

## Office of Medical Marijuana

### Request for Approval: Medical Marijuana Product, Instrument or Device 28 Pa. Code § 1151.28

Pursuant to 28 Pa. Code § 1151.28, (relating to the forms of medical marijuana a grower/processor may process for dispensing) any medical marijuana product, instrument, or device manufactured, produced, or assembled must be approved by the Department.

To request approval for a medical marijuana product, instrument, or device, submit 1) this form, 2) a Request Form Cover Page, and 3) all additional documentation listed below. **A request will be deemed incomplete, and not considered, until all required documentation has been submitted.**

#### Submitting your Request

All documents must be saved as a PDF file with the following file naming format: [name on permit]\_[name of document]. Files should be submitted in a singular correspondence via email to [RA-DHMMRCompliance@pa.gov](mailto:RA-DHMMRCompliance@pa.gov).

Please ensure the application is properly signed and dated. A signature may be scanned and provided electronically in a PDF file.

#### Documentation

Please submit the following:

- 1) The name of the product, instrument, or device for which the permittee is requesting approval by the Office of Medical Marijuana. You may also submit physical instruments or devices to the Office of Medical Marijuana, 625 Forster St., Harrisburg, PA 17120, for consideration.
- 2) The medical purpose for the product, instrument, or device.
- 3) The process for creating the product, instrument, or device (including if it necessitates the purchasing of additional manufacturing tools).
- 4) A product description, including the intended use of the product, instrument, or device by a patient.
- 5) A picture, or link to a website with a picture, of the product, instrument, or device.

#### Additional Attestation

I acknowledge that none of the products, instruments or devices discussed in this form and any attachments will be used by the medical marijuana organization outside of the specific use listed above.

Permit ID Number: \_\_\_\_\_

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name

\_\_\_\_\_  
Role in MMO

**Complete the following for any product containing additional active ingredients or materials that alters the dosage level, color, appearance, smell, taste, effect, or weight of the medical marijuana. Excipients must be pharmaceutical grade, unless otherwise approved by the Department.** 28 Pa. Code §§ 1141.21 and 1151.27(f); 35 P.S. § 10231.702(a)(5). Attach additional pages if necessary. Complete all sections.

List the Additional Ingredient, Material, or Excipient name(s):

Please indicate whether the added substance is permitted by the United States Food and Drug Administration for use in food or is generally recognized as safe under federal guidelines. 35 P.S. §§ 10231.102(3)(i) and 10231.702(a)(5) (See “*Linked References*” #2 and 4)

Please indicate whether the added substance constitutes a known hazard such as Diacetyl, CAS number 431-03-8 and pentanedione, CAS number 600-14-6. 35 P.S. § 10231.702(a)(5) (See “*Linked Reference*” #2)

Please provide the following information. (See “*Linked References*” #1):

Route of Administration:

Dosage Form:

CAS Number:

UNII Number:

Maximum Potency per unit dose:

Please indicate whether there are any known drug interactions (See “*Linked Reference*” #5):

Describe why each additional ingredient, material, or excipient is being requested including its intended medical justification:

**Linked References:**

1. [FDA Database of Inactive Ingredients \(Excipients\)](#)
2. [SCOGS \(Select Committee on GRAS Substances\)](#)
3. [Inactive Ingredient Search for Approved Drug Products: Frequently Asked Questions](#)
4. [21 CFR 101.22 Subpart B--Specific Food Labeling Requirements](#)
5. [Drug Interactions](#)

**Additional Attestation**

I acknowledge that all information provided on this form and on any attachment to it is true and correct and that there are no intentional misrepresentations, falsifications or omissions. I acknowledge that any intentionally false, misleading or omitted information is punishable under the applicable provisions of 18 Pa. C.S. Ch. 49 (relating to falsification and intimidation). I understand that any knowingly false or intentionally misleading statement or intentionally omitted information in this document and attachment(s) could result in withdrawal of any approval resulting from this submission and, additionally, could constitute grounds for action under 28 Pa. code 1141.47.

Permit ID Number: \_\_\_\_\_

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name

\_\_\_\_\_  
Role in MMO

For Internal Use Only

Request ID # \_\_\_\_\_

Date Submitted \_\_\_\_\_

Intake Initials \_\_\_\_\_