

## MEDICAL MARIJUANA TREATMENT CENTER (MMTC) Request for Usable Product and Packaging

Prior to processing and dispensing a proposed usable product, an MMTC must request approval of the proposed usable product and its packaging from the Department of Health, Office of Medical Marijuana Use (OMMU). Additionally, an MMTC must request prior approval of any changes to an existing usable product or its packaging that would alter the criteria demonstrated and representations made in an MMTC’s initial application or previously approved variance request pursuant to Rule 64-4.023, Florida Administrative Code.

To obtain approval, the MMTC must submit this request form and required supporting documentation to the OMMU. If requesting prior approval of any changes to an existing usable product or its packaging that would alter the criteria demonstrated and representations made in an MMTC’s initial application or previously approved variance request, the MMTC must provide a statement summarizing the proposed changes in addition to this request form and applicable supporting documentation.

Upon receipt of the completed request form and **all** required documentation, the OMMU will send written notice to the MMTC either permitting the MMTC to process and dispense the usable product or identifying any omissions, deficiencies, or violations.

MMTC Information			
MMTC Name		MMTC License Number	
MMTC Address			
Street	City	State	ZIP code
Contact Person Name		Contact Person Phone Number	
Contact Person Email Address			
Is this request for a new usable product? (Check “Yes” or “No”)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	

### Acknowledgment

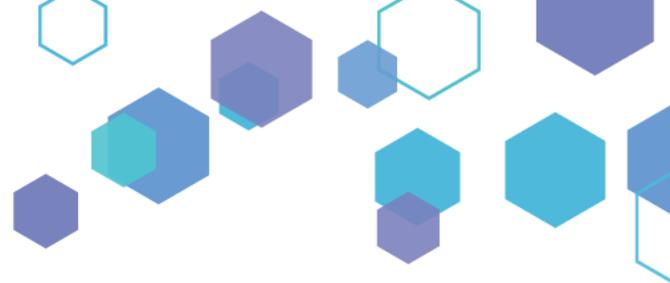
As an authorized representative of the MMTC, I am permitted to submit this request on behalf of the MMTC and to make the following representations on behalf of the MMTC. I agree that the MMTC shall comply with all applicable standards and rules should approval be granted by the OMMU. I understand that knowingly making a false statement in writing with the intent to mislead a public servant in the performance of his or her official duty is a misdemeanor of the second degree, punishable as provided in sections 775.082 or 775.083, Florida Statutes.

---

Signature
Date

---

Name of Signatory (Print or Type)



## MEDICAL MARIJUANA TREATMENT CENTER (MMTC) Request for Usable Product and Packaging

### Supporting Documentation Checklist

For new usable product and packaging, all of the following documents must be submitted. For previously approved usable product or its packaging, submit only the documents below relevant to the request **in addition to** a statement summarizing the proposed changes, including the usable product's prior approval date and reference number, if applicable. If the usable product is an edible, you must also include the documentation listed below in the "Edibles" section.

- Provide documentation showing that the receptacle complies with the United States Poison Prevention Packaging Act of 1970, 15 U.S.C. ss. 1471 et seq.
- Provide documentation showing that the receptacle for the proposed product has a firmly affixed and legible label(s) with the following information:
  - The marijuana or low-THC cannabis meets the requirements of section 381.986(8)(e)11.d., Florida Statutes.
  - The name of the patient.
  - The name of the MMTC from which the marijuana originates.
  - The product name, if applicable, and dosage form, including concentration of tetrahydrocannabinol (THC) and cannabidiol (CBD).
  - The batch number and harvest number from which the marijuana originates, and the date dispensed.
  - A warning that it is illegal to transfer medical marijuana to another person.
  - The name of the physician who issued the physician certification.
  - The MMTC's Department-approved logo.
  - A Quick Response (QR) code, or similar barcode, linking to the usable product's certificate of analysis.
- Patient package inserts with information on the specific product dispensed that includes the following detail:
  - Clinical pharmacology
  - Warnings and precautions
  - Adverse reactions
  - Contraindications
  - Dosage and administration
  - Dosage forms and strengths
  - Indications and use
- For each proposed usable product, a list of all ingredients.
- Standard operating procedures related to the manufacturing of the proposed usable product, which may include a list of equipment required to produce the proposed usable product.

### Edibles

- Provide a copy of a current valid permit to operate as a food establishment pursuant to Chapter 500, F.S., from the Department of Agriculture and Consumer Services.
- Provide documentation from a nationally accredited certifying body that the MMTC's processing facility, including the area where edibles will be produced, has passed a Food Safety Good Manufacturing Practices inspection.

### *How to Claim a Public Records Exemption*

If the MMTC intends to claim any exemption from public records disclosure under section 119.07, Florida Statutes, or any other exemption from public records disclosure provided by law for any part of its request, it must indicate on the request the specific sections for which it claims an exemption and the statutory basis for the exemption. The requestor shall submit a redacted copy of the request redacting **only** those items identified as exempt concurrent with the submission of the request for approval. Failure to provide a redacted copy of the request at the time of submission, or failure to identify and redact information claimed as trade secret will result in the release of all information in response to a public records request unless the information falls under another public records exemption.