pennsylvania
DEPARTMENT OF HEALTH
OFFICE OF MEDICAL MARIJUANA

Office of Medical Marijuana
Request for Approval: Medical Marijuana Product, Instrument or Device
28 Pa. Code § 1151a.28

Pursuant to 28 Pa. Code § 1151a.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. A grower/processor may not manufacture, produce or assemble any medical marijuana product, instrument or device without the prior written approval of the Department.

To request approval for a medical marijuana product, instrument, or device, submit: 1) this Request for Approval Form, 2) a Request Form Cover Page, and 3) all additional documentation necessary to answer A through G 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. Files should be submitted in a singular correspondence via email to RA-DHMMRCompliance@pa.gov. Any submissions connected to a shared drive may cause delays.

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

Documentation

Please submit the following in accordance with the Instruction Guide that has been provided:

A. The name of the product, instrument, or device for which the permittee is requesting approval by the Office of Medical Marijuana.

B. The medical purpose for the product, instrument, or device.

C. The process for creating the product, instrument, or device (including if it necessitates the purchasing of additional manufacturing tools).

D. A product description, including the intended use of the product, instrument, or device by a patient.

E. Detailed information regarding the formulation of the final form product to include the name and amount of each additional ingredient or material used in the product that alters the dosage level, color, appearance, smell, taste, effect, or weight of the final form product.

F. The Material Safety Data Sheet (MSDS) or Safety Data Sheet (SDS) for each additional ingredient or material used in the final form product that alters the dosage level, color, appearance, smell, taste, effect, or weight of the final form product.

G. A picture of the product, or a link to the manufacturing website with a picture of the instrument or device.

Additional Attestation

I acknowledge, as the representative of the medical marijuana organization, that the medical marijuana organization will use the products, instruments or devices only as submitted in this form and any attachments, and any use outside of the scope of this request will require a separate submission.

Permit ID Number: _____

_____
Signature Date

_____
Name Title

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Using the Instruction Guide and its corresponding numbers, complete the following for <u>any</u> product containing additional 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 §§ 1141a.21 and 1151a.27(f); 35 P.S. § 10231.702(a)(5).

1. **List the name and amount of each additional ingredient or material used in the final form product**.

   ➔ *See section 1 in "Instructions to Complete the Additional Ingredients or Materials Information" for assistance completing this question.*

   <u>NOTE:</u> You may not simply list the name of an externally sourced product: you must list each ingredient contained in that externally sourced product.

ADDITIONAL INGREDIENTS OR MATERIALS LIST		
Additional Ingredient or Material	**Amount per product**	**Amount per dose**

2. **For each additional ingredient, utilize the following FDA link and complete the below table to demonstrate that each additional ingredient or material used in the final form product is permitted by the United States Food and Drug Administration.** 35 P.S. §§ 10231.102(3)(i) and 10231.702(a)(5).

   ➔ *See section 2a in "Instructions to Complete the Additional Ingredients or Materials Information" for assistance completing this question.*

   FDA Inactive Ingredient Search for Approved Drug Products

Additional Ingredient or Material	Route of Administration	Dosage Form	CAS Number	UNII Number	Maximum Potency per dose	Maximum daily exposure

3. **If you have additional ingredients or materials <u>not</u> located in the FDA Database of Inactive Ingredients, utilize the following Select Committee on GRAS Substances (SCOGS) and the eCFR Title 21 links to demonstrate that each additional ingredient or material used in the final form product is permitted by the United States Food and Drug Administration.** 35 P.S. §§ 10231.102(3)(i) and 10231.702(a)(5).

   ➔ *See footnote 2 and section(s) 2b(i), 2b(ii), and 2c in "Instructions to Complete the Additional Ingredients or Materials Information" for assistance completing this question.*

SCOGS (Select Committee on GRAS Substances)

eCFR Title 21: Food and Drugs Database

Additional Ingredient or Material	CFR Citation Deeming Additional Ingredient Safe for Use

4. **If you have additional ingredients or materials <u>not</u> located in the FDA Database of Inactive Ingredients or SCOGS, utilize the following Select Committee on GRAS Substances (SCOGS) "GRAS NOTICES" link to demonstrate that the additional ingredient or material used in the final form product has been recognized by SCOGS and the United States Food and Drug Administration.** 35 P.S. §§ 10231.102(3)(i) and 10231.702(a)(5).

   ➔ *See section 2b(iii)(1) in "Instructions to Complete the Additional Ingredients or Materials Information" for assistance completing this question.*

   SCOGS GRAS Notices

Additional Ingredient or Material	"FDA has no questions"

5. If an additional ingredient or material is not found using any of the above resources, please provide information and documentation that supports the additional ingredient or material's use in the final form product.

➔ *See section 3 in "Instructions to Complete the Additional Ingredients or Material Information" for assistance completing this question.*

Additional Ingredient or Material	Type of Evidence	Title of Document	Citation/Reference

6. If any additional ingredients or materials constitute a known hazard, indicate them below. 35 P.S. § 10231.702(a)(5).

➔ *See section 4 in "Instructions to Complete the Additional Ingredients or Materials Information" for assistance completing this question.*

EXAMPLE: Diacetyl, CAS number 431-03-8 and pentanedione, CAS number 600-14-6.

Additional Ingredient or Material	CAS Number	Hazard Classification (ex: flammable liquid)

7. Provide the Material Safety Data Sheet (MSDS) or Safety Data Sheet (SDS) for each additional ingredient or material.

➔ *See section 5 in "Instructions to Complete the Additional Ingredients or Materials Information" for assistance completing this question.*

Additional Ingredient or Material	Does the CAS number match? Y/N	Check if "No MSDS or SDS is federally required for additional ingredient or material and therefore, cannot be provided."

8. Utilizing the following link, list any known drug interactions for each additional ingredient or material used in the final form product.

➔ *See section 6 in "Instructions to Complete the Additional Ingredients or Materials Information" for assistance completing this question.*

Drug Interactions Checker

Additional Ingredient or Material	Interacts with	Interaction Description

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9. Describe why each additional ingredient or material used in the final form product is necessary, including justification for its intended medical use.

➔ *See section 7 in "Instructions to Complete the Additional Ingredients or Materials Information" for assistance completing this question.*

Additional Ingredient or Material	Purpose/Benefit	If applicable, does the condition of the intended use match the GRAS designation: (Y/N)

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Additional Attestation

I acknowledge, as the representative of the medical marijuana organization, 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 could result in a penalty or sanction under 28 Pa. code § 1141a.47.

Permit ID Number: _____

_____

Signature Date

_____

Name Title

For Internal Use Only
Request ID #_____
Date Submitted_____
Intake Initials_____