cannabis-infused product is an oil, wax, ointment, salve, tincture, capsule, suppository, dermal patch, cartridge, or other product that contains medical cannabis or medical cannabis concentrate that has been processed so that the dried leaves and flowers are integrated into other material. (See COMAR 10.62.01.01B(30))

Table 1. Medical Cannabis-Infused Product versus Edible Cannabis Product

Medical Cannabis-Infused Product	Edible Cannabis Product
<ul style="list-style-type: none"> ● A topically-applied cannabis product, such as an oil, a wax, an ointment, or a salve ● Suppository ● Dermal patch ● Vaporizer cartridge ● Any orally-consumed capsule that <u>does not</u> contain food ingredients ● Tincture (as defined in COMAR 10.62.23.01) ● Any other dosage form that is recognized by the United States Pharmacopeia, the National Formulary, or the Food and Drug Administration AND approved by the Commission 	<ul style="list-style-type: none"> ● A medical cannabis product intended for human consumption by oral ingestion, in whole or in part, including products that dissolve or disintegrate in the mouth ● Does not include: <ul style="list-style-type: none"> ● Cannabis concentrates ● Cannabis-infused products ● Dried leaves and flowers of the cannabis plant



Tinctures

Pursuant to COMAR 10.62.23.01B(3), a tincture is a cannabis-infused solution derived either:

- Directly from the cannabis plant; or
- (a) From a processed cannabis extract that is combined with 50 percent or greater food grade ethyl alcohol, glycerin, or vegetable oil (b) is distributed in a dropper bottle of 4 ounces or less, and (c) contains no additional non-cannabis ingredients except potable water, unless approved by the Commission.

Note: Any tincture containing vegetable oil **must** be manufactured in accordance with COMAR 10.62.37 – *Edible Cannabis Products*, but is exempt from the requirements under COMAR 10.62.37.03 and COMAR 10.62.37.12B. Vegetable oils are a food ingredient and have the potential of containing foodborne hazards. Therefore, tinctures that are made with vegetable oils are expected to be manufactured in accordance with all applicable edible cannabis product regulations related to manufacturing and sanitation.

Edible Cannabis Regulation Exemptions

The following orally-ingested products are exempt from the definition of edible cannabis products and the edible cannabis product regulations:

1. An orally-ingested medical cannabis-infused product indicated in Table 1; and
2. A dosage form recognized by the United States Pharmacopeia, the national formulary, or the Food and Drug Administration if the licensed processor:
 - i. Is certified by an accredited third-party certification body in an alternative pharmaceutical or dietary supplement certification approved by the Commission, and
 - ii. Submits an application in a form prescribed by the Commission to exempt the product.

II. Acceptable Edible Cannabis Products

Pursuant to COMAR 10.62.37.10, all permittees must establish standard operating procedures to ensure consistent and safe production of edible cannabis products and ensure that manufacturing processes reduce or eliminate microorganisms. Additionally, finished products must have a water activity level (aw) of 0.85 or less to help reduce the potential for microbial contamination during transport and storage (see COMAR 10.62.37.12)

Solid edible cannabis products

Pursuant to COMAR 10.62.37.12B(3), solid edible cannabis products **must** be physically separated into single servings.



Servings **may not** be merely demarcated or delineated, while multiple servings remain intact.



Non-solid edible cannabis products

Pursuant to COMAR 10.62.37.12B(4), a package containing more than one serving of a non-solid (such as a liquid or powder) edible cannabis product shall:

1. Have a resealing cap or closure; and
2. Include within the package a measuring device that is appropriate for the product form (e.g. a measuring cap or dropper for liquids, or a measuring spoon for powders).

Non-solid edible cannabis product packaging must contain a suitable device that allows a patient to easily identify a single serving.

Product Restrictions

COMAR 10.62.37.12 establishes specific product standards for edible cannabis products. These product standards include appearance and ingredient restrictions.

Appearance

A solid edible cannabis product may only be manufactured or distributed in geometric shapes.

An edible cannabis product **may not**:

1. Due to its shape, design, or flavor be likely to appeal to minors.
2. Bear any likeness to a human, animal, or fruit.
3. Contain characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings.
4. Resemble a commercially available food or beverage product that targets, or is primarily marketed to, minors.



Ingredients

An edible cannabis product **may not**:

1. Contain meat, seafood, unpasteurized eggs, or unpasteurized dairy of any type.
2. Be an alcoholic beverage, as defined in the Alcoholic Beverage Article, §1-101, Annotated Code of Maryland.



3. Contain any non-cannabis additive that would increase potency or toxicity, or that would create an unsafe combination with other psychoactive substances. **Note:** Prohibited additives include but are not limited to, nicotine and caffeine. This prohibition does not apply to products containing naturally-occurring caffeine, such as coffee, tea, or chocolate.

Dosage Requirements

Homogeneity and stability studies must be conducted to demonstrate that a medical cannabis-infused product or edible cannabis product is homogenous between servings, packages, and production lots, and the content of therapeutic compounds remains stable throughout the manufacturer-suggested shelf life. See COMAR 10.62.37.18, and the Commission's *Technical Authority for Medical Cannabis Testing*.

Edible cannabis products may not have more than 10 milligrams (mg) of Delta-9 tetrahydrocannabinol (D9-THC) in a single serving, or 100mg of D9-THC per package.

Example:

- 10 single servings with 10mg D9-THC in each serving
- 20 single servings with 5mg D9-THC in each serving
- 40 single servings with 2.5mg D9-THC in each serving