pennsylvania
DEPARTMENT OF HEALTH
OFFICE OF MEDICAL MARIJUANA

Product Approval Form
Instruction Guide

To successfully complete the product approval request form, please follow the instruction guide below. **If the form is not completed in its entirety, the request will be deemed incomplete, and not considered, until all required documentation has been submitted.**

To Submit the Request:

☐ Follow the instructions to complete the Request Form Cover Page.

☐ Follow the instructions to complete steps A through G of the Product Approval Request Form.

☐ If applicable, follow the instructions to complete steps 1 through 9 of the Additional Ingredients or Materials Information Section on the Product Approval Request Form.

☐ Ensure all attestations are fully executed.

☐ Save all documents (the Request Form Cover Page, Request for Approval Form, and all additional documentation) as a PDF file. It is helpful, but not necessary, to submit one combined PDF for each product that an MMO wishes to produce.

☐ All PDF files are to be submitted in a singular correspondence via email to **RA-DHMMRCompliance@pa.gov.** It is permissible to submit multiple product requests for review in the same email.

Instructions to Complete the Request Form Cover Page

1. Complete the required information for your permit: Permit name, permit number, submission date, name of requester, contact information, and permit type.
2. Indicate the purpose of this request form. Check the box for Additional Medical Marijuana Product.
3. Sign and date the document.

Instructions to Complete Required Documentation on Page 1, A through G, of the Product Approval Request Form

A. Provide the name of the product, instrument, or device for which the permittee is requesting approval.

B. Provide the medical purpose of the product, instrument, or device.

- The product must provide a medical benefit to patients and any relevant serious medical conditions approved under the Act and regulations should be identified. The instrument or device must aid patients in the administration of medical marijuana.

C. Detail the process for creating the product, instrument, or device (including a list of the required manufacturing tools and any associated facility alteration request(s)).

- All necessary facility alteration requests must be submitted and approved *prior* to submission of the product request.
- Describe in detail the extraction process and include any SOPs, if available. If a process has already been approved, please still provide the pertinent SOP and detail the process for each product the MMO wishes to produce. A statement that a process has already been approved by the OMM is not sufficient and will be deemed incomplete.
    - If an MMO wishes to produce different types of concentrates, each concentrate is considered a new and separate product, and must be submitted for approval.
    - Likewise, the addition of any ingredient or material to an already approved product requires a new product submission.

D. Provide a product description, including the intended use of the product, instrument, or device. Include the Safety Data Sheet for the instrument, product, or device.

- Include how the product will be used or consumed.

E. Provide detailed information regarding the formulation of the final form product.

- Provide ALL ingredients AND any "sub ingredients[1]," the amount of each additional ingredient or material that will be in the final form product, as well as in each dose.
    - If the product has additional ingredients or materials 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. Include a picture of the product, or a link to the manufacturing website with a picture of the instrument or device.

- The request will be deemed incomplete and returned if this information is not completed.

Additional Attestation Instructions

Complete all additional attestations found on the Request Form Cover Page and Request for Approval: Medical Marijuana Product, Instrument or Device Form by providing the MMO Permit ID number, the authorized representative's signature, date, name, and the title or role of the authorized representative in the MMO.

- **The request will be deemed incomplete and returned if any attestation is not fully executed**. A signature may be scanned and provided electronically in a PDF file.

[1] The ingredients contained in an externally sourced product. For example, if the ingredient is lemonade, the sub-ingredients refer to the ingredients that make up the lemonade. (Example: lemon, sugar, and water are the sub-ingredients of the main ingredient lemonade).

Instructions to Complete the Additional Ingredients or Materials Information

***NOTE**: This section must be completed for any product with additional ingredients or materials that alter the dosage level, color, appearance, smell, taste, effect, or weight of the final form product. If the proposed product does not contain any additional ingredients or materials, please put "N/A" in all applicable areas of the form unless specified otherwise.

***NOTE:** The department does not provide a blanket approval for additional ingredients because any addition from a previous approval creates a new distinct product that needs its own approval type.

1. **List the name and amount of each additional ingredient or material used in the final form product.**
    a. Simply listing the name of an externally sourced product is insufficient. The MMO must also list sub-ingredients. Refer to footnote for the definition and example of sub-ingredient.
    b. The amount of each additional ingredient or material includes both the amount of the ingredient or material per product and the amount of the ingredient or material per dose.

2. **All additional ingredients or materials used in the final form product must be permitted by the United States Food and Drug Administration. Use the following links to demonstrate that each additional ingredient or material is FDA approved.**
    a. FDA Inactive Ingredient Search for Approved Drug Products
        i. Search the ingredient or material name
            1. When an ingredient or material appears on this list, fill in the below information for *EACH additional ingredient or materials* in the chart provided:
                a. Additional ingredient or material
                b. Route of Administration
                c. Dosage Form
                d. CAS Number
                e. UNII Number
                f. Maximum potency per unit dose, if any
                g. Maximum daily exposure, if any
    b. For EACH additional ingredient or material not found on the Inactive Ingredient Database, use the following links to demonstrate the additional ingredient or material is considered GRAS.[2]
        i. eCFR Title 21: Food and Drugs Database
        ii. SCOGS (Select Committee on GRAS Substances)
        iii. If not found using the previous link, the ingredient may have a GRAS Notice that is acceptable evidence of GRAS. GRAS Notices.
            1. If the "FDA's Letter" column states "FDA has no questions", provide the linked document in the chart.

[2] "GRAS" is an acronym for Generally Recognized as Safe. This applies to any substance that is intentionally added to ***food*** as a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe ***under the conditions of its intended use***, or unless the use of the substance is otherwise excepted from the definition of a food additive. A GRAS status does **NOT** apply to products that are not ingested.

c. An assertion that an additional ingredient or material is GRAS is not sufficient. An MMO must provide evidence that supports an additional ingredient or material's GRAS designation.

3. **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.**
    a. This type of evidence includes:
        i. Any references to current food or drug products containing the ingredient or material.
        ii. Product or scientific literature specific to the proposed added ingredient or material.
        iii. Examples of similar products (food or drug) using the added ingredient in the same form and fashion as proposed in this request.
    b. When using the the chart under number 5 of the submission request:
        i. "Type of Evidence" refers to 3a(i)–(iii) above.
        ii. Provide the exact name of the pdf document(s) attached as evidence in "Title of Document." If the submission request is one combined pdf, please also provide the pdf page number(s).
        iii. In the "Citation/Reference" column, please provide the full and proper citation/reference for the evidence provided. If any website link exists, please also provide here.

4. **Indicate whether the additional ingredient or material 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).**

5. **Include the SDS for each additional ingredient or material.**
    a. The SDS must be from the company supplying the additional ingredient or material.
    b. If an SDS exists for the additional ingredient or material an MMO wishes to use, then it must be provided. If an SDS does not exist, please indicate that "No SDS is federally required for the additional ingredient or material and therefore, cannot be provided."
    c. The CAS number on the SDS must match the CAS number identified in the additional ingredient or material information section. The CAS number must also match the additional ingredient or material an MMO wishes to use.
        i. Example: Anhydrous Citric Acid CAS 77929 is a different substance from Citric Acid Monohydrate CAS 5949291. It must be specified which Citric Acid is being used and the proper CAS number must be listed.

6. **Use the link below to demonstrate any known drug interactions for each additional ingredient or material used in the final form product.**
    a. Drug Interactions Checker
        i. For each additional ingredient or material, provide what the additional ingredient or material interacts with and the description of the interaction, such as symptoms, side effects, and adverse events.

7. **Describe why each additional added ingredient or material used in the final form product is necessary.**
    a. This description should include:
        i. The purpose of the additional ingredient or material.
        ii. The patient benefit, identifying any relevant serious medical conditions approved under the Act and regulations, for including the additional ingredient or material.
        iii. The product benefit for including the additional ingredient or material (stability, palatability, efficacy, etc.).
    b. The condition of its intended use must match the GRAS designation.
        i. Example: The FDA has deemed limonene (d-, l-, and dl-) as GRAS as a synthetic flavoring substance and adjuvant (condition of its intended use) under 21 CFR 182.60.